Recommendations of the SEC (Oncology & Haematology) made in its 147th meeting held on 27.04.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	4- 76/NovoNordisk/PAC-R-Cartidecacog/2021-BD Catridecacog (recombinant coagulation factor XIII) 2500 IU Lyophilized powder for concentrate for solution for Injection	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented the protocol for conduct of post marketing surveillance study titled "post marketing surveillance program of catridecacog (Novothirteen®) use in congenital FXIII A-subunit deficiency patients of India" as per Protocol No. NN1841-7592, version 1.0 dated 24 Nov. 2022. After detailed deliberation, the committee recommended for grant of permission to conduct the post marketing surveillance study as per presented protocol subject to the following conditions- 1. The firm should submit safety data generated globally so far to CDSCO. 2. The firm should include more centers/sites to get adequate number of patients for the proposed PMS study.
2.	4-BIO/IMP/18/000006 Inotuzumab Ozagamicin	M/s. Pfizer Products India Private Limited	The firm presented their protocol for conduct of retrospective, non-interventional study titled "A retrospective analysis of Inotuzumab ozogamicin (Inonza) usage in adult patients with relapsed/refractory (R/R) B-cell Acute Lymphoblastic leukemia (ALL)" as per protocol number B1931043, version 1.0 dated 14 Nov. 2022. After detailed deliberation, the committee noted that the study is for retrospective evaluation of data from medical records of patients who have already been treated with the drug and recommended that this study does not require regulatory approval. However, other applicable guidelines should be followed.
3.	BIO/IMP/23/000003 Enfortumab vedotin 20mg & 30mg	M/s. Astellas Pharma India Pvt. Ltd.	The firm presented the proposal for import & marketing of Enformutab Vedotin 20mg & 30mg powder for solution for infusion along with request for local clinical trial waiver. The drug is indicated as monotherapy for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a programmed death

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			receptor 1 or programed death ligand 1 [PD-(L)1] inhibitor. The drug is approved in USA, EU, Japan, Canada, Australia, Singapore. After detailed deliberation, the committee did not consider the proposal for local clinical trial waiver as there is no safety and efficacy data available on Indian patients. Accordingly, the firm should submit clinical trial protocol for further consideration.
4.	BIO/CT04/FF/2023/36365 Pegfilgrastim 6mg/0.6 mL solution for injection	M/s. CuraTeQ Biologics Private Limited	The firm presented the protocol to conduct Phase I clinical trial entitled "Single dose study to compare pharmacokinetic, pharmacodynamics, immunogenicity and safety of BP14 (Pegfilgrastim) 6mg/0.6mL solution for Injection and 'Neulasta' (Pegfilgrastim) 6mg/0.6mL solution for Injection in healthy adult male subjects as per protocol No. C1B02880/BP14-102, version 02 dated 07-Mar-2023 for regulatory submission in EU. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial as per presented protocol. However, the firm is required to provide clarifications for the queries raised by CDSCO.
SND Division			
5.	SND/IMP/22/000042 Ruxolitinib tablets 5mg, 10mg, 15mg, 20mg	M/s. Novartis Healthcare	The firm presented the safety and efficacy data of global study and post marketing data related to the Ruxolitinib tablets 5mg, 10mg, 15mg, 20mg for the 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" The committee noted the results with respect to Ruxolitinib tablets 5mg, 10mg, 15mg, 20mg. After detailed deliberation, the committee recommended that the firm should submit details of serious adverse event, deaths occurred during the trails along with causality assessment for further review by the committee.

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6.	SND/MA/23/000061 Methotrexate oral solution 2mg/ml	M/s. Beta Drugs Ltd.	The firm presented the proposal for manufacturing and marketing of Methotrexate oral solution 2mg/ml along with request for waiver of BE study and clinical trial. The committee noted that Methotrexate oral solution 2mg/ml is approved in US. After detailed deliberation, the committee recommended that the firm should conduct BE study with reference drug product. Accordingly, protocol for BE study should be submitted for further review by the committee and request for waiver of clinical trial should be deliberated after submission of BE study reports.
7.	SND/MA/23/000054 Ferric Carboxymaltose Injection 50mg/ml, 100mg/2ml, 500mg/10ml, 750mg/15ml & 1000mg/20ml vials	M/s. Dr. Reddy's Laboratories Ltd.	The firm presented the proposal for manufacturing and marketing of Ferric Carboxymaltose Injection 50 mg/ml in fill volumes 100mg/2mL, 500mg/10mL, 750mg/15mL and 1000mg/20mL vials (Ferric Carboxymaltose Injection 50mg/mL in 2mL vial, 10mL vial, 15mL vial and 20 mL vial) as additional pack sizes indicated "for the treatment of iron deficiency in adults when oral iron preparations are ineffective or cannot be used". The firm also presented the comparative pharmaceutical data with reference product along with justification for BE study and clinical study waiver. After detailed deliberation, the committee recommended that firm should submit animal toxicity data as per New Drugs and Clinical Trial Rules 2019 for review by the committee for further consideration of the BE study and clinical study waiver.
8.	SND/IMP/20/000072 Osimertinib film coated tablet 40mg & 80mg	M/s. Astrazeneca	The proposal is deferred for next SEC meeting.
9.	SND/MA/21/000506 Enzalutamide solution 32mg/ml(160mg/5ml)	M/s. BDR Pharmaceuticals International Pvt. Ltd.	The firm presented the proposal for manufacturing and marketing of Enzalutamide Solution 32mg/ml (160mg/5ml) along with the results of the BE study. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Enzalutamide Solution 32mg/ml (160mg/5ml) for already approved indications i.e

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			(1) In the treatment of adult men with metastic castration-resistant prostate cancer who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated. (2) For the treatment of adults with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed on or after Docetaxel therapy. (3) For the treatment of adults with metastatic castration-resistant prostate cancer whose disease has progressed on or after Docetaxel therapy, subject to condition that the firm should conduct a Phase IV clinical trial for which protocol should be submitted to CDSCO within 3 months from grant of approval.
GCT Division			
10.	CT/04/23 Online Submission (35658) HT-6184	M/s. CBCC	The firm presented protocol to conduct Phase-IIa clinical trial, as per protocol number –HT-6184-MDS-001, version-2, dated 27 Dec. 2022, before the committee. After detailed deliberation, the committee recommended that the proposal is required to redeliberated with more details as below- 1. Supportive preclinical data. 2. Clarification in the study design with respect to the placebo arm/ 'other chronic anemic states' arm, NGS based molecular classification of MDS patients and the cutoff of VAF% to incorporate MDS cases. Accordingly, the firm should submit above details for further consideration.
11.	CT/44/21 Online Submission (23581) Atezolizumab	M/s. Roche	The proposal is deferred for next SEC meeting.
12.	CT/124/22 Online Submission (34341) ABL001	M/s. Novartis	The proposal is deferred for next SEC meeting.

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	(Asciminib)		
13.	CT/97/21 Online Submission (22605) Amivantamab + Lazertinib	M/s. J&J	The proposal is deferred for next SEC meeting.
14.	CT/23/21 Online Submission (20045) Trastuzumab Deruxtecan (T-DXd)	M/s. Astrazeneca	The proposal is deferred for next SEC meeting.