

Recommendations of the SEC (Oncology & Haematology) made in its 153rd meeting held on 25.07.2023 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-08/23-DC (Pt-90) 5-Flurouracil Injection	AIIMS, Raipur	<p>Study investigator AIIMS, Raipur deliberated their proposal to conduct academic clinical trial with drug 5-Flurouracil.</p> <p>After detailed deliberation, the committee opined that the trial design should be more elaborative with inclusion of IHC and other markers for quantification of fibrosis.</p> <p>Accordingly, revised protocol should be submitted before the committee for further consideration.</p>
2.	ND/MA/23/000094 Erdafitinib Tablets 3mg, 4mg and 5mg	M/s. Natco Pharma Limited	<p>The firm presented their proposal for grant of permission to manufacture and market Erdafitinib Tablets 3mg, 4mg and 5mg along with bioequivalence study data as well as Phase III clinical trial study waiver.</p> <p>After detailed deliberation, the committee did not recommend the waiver of Phase III clinical trial.</p> <p>Accordingly, the firm should submit the Phase III clinical trial protocol before the committee for further consideration.</p>
3.	12-01/23-DC(Pt-86) Goserelin Acetate Depot Injection 10.8mg (Zoladex)	M/s. AstraZeneca Pharma India Limited	<p>The firm presented their proposal for the expansion of present warning statement under Condition 04 of the marketing permission i.e. “To be sold on the prescription of an oncologist only” to “To be sold on the prescription of an oncologist/specialist only”.</p> <p>After detailed deliberation, the committee did not recommend the expansion of present warning statement in the present form.</p> <p>Accordingly, the committee recommended that the firm should submit the revised application with the request of inclusion of urologist instead of specialist for further consideration.</p>

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4.	ND/MA/22/000144 Relugolix Tablets 120mg	M/s. Zydus Lifesciences Ltd.	<p>In light of earlier recommendation dated 30-May-2023, the firm presented the innovator's safety and efficacy data available in public domain for grant of permission to manufacture and market the drug Relugolix Tablets 120mg with local Phase III clinical trial waiver.</p> <p>After detailed deliberation, the committee noted that Relugolix Tablets 120mg is approved in US and EU. Also, the committee already recommended for grant of permission to manufacture and market Relugolix Tablets 120mg to other firm vide its meeting dated 28-Mar-2023.</p> <p>The committee also opined that there is an unmet medical need in the country.</p> <p>Accordingly, the committee recommended for the grant of permission to manufacture and market drug Relugolix Tablets 120mg with local Phase III clinical trial waiver subject to the condition that firm should conduct Phase IV clinical trial within 3 months of approval and accordingly Phase IV clinical trial protocol should be submitted to CDSCO.</p>
Biological Division			
5.	BIO/CT04/FF/2023/3 6803 Denosumab Injection 120 mg/1.7 mL	M/s. Hetero Biopharma Limited	<p>The firm presented the proposal to conduct Phase IIIb clinical trial titled "A Phase IIIb, Prospective, Multicenter, Parallel, Assessor Blinded Extension Study to Evaluate the long-term Efficacy, Immunogenicity, Safety of Subcutaneous Injection of Denosumab (Hetero) in patients with bone metastases from solid tumours" as per protocol No. HCR/IIIb/DENOSOLEXT/01/2023, Version 1.0, dated 08 Mar 2023" which is an extension study of already approved clinical study vide protocol HCR/III/DENOSOL/12/2019 to evaluate the long-term efficacy, immunogenicity and safety of subcutaneous Hetero-denosumaband Reference medicinal product (Denosumab, Amgen) in patients with</p>

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			<p>bone metastases from solid tumours, who have completed 24 weeks (06 months) treatment on the HCR/III/DENOSOL/12/2019 study.</p> <p>After detailed deliberation, the committee recommended for approval of the presented protocol HCR/IIIb/DENOSOLEXT/01/2023, Version 1.0, dated 08 Mar 2023 to conduct the study. Note: Dr C.K. Bose did not participate in the deliberation.</p>
6.	<p>BIO/CT18/FF/2022/34156</p> <p>Nivolumab 10 mg/ml concentrate for solution for infusion (40 mg & 100 mg)</p>	M/s. Bristol-Myers Squibb India Pvt. Ltd.	<p>In light of the SEC recommendation dated 10.01.2023 the firm presented the additional data for justification of clinical trial waiver.</p> <p>After detailed deliberation, the committee recommended for approval of the additional indication “Nivolumab indicated for treatment of patients with advanced renal cell carcinoma (RCC) in combination with Cabozantinib” with waiver of Phase III clinical trial in the country with the condition that the firm should conduct Phase IV clinical trial. Accordingly, firm should submit Phase IV clinical trial protocol to CDSCO within three months of additional indication approval.</p>
SND Division			
7.	<p>SND/MA/23/000145</p> <p>Arsenic Trioxide Oral Solution 1mg/ml – 5ml (Additional dosage form & Indication)</p>	M/s Cipla Ltd.	<p>The firm presented their proposal for manufacture and marketing of Arsenic Trioxide Oral Solution 1mg/ml-5ml (additional dosage form and Indication) along with therapeutic rationale & justification for Phase III clinical trial waiver and BE study protocol before the committee.</p> <p>The Committee noted that the product Arsenol (arsenic trioxide) solution for oral use only 5mg in 5ml (1mg/ml) with same indication is approved since 2008 in the Hongkong.</p> <p>After detailed deliberation, the Committee recommended to conduct BE study as per protocol presented and firm</p>

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			should submit BE study report for further consideration of Phase III clinical trial waiver.
8.	SND/MA/23/000150 Bortezomib 2.5mg/ml & Bortezomib 3.5mg/1.4ml, 2.5mg/ml (Ready to use)	M/s Dr. Reddy's Laboratories Ltd.	The firm presented their proposal for manufacture and marketing of Bortezomib 2.5mg/ml & Bortezomib 3.5mg/1.4ml, 2.5mg/ml (Ready to use) (additional dosage form) along with therapeutic rationale & justification for Phase III clinical trial waiver before the committee. It was informed that the product is already approved in US and EU with same dosage form. After detailed deliberation, the committee recommended for grant of permission to manufacture Bortezomib 2.5mg/ml & Bortezomib 3.5mg/1.4ml, 2.5mg/ml (Ready to use) with clinical trial waiver subject to the condition that firm should conduct Phase IV clinical trial and accordingly, Phase IV clinical trial protocol should be submitted to CDSCO within 3 months of approval.
9.	SND/MA/22/000313 Micronized Purified Flavonoid Fraction 500mg Tablets	M/s. Servier Pvt. Ltd.	The proposal was deferred for next meeting.
10.	SND/MA/23/000129 Megestrol Acetate Oral Suspension 125mg/ml	M/s. Beta Drugs Ltd.	The proposal was deferred for next meeting.
GCT Division			
11.	CT/36/22 Online Submission (21074) Selpercatinib	M/s. Eli Lilly	The proposal was deferred for next meeting.
12.	CT/46/23 Online Submission (37340) Elrantamab +	M/s. Pfizer	The proposal was deferred for next meeting.

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	Daratumumab + Lenalidomide		
13.	CT/44/23 Online Submission (37301) Pozelimab & Cemdisiran	M/s. Parexel	The proposal was deferred for next meeting.
14.	CT/40/17 Online Submission (25623) Abemaciclib	M/s. Eli Lilly	The proposal was deferred for next meeting.
15.	CT/132/20 Online Submission (21879) BP01 (Bevacizumab)	M/s. Curateq	The proposal was deferred for next meeting.
16.	CT/110/20 Online Submission (21777) Durvalumab	M/s. AstraZeneca	The proposal was deferred for next meeting.
17.	CT/55/21 Online Submission (24122) TAR-200	M/s. PRA	The proposal was deferred for next meeting.
18.	CT/172/21 Online Submission (24324) Elrantomab	M/s. Pfizer	The proposal was deferred for next meeting.
19.	CT/111/22 Online Submission (25398) Teclistamab	M/s. J&J	The proposal was deferred for next meeting.
20.	CT/87/21 Online Submission (23899) Adjuvant Giredestrant	M/s. Roche	The proposal was deferred for next meeting.

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Medical Device Division			
21.	CI/MD/2022/77493 Cervical Cancer Screening Device (CerviScan)	M/s. Sascan Meditech Pvt. Ltd	In light of earlier SEC recommendations dated 11.05.2023, the firm presented their revised clinical investigation protocol for the conduct of pivotal clinical investigation of the proposed product Cervical Cancer Screening Device (CerviScan) before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the pivotal clinical investigation of the proposed product in Indian population with the following conditions: 1. Sample size of the study should be minimum of 2500. 2. There should be adequate control (Non-diseased) at each centre. 3. All the cases and controls to be confirmed with biopsy study.
New Drug Division			
22.	ND/CT/22/000022 Alpelisib film coated tablets 50mg, 150, and 200mg	M/s. Sandoz Private Limited	The proposal was deferred for next meeting.