Recommendations of the SEC (Oncology & Haematology) made in its 134th meeting held on 07.10.2022 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	4-51/Novo Nordisk/PAC-R-Eptacogalfa/2021-BD Eptacogalfa (activated) 1 mg/vial & 2 mg/vial	M/s Novo Nordisk India Pvt. Ltd.	The firm presented the proposal for approval of additional indication viz "for the treatment of severe postpartum haemorrhage when uterotonics are insufficient to achieve haemostasis". The committee noted that, the proposed indication is approved by EMA. After detailed deliberation, the committee recommended for grant of approval of Eptacogalfa (activated) 1 mg/vial & 2 mg/vial for proposed indication in line with EMA approval with the condition that, firm should conduct Phase IV study for the proposed indication. Accordingly, the firm should submit Phase IV study protocol to CDSCO within three months of approval of the additional indication.
2.	71/PMS/Baxalta/16-BD Recombinant Coagulation Factor IX	M/s Baxalta Bioscience India Pvt. Ltd.	The firm presented Phase IV study results of the Recombinant Coagulation Factor IX drug as per approved protocol. After detailed deliberation, the committee noted the results of the study.
3.	BIO/IMP/22/000060 Cetuximab sarotalocan sodium IV infusion 250 mg	M/s Rakuten Medical Private Limited	The firm presented proposal for import & marketing of the drug as Photoimmunotherapy in indication "Unresectable locally advanced or recurrent head and neck cancer" with local Phase III clinical trial waiver and with the commitment for conduct of Phase IV study in India. The committee noted that, the drug is only approved in Japan based on Phase I study conducted in limited number of patients in Japan (3 patients) and Phase I/II study conducted in USA (40 patients). Further, the Phase III study of the drug is still ongoing in USA and Japan. After detailed deliberation, the committee recommended that, the firm should conduct local Phase III study in India in

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			reasonable number of patients considering disease burden of the proposed indication in Indian population.
SND Division			
4.	SND/IMP/22/000042 Ruxolitinib Tablets 5mg,10mg,15mg and 20mg	M/s Novartis Healthcare	The firm presented their proposal alongwith proposed Package Insert of Ruxolitinib Tablets 5mg, 10mg, 15mg and 20mg. After detailed deliberation, the committee recommended the proposed Package Insert of Ruxolitinib Tablets 5mg, 10mg, 15mg and 20mg presented by the firm.
5.	SND/IMP/22/000063 Eribulin Mesylate solution for injection 2.5mg in 5ml vial	M/s Emcure Pharma	The firm presented their proposal of manufacture and marketing permission of Eribulin Mesylate solution for injection 2.5mg in 5ml vial alongwith their justification for this new pack size before the committee. After detailed deliberation, the committee opined that the proposed pack size of Eribulin Mesylate solution for injection is not recommended.
GCT Division			
6.	CT/44/21 Online Submission (14540) Atezolizumab & Trastuzumab	M/s. Roche	The firm presented the proposed protocol amendment to version 2.0 dated 11-Aug-2021 under the protocol no. WO42633 (Astefania) before the committee. After detailed deliberation, it was noted that there was no change in the no. of subjects already approved in the country owing to the proposed protocol amendment as globally the sample size changed from 1590 to 1700. After detailed deliberation, the committee recommended for approval of proposed protocol amendment. The committee also suggested that the firm should submit comparative summary of proposed changes in protocol with rationale to CDSCO.
7.	CT/104/21 Online Submission (17622) LY3484356 (Imlunestrant) and	M/s. Eli Lilly	The firm presented the proposed protocol amendment (a) dated 08-Oct-2021 under the study protocol no. J2J-OX-JZLC (EMBER-3) before the committee. After detailed deliberation, the committee recommended for approval of proposed

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	LY2835219 (Abemaciclib)		protocol amendment with condition that 1) The firm should submit study safety data on half yearly basis to CDSCO. 2) Submit approval of other participating countries for the proposed amendment. 3) As submitted by the firm, there is no increase in the number of subjects from the country due to the proposed amendment.
8.	CT/55/21 Online Submission (17790) TAR-200	M/s. PRA	The firm presented the protocol clarification(s) for the approved protocol no. 170000139BCL3001, Amendment 2 dt. 02Aug2021 before the Committee. After detailed deliberation, the committee accepted the clarification(s) and accordingly recommended to conduct the study.
9.	CT/101/21 Online Submission (19161) Dabrafenib plus trametinib	M/s. Novartis	The firm presented the proposed protocol amendment version 2 dated 22Apr2022 under the study protocol no. CDRB436J12301 before the Committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
FDC Division			
10.	FDC/MA/22/000258 Transdermal Liposomal Lotion containing Ferrous BisGlycinate 10mg+Vitamin B12 0.8mcg+Vitamin D3 20mcg + Folic acid 100mcg	M/s. Murli Krishna Pharma Pvt. Ltd.	The firm presented their proposal of conducting clinical trial before the committee. The Committee noted that – 1. The firm did not present any scientific justification for the proposed dosage form and the doses. 2. The firm did not present any proof of concept. 3. Proposed FDC is not approved internationally. 4. The firm did not present any preclinical studies data After detailed deliberation, the committee did not recommend the conduct of the proposed study.