

Recommendations of the SEC (Oncology & Haematology) made in its 155th meeting held on 24.08.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT/18/000002 Leuprolide Acetate for Injection 3.75mg (Depot)	M/s. Bharat Serum	The firm presented the Phase III clinical trial report which was deliberated by the committee in detailed. 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.
2.	ND/CT/20/000022 Alpelisib Tablets 50mg	M/s. Sandoz Pvt. Ltd.	The firm presented the protocol amendment version 03 dated 03.03.2023 before the committee. After detailed deliberation, the committee recommended for grant of approval for the protocol amendment version 03 dated 03.03.2023. Further, the firm should submit the complete Global clinical trial report of earlier studies including report on Indian patients to CDSCO.
Biological Division			
3.	BIO/CT04/FF/2023/37064 Eptacog Alfa Factor VIIa (NovoSeven) 1mg/ml and 2mg/mL	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented their proposal to conduct Phase IV study protocol titled “safety of Eptacog alfa in postpartum Hamorrhage in India: A Phase IV interventional study” vide protocol no NN7711-7717 version 1.0 dated 07 Apr 2023 as part of the condition of approval of additional indication for the treatment of severe postpartum haemorrhage when uterotonics are insufficient to achieve haemostasis”. After detailed deliberation, the committee recommended for approval of the study to conduct the Phase IV as per the protocol presented by the firm.
4.	BIO/CT04/FF/2023/35976 Pegfilgrastim 6mg/0.6ml solution	M/s. Lupin Limited	The firm presented their proposal to conduct PK study titled “An open label, balanced, randomized, single-dose, two-treatment, two-sequence, four-period, crossover, fully-replicate, reference

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	for injection		<p>scaled comparative pharmacokinetics study of Lupin's Pegfilgrastim on body injector filled with Pegfilgrastim prefilled syringe solution for subcutaneous injection (Test) to deliver 6 mg/0.6 mL with Lupin's Pegfilgrastim solution in a single-dose prefilled syringe for manual subcutaneous injection (Reference) to deliver 6 mg/0.6 mL in Healthy, Adult, Human Subjects" vide protocol no. LBC-P-023-23 version 00 dated 06.04.2023.</p> <p>After detailed deliberation, the committee recommended for approval to conduct the study as per the protocol presented by the firm.</p>
5.	BIO/CT04/FF/2023/3 7010 Densoumab 70mg/ml injection	M/s. Virchow Biotech Private Limited	<p>The firm presented their proposal to conduct Phase III study titled "comparative pharmacokinetic, 2 pharmacodynamic, safety, efficacy and immunogenicity study of VBDNSM01 (Virchow Denosumab) versus Xgeva (Amgen Denosumab) in patients with bone metastasis from solid tumours" vide protocol no VBDNSM01/2023-CT1 version 01 dated 23.01.2023.</p> <p>After detailed deliberation, the committee recommended for approval to conduct the study with the following changes in the protocol:</p> <ol style="list-style-type: none"> 1) Calcium and Vitamin D level at baseline 2) Bone mineral deposit (BMD) to be monitored by bone DXA/DEXA scan. 3) The number of evaluable subjects in the test arm should not be less than 100. <p>Accordingly, the firm should submit the revised protocol to CDSCO for further review.</p>
6.	BIO/CT04/FF/2023/3 7386 Pegylated Erythropoietin 100mcg/0.3ml injection	M/s. Cliantha Research Limited	<p>The firm presented their proposal to conduct PK/PD study titled "A randomized, observer blind, parallel-group, active controlled, single dose study to compare pharmacokinetic, pharmacodynamic, safety and immunogenicity of Pegylated</p>

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			<p>Erythropoietin 100 mcg/0.3 ml injection (PEG-EPO) of Incepta and Methoxy Polyethylene Glycol-Epoetin Beta 100 micrograms/0.3 ml solution for injection of Roche (Mircera) in healthy adult human subjects” vide protocol no C1B02794 version 02 dated 25.04.2023.</p> <p>After detailed deliberation, the committee recommended for approval of the study as per presented protocol with the condition that the firm should submit the safety data of initial ten subjects (five in each arm of test and reference product) for review by the committee for further continuation of the study.</p> <p>Accordingly, the firm should submit the revised protocol for further review by the committee along with the data sought by CDSCO.</p>
SND Division			
7.	<p>SND/MA/22/000313</p> <p>Micronized Purified Flavonoid Fraction 500 mg tablets</p>	M/s. Servier Pvt. Ltd.	<p>In light of earlier SEC recommendations dated 28.03.2023 & 29.03.2023, the firm presented pathophysiology of proposed indications and mechanism of action of drug product along with supportive evidence from Indian and International guidelines before the committee.</p> <p>The committee noted that the Micronized Purified Flavonoid Fraction 500 mg and 1000mg tablets are approved in many countries like Canada, Spain, Portugal, Italy, Austria, Belgium, Denmark, Hungary, Luxembourg, Russia etc. for the proposed indications.</p> <p>The committee also noted that M/s. Servier Pvt. Ltd. in already holding permission of Micronized purified Flavonoid fraction 1000mg tablets since 2013.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Micronized Purified Flavonoid Fraction 500 mg tablets with clinical trial waiver for following additional Indication:</p> <p>1. Treatment of symptoms related to venolymphatic insufficiency (heavy legs,</p>

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			pain, restless leg syndrome). 2. Treatment of functional symptoms related to hemorrhoidal attack.
8.	SND/MA/23/000129 Megestrol Acetate Oral Suspension 125 mg/ml	M/s. Beta Drugs Ltd.	<p>The firm presented their proposal for manufacture and marketing of Megestrol Acetate oral suspension 125mg/ml (additional strength) along with justification for waiver of clinical trial and bioequivalence study protocol before the committee and informed that formulation is already approved in US market since 1993 under the brand name MEGACE ES.</p> <p>It was also informed by the firm that bioequivalence study was proposed to be conducted with megestrol acetate 125mg/ml oral suspension Vs. Megestrol 160mg of tablets Mfg. by M/s. Adley Formulations Pvt. Ltd. as the US approved product is not currently available in the US Market.</p> <p>After detailed deliberation, the committee opined that the bioequivalence study should be conducted preferably with similar formulation i.e. Megestrol acetate oral suspension 125mg/ml which is approved by USFDA.</p> <p>Therefore the committee recommended that the firm should provide the current availability status of drug product in US Market for further review by the committee.</p>
GCT Division			
9.	CT/110/22 Online Submission (26486) Xevinapant	M/s. IQVIA	The proposal was deferred for next SEC meeting.
10.	CT/143/22 Online Submission (26154) (VAYHIT2)	M/s. Novartis	The proposal was deferred for next SEC meeting.
11.	CT/54/23 Online Submission (37470) Naptumomab Estafenatox	M/s. PFC Pharma	The proposal was deferred for next SEC meeting.

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12.	CT/136/21 Online Submission (25868) Belantamab Mafodotin (GSK2857916)	M/s. GSK	The proposal was deferred for next SEC meeting.
13.	CT/86/23 Online Submission (38577) TK-112690	M/s. Biosphere Clinical Research	The proposal was deferred for next SEC meeting.
Medical Device Division			
14.	CI/MD/2023/89176 Onco Veryx	M/s. Clinfinite Solutions	<p>The firm presented the proposal before the committee for conduct of clinical investigation of the proposed product OncoVeryx before the committee as per protocol No: CLI-PDMX-IND-009, version 1.0 dated 03 Feb, 2023.</p> <p>The firm clarified that they are the Sponsor & have developed product indigenously & they will be planning for commercialization of the product and the purpose of the proposed study is to generate clinical data on the Indian patient specimen samples.</p> <p>After detailed deliberation, the committee opined as under:</p> <ol style="list-style-type: none"> 1. Since the firm has not submitted verification & validation data, any QC data & any published data on the applied product, the firm needs to submit the same. 2. After review of the clinical investigation plan, the committee opined that subject with either high-grade dysplasia, autoimmune disease, or chronic kidney disease should be included in the study & accordingly inclusion criteria of clinical investigation plan should be revised. 3. As the study is to be conducted on patient specimen samples, the opinion from the Subject experts of In-Vitro Diagnostic (IVD) kits shall also be obtained prior to taking further decision in the matter.