Recommendations of the SEC (Oncology & Haematology) made in its 110th meeting held on 13.07.2021 & 14.07.2021 at CDSCO HQ New Delhi.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	04-05/Roche/PAC-R-Atezolizumab/2021-BD Atezolizumab	Roche Products (India) Pvt Ltd	The firm presented its proposal for grant of approval for additional indication. After detailed deliberation, the committee recommended for grant of approval of the drug for the additional indication.
2.	BIO/IMP/18/000001 Durvalumab inj. for infusion 120 mg/2.4 mL or 500 mg/10 mL	AstraZeneca Pharma India Limited.	The firm presented its proposal for continued use of approved indication of metastatic Urothelial Carcinoma in light of outcome of Phase-III clinical trial. The committee noted that the drug was granted conditional accelerated approval by US FDA subject to conduct of post marketing clinical studies and successful outcome of confirmatory DANUBE study. The drug failed to meet its co-primary endpoints in the clinical study. Consequently, the firm withdraw marketing of the drug for the said indication in USA. Further, the indication is not approved in EU. After detailed deliberation, the committee opined that the subject indication was granted approval in India based on the accelerated approval of the US FDA and therefore continued marketing should be examined based on the regulatory status of the drug in USA. Accordingly, the committee recommended the firm should withdraw marketing of the product for the metastatic urothelial carcinoma indication with immediate effect. However, the drug may continue to be marketed for other

			approved indications.
3.	BIO/MA/21/000028 Recombinant-Peg GCSF Injection	Virchow Biotech Private Limited	The firm presented the proposal for grant of marketing authorization for Recombinant-Peg GCSF Injection based on the results of Phase I (PK-PD) and Phase III clinical trial in the country. After detailed deliberation, the committee recommended for grant of marketing authorization for the drug subject to conduct of Phase IV study. Accordingly, firm shall submit Phase IV study protocol within 3 months of the approval.
4.	BIO/IMP/21/000035 Nivolumab	Bristol-Myers Squibb India Pvt. Ltd.	The firm presented proposal for approval of additional indication i.e Esophageal squamous cell carcinoma(ESCC) After detailed deliberation, the committee recommended for grant of approval for the additional indication.
5.	4-44/MSD/PAC-R-Pembrolizumab/2021-BD Pembrolizumab	MSD Pharmaceuticals Private Limited	The firm presented proposal for approval of additional indication. i.e Metastatic Nonsquamous and squamous Non-Small Cell Lung Carcinoma, (NSCLC) and Urothelial carcinoma along with the status of ongoing Phase-IV study in the country. After detailed deliberation, the committee noted that the Phase-IV clinical trial permission was granted in 2018 and there is significant delay in the enrolment of patients in the study. The committee recommended that the firm should complete the enrolment of the patients in the study for considering the proposal for approval of the additional indication.
6.	BIO/CT18/FF/2021/25302 Pertuzumab-Trastuzumab for injection 600mg/600mg and 1200mg/600mg vial	M/s. Roche Products (India) Pvt. Ltd	The firm presented its proposal for grant of marketing authorization of Fixed dose combination of the drug with waiver of local clinical trial and committed to conduct Phase-IV clinical trial. Further, the firm

			mentioned that they will enrol 25 patients in two GCTs. The committee noted that the individual active ingredients in the drug are already approved for marketing in the country for the firm. After detailed deliberation, the committee recommended for grant of permission for import and marketing the drug in the country subject to conduct of Phase IV study. Accordingly, firm shall submit Phase IV study protocol within 3 months of the approval.
SND Division			
7.	SND/MA/21/000081 Enzalutamide 160 mg Tablet	M/s Dr. Reddy's Labs	The firm presented their proposal for manufacturing and marketing permission for Enzalutamide Tablets 160mg along with BE Study protocol. After detailed deliberation committee recommended for grant of permission to conduct the BE Study.
8.	12-138/2017-DC (Pt-HLL-SND) Ormeloxifene 120mg Tablet	M/s HLL Life Care.	The firm presented the revised Phase II clinical trial protocol before the committee. Earlier, CDSCO had already issued NOC for conduct of Phase II CT study, The firm had stated that the inclusion and exclusion criteria for the above study, were too stringent and they are finding difficulty in recruiting the patients. Therefore, they have submitted the revised Phase II CT study protocol. After detailed deliberation the committee recommended for amendment in the Phase II CT protocol as presented.
9.	SND/MA/21/000101	M/s Reliance Life Science.	The firm presented their proposal for manufacturing and marketing of Lanalidomide Capsule 5/10/15/mg

	Lanalidomide Capsule 5/10/15/mg		for additional indication along with Clinical trial waiver. After detailed deliberation the committee recommended for grant of permission for the additional indication, "1. Follicular Lymphoma: Lenalidomide in combination with a Rituximab product, is indicated for the treatment of adult patients with previously treated follicular lymphoma (FL). 2. Marginal Zone Lymphoma: Lenalidomide in combination with a Rituximab product, is indicated for the treatment of adult patients with previously treated marginal zone lymphoma (MZL)".
10.	SND/IMP/21/000038 Triptroelin Powder for injection 3.75mg/vial (Additional Indication)	M/s Dr. Reddy's Labs	The firm presented their proposal for grant of permission for additional indication "Indicated for the adjuvant treatment in combination with Tamoxifen or an Aromatase inhibitor, of harmone receptor-positive early stage breast cancer in women at high risk of recurrence who are confirmed as per-menopausal after completion of chemotherapy". After detailed deliberation the committee recommended for the grant of permission to Import & Market Triptroelin Powder for Injection 3.75mg/vial for the additional indication.
11.	SND/MA/21/000072 Enzalutamide Hard Gelatine Capsule 80 mg	M/s BDR Pharmaceuticals	The firm presented their proposal for Enzalutamide Hard Gelatine Capsule 80 mg for additional indication, "In the treatment of adult men with metastatic castration-resistant prostate cancer who are asymptomatic or mildly

			symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated" After detailed deliberation the committee recommended for approval of the additional indication.
12.	SND/MA/21/000294 Pemetrexed Solution for Infusion 5 mg/ml, 6 mg/ml, 6.5 mg/ml, 7 mg/ml, 7.5 mg/ml, 8 mg/ml, 8.5 mg/ml, 9 mg/ml, 10 mg/ml & 11 mg/ml, 100 ml Ready to Use Infusion Bag	M/s Sun Pharma	The firm presented their proposal for manufacturing and marketing of Pemetrexed Solution for Infusion 5 mg/ml, 6 mg/ml, 6.5 mg/ml, 7 mg/ml, 7.5 mg/ml, 8 mg/ml, 8.5mg/ml, 9 mg/ml, 10 mg/ml & 11 mg/ml, 100 ml Ready to Use Infusion Bag requesting local clinical trial waiver. After detailed deliberation the committee recommended for grant of permission for manufacturing and marketing of Pemetrexed Solution for Infusion 5 mg/ml, 6 mg/ml, 6.5 mg/ml, 7 mg/ml, 7.5 mg/ml, 8 mg/ml, 8.5mg/ml, 9 mg/ml, 10 mg/ml & 11 mg/ml, 100 ml Ready to Use Infusion Bag for the following indication 1. Malignant pleural mesothelioma Pemetrexed in combination with Cisplatin, is indicated for the treatment of chemotherapy naive patients with unresectable malignant pleural mesothelioma. 2. Non-small cell lung cancer (NSCLC) Pemetrexed in combination with Cisplatin, is indicated for the first line treatment of patients with locally advanced or metastatic NSCLC other than predominantly squamous cell histology.

			Pemetrexed is indicated as a monotherapy for the second-line treatment of patients with locally advanced or metastatic NSCLC other than predominantly squamous cell histology. Pemetrexed is indicated as a monotherapy for the maintenance treatment of locally advanced or metastatic NSCLC other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. Pemetrexed in combination with Pembrolizumab and platinum chemotherapy, is indicated for the initial treatment of patients with metastatic non-squamous NSCLC, with no Estimated Glomerular Filtration Rate (eGFR) or ALK genomic tumor aberrations.
13.	SND/IMP/21/000017 Lorlatinib 25 mg & 100 mg tablet (Additional Indication)	M/s Pfizer Products	The firm presented their proposal for grant of permission for additional indication "For the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumours are anaplastic lymphoma kinase (ALK) positive". After detailed deliberation the committee recommended for grant of permission to Import & Market Lorlatinib 25 mg & 100 mg tablet for the additional indication.
14.	SND/IMP21/000026 Palbociclib Capsule & Tablets 75/100/125 mg	M/s Pfizer Products	The firm presented their proposal for grant of permission for Additional Indication *"Palbociclib is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor 2 (HER2)-*

			negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy and with Fulvestrant in patients who have received prior therapy for Male patients". After detailed deliberation the committee recommended for grant of permission to Import & Market Palbociclib Capsule & Tablets 75/100/125 mg for the additional indication
GCT Division			
15.	CT/29/19 Online Submission (10456) AZD5363 (Capivasertib)	M/s. AstraZeneca	The firm presented the proposed Protocol Amendment Version 5.0 dated 06-Nov-2020 under the phase III GCT protocol no. D3614C00001 (CAPItello 290 study). After detailed deliberation, the Committee recommended for approval of the proposed protocol amendment.
16.	CT/10/18Online Submission (11200) Atezolizumab	M/s. Roche	The firm was not ready for the presentation.
17.	CT/57/21 Online Submission (25918) Encorafenib	M/s. Pfizer	The firm presented the proposed phase III study protocol no. C4221015, Amendment 3.0 dated 24Feb2021 before the committee. **Assessment of risk vs. Benefit to the** patients: The safety profile of the study drugs from preclinical toxicology, Phase I & II studies including repeat dose toxicity study justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic option:** The Purpose of the study is to determine the safety and tolerability of EC + mFOLFOX6 and EC

			+ FOLFIRI. **Unmet Medical need in the country:** The test drug may potentially provide treatment in patients with metastatic BREF V600E-mutant colorectal cancer. After detailed deliberation the committee recommended for grant of permission to conduct the study.
18.	CT/68/20 Online Submission (11627) Amivantamab & Lazertinib (Combination therapy)	M/s J&J	The firm did not turn up.
19.	CT/29/16 Offline Submission (4700) Avelumab	M/s. Pfizer	The firm presented the proposed protocol amendment 6 dated 08Mar2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
20.	CT/44/21 Online Submission (25388) Atezolizumab & Trastuzumab (Additional Agenda)	M/s Roche	The firm presented the proposed study protocol no. WO42633, Amendment no. 1 dated 14 Oct 2020 before the committee**. Assessment of risk vs. Benefit to the** patients: The safety profile of the study drugs from preclinical toxicology studies including repeat dose toxicity study justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic option:** the purpose of the study is to evaluate the efficacy and safety of adjuvant atezolizumab or placebo and trastuzumab emtansine for her2-positive breast cancer at high risk of recurrence following preoperative therapy **Unmet Medical need in the country:** The test drug may potentially provide treatment in patients with her2-positive breast cancer After detailed deliberation the

			committee recommended for grant of permission to conduct the study. Dr. Raju Titus Chacko has not participated in the deliberation.
21.	CT/29/20 Online Submission (11416) Fitusiran (Additional Agenda)	M/s Sanofi	The firm presented the proposed protocol amendment 01 dated 29 Mar 2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
22.	CT/52/17 Online Submisison (11199) Atezolizumab (Additional Agenda)	M/s Roche	The firm did not turn up.
FDC Division			
23.	FDC/MA/20/000187 Combipack of Netupitant 300 mg + Palonosetron 0.5mg tablet	M/s. Cadila Healthcare Ltd	In light of the earlier recommendation of SEC committee dated 06.01.2021 & 07.01.2021, the firm presented the BE report before the committee. After detailed deliberation, committee recommended for grant of permission to manufacture and market the proposed combipack.