Recommendations of the SEC (Oncology & Hematology) made in its 163rd meeting held on 07.12.2023 & 08.12.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/CT/18/000002 Leuprolide Acetate for Injection 3.75mg (Depot)	M/s. Bharat Serums and Vaccines Limited	During the SEC dated 24.8.23, the firm presented the Phase III clinical trial report of Leuprolide Acetate for Injection 3.75 mg (Depot)which was noted by the committee in detailed that the adverse event of hot flashes which is one of the most common side effects with the drug was found to be very low in clinical trial as compared to the reported percentage. The committee therefore recommended that the firm should submit clarification to CDSCO for further consideration. In the light of above, the firm presented the clarification with respect to the adverse event of hot flashes during the Phase III CT report of Leuprolide Acetate for Injection 3.75 mg (Depot). After detailed deliberation, the committee noted and agreed the results of the presented phase III CT study report.
Biological Division			
2.	BIO/CT04/FF/2023/38948 Dostarlimab concentrate for solution for injection50mg/mL	M/s. GSK Pharma	The firm presented the proposal to conduct Phase IV clinical study titled "Phase 4, open label, non-comparative, interventional, multicenter study to evaluate the safety of dostarlimab in adult patients in India with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regime" vide Protocol No. 221460 dated 25.07.2023. After detailed deliberation, the committee recommended for conduct of the Phase IV clinical study as per presented protocol with a condition that total evaluable patients in the study should be minimum 30.

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3.	BIO/CT18/FF/2023/39095 Trastuzumab deruxtecan concentrate solution for infusion 100mg	M/s. AstraZeneca Pharma India Limited	The firm presented the proposal for approval of additional indication for Trastuzumab Deruxtecan Powder for Concentrate for Solution for Infusion (Enhertu 100mg) i.e. "for the treatment of adult patients with unresectable or metastatic HER2-Low (IHC 1+ or IHC 2+/ISH-) breast cancer who have received a prior systemic therapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy. Patients with hormone receptor-positive (HR+) breast cancer should additionally have received or be ineligible for endocrine therapy" under the category of life-threatening & unmet need in the country with the request for waiver of the local clinical trial. The firm presented the results of clinical study conducted in other countries. The committee noted that the proposed indication of the drug is approved in other countries including US, EU, Canada and there is unmet medical need in the country for the proposed indication. After detailed deliberation, the committee recommended for approval of the proposed additional indication with a local clinical trial waiver.
4.	BIO/CT18/FF/2023/39189 Trastuzumab deruxtecan concentrate solution for infusion 100mg	M/s. AstraZeneca Pharma India Limited	The firm presented the proposal for addition of indication for Trastuzumab Deruxtecan Powder for Concentrate for Solution for Infusion (Enhertu 100mg) i.e. "for the treatment of adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior anti-HER2-based regimen" under the category of life-threatening & unmet need in the country with the request for waiver of the local clinical trial. The firm presented the results of clinical trial conducted in other countries. The committee noted that the proposed indication of the drug is approved in other countries including US, EU, Japan, South Korea and there is unmet

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			medical need in the country for the proposed indication. After detailed deliberation, the committee recommended for approval of the proposed additional indication with a local clinical trial waiver with a condition to conduct Phase IV clinical trial for Trastuzumab Deruxtecan Powder for Concentrate for Solution for Infusion 100mg in the proposed indication. Accordingly, the firm should submit Phase IV protocol to CDSCO within 3 months of approval of the additional indication.
5.	BIO/CT18/FF/2023/39191 Trastuzumab deruxtecan concentrate solution forinfusion 100mg	M/s. AstraZeneca Pharma India Limited	The firm presented the proposal for addition of indication for Trastuzumab Deruxtecan Powder for Concentrate for Solution for Infusion (Enhertu 100mg) under the category of life-threatening & unmet need in the country with the request for waiver of the local clinical trial. The proposed additional indication is "for the treatment of adult patients with unresectable or metastatic NSCLC whose tumors have activating HER2 (ERBB2) mutations and who have received a prior systemic therapy" The committee noted that India is part of an ongoing Phase III global clinical trial. After detailed deliberation, the committee recommended that firm should submit the safety and efficacy data of Indian patients for the proposed indication before the committee for consideration of the additional indication.
6.	BIO/CT04/FF/2023/39652 Lyophilized Recombinant L-asparaginase-II for Injection 10000IU	M/s. Gennova Biopharmaceuticals Limited	The firm presented protocol for conduct of Phase I clinical study titled "A double blinded, balanced, randomized, single dose, parallel group, active-controlled study to compare the pharmacokinetics of the test product GBL19 (recombinant asparaginase, Gennova Biopharmaceuticals Ltd.) with the reference product Spectrila®(Medac

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			GmbH) at 5000 IU/m2, in healthy, adult subjects and support modelling and simulation based extrapolation to paediatrics" vide Protocol number: PR/BE/23/281 version :00 dated15.09.2023 with waiver of clinical safety and efficacy study for marketing approval. The committee noted that recombinant L-Asparginase is presently not approved in India. Further, safety, efficacy and PK/PD parameters of the test product needs to be compared with the innovator product in multiple dosing regimen in patients for establishing the safety and efficacy of the applied product. After detailed deliberation, the committee recommended the firm to conduct Phase I/III clinical trial in patients to establish the safety, efficacy and immunogenicity parameters as per the regulatory requirements. Accordingly, firm should submit the revised protocol to CDSCO for further deliberation before the committee.
7.	4-04/Intas/PAC-R-Romiplastim/2021-BD Romiplostim powder & solvent for injection 125mcg in vial	M/s. Intas Pharmaceuticals Ltd.	The firm presented the proposal for additional pack of Romiplostim Injection (r-DNA Origin) 125 mcg/vial to already approved Romiplostim Powder and Solvent for Solution for Injection 250 mcg and 500 mcg (in Vial) packs. After detailed deliberation, the committee recommended for approval of the additional pack of Romiplostim Injection (r-DNA Origin) 125 mcg/vial to the firm.
8.	4-449/Roche/16-BD Emicizumab Injection (r-DNA origin) Solution for Injection	M/s. Roche Products India Pvt. Ltd.	The firm did not turn up for presentation.
9.	4-101 / Reliance / PACR-Interferon alfa 2b/2020-BD Interferon Alfa 2b injection	M/s. Reliance Life Sciences Pvt. Ltd	The firm presented the proposal for approval of revision in package insert for the approved product ReliFeron® (interferon alpha 2b) injection. The committee noted that the changes are proposed in line with the innovator product.

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			After detailed deliberation, the committee recommended for approval of the updated package insert Version 03 dated September 2022 for the product ReliFeron® (interferon alpha 2b) injection.
GCT Division			
10.	CT/61/23 Online Submission (37803) PTG-300	M/s. Medpace	In light of earlier SEC recommendation the proposal was deliberated on 26.09.2023 & 27.09.2023, the firm presented phase-III clinical study protocol No. PTG-300-11 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm subject to condition that at least 20% of sample size has to be from Indian patients.
11.	CT/172/21 Online Submission (28437) Elranatamab (PF-06863135)	M/s. Pfizer	The firm presented Protocol amendment 4 dated 14 August 2023, Protocol no. C1071007. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
12.	CT/105/22 Online Submission (28558) Giredestrant	M/s. Roche	The firm didn't turn up for presentation.
13.	CT/137/22 Online Submission (28454) Imlunestrant Vs standard Adjuvant	M/s. Eli Lilly	The firm presented Protocol amendment (c) dated 14 July 2023, Protocol no. J2J-MC-JZLH. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
14.	CT/30/21 Online Submission (28543) Olaparib	M/s. AstraZeneca	The firm presented Protocol amendment version 2.0 dated 09 August 2023, Protocol no. D9319C00001 After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm. The firm is also required to submit the

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			other regulatory approval globally to CDSCO for decrease the sample size.
15.	CT/29/19 Online Submission (28711) Capivasertib+ Paclitaxel	M/s. AstraZeneca	The firm presented Protocol amendment version 7.0 dated 24 July 2023, Protocol no. D3614C00001 After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm
16.	CT/25/16 Online Submission (7413) Abemaciclib	M/s. Eli Lilly	The firm presented Protocol amendment (i) dated 14 July 2023, Protocol no. 13Y-CR-JPBQ After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm
17.	CT/104/21 Online Submission (28233) LY3484356	M/s. Eli Lilly	The firm presented Protocol amendment (d) dated 31 July 2023, Protocol no.J2J-OX-JZLC After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm
18.	CT/102/23 Online Submission (39131) Belantamab Mafodotin (GSK2857916) for Injection 100mg	M/s. GSK Pharma	In light of earlier SEC, meeting dated 09.11.23 & 10.11.23. The firm presented phase –I Clinical trial, protocol no. 209664 After detailed deliberation, the committee opined that considering the serious adverse events in the study data presented by the firm (phase-I & II),it should be further evaluated through detailed results of adverse events on the ongoing study for further more cycle therapy. In addition, the firm should present separately the toxicity profile of Indian subjects. The committee opined that the proposal should be re-deliberated for further consideration.
19.	CT/151/22 Online Submission (34938) KRC-01	M/s. Prorelix Service	In light of earlier SEC dated 11.04.2023 & 11.05.2023, the proposal was re-deliberated before the committee for Phase-1/2 clinical trial, protocol KRC-

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			01-C01. After detailed deliberation the committee recommended that the firm should submit following data: 1. Published literature/academic research data in patients for locally advanced cervical cancer by administrating said drugs. 2. Regulatory approval from other countries. The committee also recommended that the proposal should be re-deliberated in presence of radiation oncologist for review by the committee.
20.	CT/36/22 Online Submission (28991) Selpercatinib	M/s. Eli Lilly	The firm didn't turn up for Presentation.
BA/BE Division			
21.	File No. 12-09/ 2023/BA-BE/ MISC-36/DC (B) BABE/CT05/FF/2023 /39162 Cabozantinibmonolaurylsulphate Capsule 30 mg	M/s. Cliantha Research Limited, Ahmedabad.	The firm presented their proposal before the committee. After detailed deliberation, the committee recommended to conduct BABE study with proposed protocol.
22.	File No. 12-09/2023/BA-BE/MISC-37/DC BABE/CT05/FF/2023 /39179 Cabozantinibmonolaurylsulphate Capsule 30 mg	M/s. Cliantha Research Limited, Ahmedabad.	The firm presented their proposal before the committee. After detailed deliberation, the committee recommended to conduct the BA/BE study as per the proposed protocol.