Recommendations of the SEC (Oncology & Haematology) made in its 159th meeting held on 10.10.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2022/35249 Ipilimumab 5 mg/mL concentrate for solution for infusion	M/s. BMS	In light of earlier SEC recommendations dated 08.06.2023, the firm presented the study status report of the on-going Phase-IV clinical trial of Nivolumab in combination with Ipilimumab. After detailed deliberation, the committee recommended for grant of additional indication i.e., Ipilimumab in combination with Nivolumab for first-line treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) with the condition that the firm should conduct Phase IV study for the proposed indication in India. Accordingly, the firm should submit Phase IV protocol within three months of approval of additional indication.
2.	BIO/CT18/FF/2022/35291 Nivolumab 10 mg/mL concentrate for solution for infusion 40 mg & 100 mg	M/s. BMS	In light of earlier SEC recommendations dated 08.06.2023, the firm presented the study status report of the on-going Phase-IV clinical trial of Nivolumab in combination with Ipilimumab. After detailed deliberation, the committee recommended for grant of below additional indications with the condition that the firm should conduct Phase-IV study for the proposed indications in India. 1.Esophageal Squamous Cell Carcinoma (ESCC)-Nivolumab, in combination with fluoropyrimidine- and platinum-containing chemotherapy Or In Combination with Ipilimumab for the treatment of advanced or metastatic esophageal squamous cell carcinoma (ESCC) 2. Urothelial Carcinoma (UC)-Nivolumab is indicated for the adjuvant treatment of adult patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection of UC. Accordingly, the firm should submit

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			Phase IV protocol within three months of approval of additional indications.
3.	39/PMS/Roche/13-BD (Part-II) Rituximab	M/s. Roche	The firm requested for deliberation of proposal in SEC (Analgesic and Rhematology) as the proposed indication are treated by Rheumatologists.
4.	BIO/CT18/FF/2023/35290 Enfortumab vedotin 20mg & 30mg	M/s. Astellas Pharma	In light of earlier SEC recommendations dated 27.04.2023, the firm presented justification for reconsideration of their proposal to import and market Enfortumab vedotin powder for concentrate for solution for infusion in India for the treatment of locally advanced or metastatic urothelial cancer with local clinical trial waiver. The committee noted that the drug falls under the orphan drug category and proposed indication is a rare disease. After detailed deliberation, the committee recommended for grant of permission to import and market Enfortumab vedotin powder for concentrate for solution for infusion in India as monotherapy indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and a programmed death receptor 1 or programmed death ligand 1 inhibitor with local clinical trial waiver with a condition to conduct Phase IV study in more than 100 patients in India. Accordingly, the firm should submit Phase IV protocol within three months of approval of marketing authorization.
SND Division			
5.	SND/MA/23/000061 Methotrexate Oral Solution 2mg/ml	M/s. Beta Drugs Limited	In light of earlier SEC recommendation 27.04.2023, the firm presented Bioequivalence protocol before the committee. The firm proposed to conduct bioequivalence study on healthy subject for Methotrexate oral solution 2mg/ml comparing with Methotrexate tablets and

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			stated that the innovator (USFDA product) is in short supply and not readily available. After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study on healthy subject as per protocol presented by the firm and submit the BE report for further consideration.
FDC Division			
6.	FDC/MA/22/000258 Ferrous Bis Glycinate IH 10mg + Vitamin B12 IP 0.8mcg + Vitamin D3 IP 20mcg + Folic Acid IP 100mcg Lotion	M/s. Murli Krishna Pharma Pvt. Ltd.	In light of earlier SEC recommendation dated 12.09.2023, the firm presented their proposal along with revised Phase III clinical trial protocol and justification for PK study waiver before the committee. After detailed deliberation, the committee opined that conduct of Phase III Clinical trial may be considered with following conditions: I. Venous sample should be collected to estimate the Haemoglobin level at each visit. II. More government sites to be included which should be geographically distributed. III. The firm should confirm that the reference product is approved for manufacturing and marketing in the country. IV. The clinical study data on 50 subjects should be presented before SEC for review to take decision on continuation of the study. However, the committee did not consider the justification for PK study waiver, and accordingly the firm should present PK study protocol before SEC. The committee also recommended that Phase III Clinical trial should be conducted after submitting the results of PK study.
GCT Division			
7.	CT/111/20 Online Submission (27019) Trastuzumab Deruxtecan (T-DXd,	M/s. AstraZeneca	The firm presented protocol amendment version 3.0 dated 02 May 2023, protocol number: D967VC00001 before the committee. After detailed deliberation, the committee

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	DS-8201a)		recommended for approval of the proposed amendment as presented by the firm.
8.	CT/44/21 Online Submission (26732) Atezolizumab, Trastuzumab Emtansine and Trastuzumab	M/s. Roche Products	The firm presented the proposal to increase in Indian patient enrollment number from 45 to 60 patients at the currently registered investigator sites vide study protocol number: Protocol no. WO42633 version 3.0 dated 23 Feb 2022 After detailed deliberation, the committee recommended for approval to increase in Indian patient enrollment number from 45 to 60 patients as presented by the firm.
9.	CT/54/20 Online Submission (27037) Trastuzumab Deruxtecan (T-DXd)	M/s. AstraZeneca	The firm presented protocol amendment Clinical Study Protocol (CSP) version 5.0, Protocol Number D9670C00001 dated 23-May-2023 before the committee. After detailed deliberation, the committee recommended for approval of the proposed amendment as presented by the firm.
10.	CT/24/21 Online Submission (27038) Trastuzumab Deruxtecan (T-DXd)	M/s. AstraZeneca	The firm presented protocol amendment Clinical Study Protocol (CSP) Amendment 3.0 (version 4.0dated 24 May 2023) Protocol Number D967UC00001 before the committee. After detailed deliberation, the committee recommended for approval of the proposed amendment as presented by the firm.
11.	CT/15/20 Online Submission (22812) MBG453	M/s. Novartis	The firm presented protocol amendment version 03 dated 23 Jun 2022, Protocol Number CMBG453B12301 before the committee. After detailed deliberation, the committee recommended for approval of the proposed amendment as presented by the firm.