

**Recommendations of the SEC (Oncology &Haematology) made in its 158<sup>th</sup> meeting held on 26.09.2023 & 27.09.2023 at CDSCO (HQ), New Delhi:**

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drug Division</b>			
1.	ND/CT/23/000056  Niraparib Tablets 100mg	M/s. GSK Pharma India Pvt. Ltd.	<p>The firm was granted permission on 01.05.2023 for import of drug for sale and distribution in the country with condition that the firm should conduct Phase IV clinical trials.</p> <p>The firm presented Phase IV clinical trial protocol for drug Niraparib tablets 100mg.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial as per the protocol presented.</p>
<b>SND Division</b>			
2.	SND/MA/22/000246  EribulinMesylate Solution for Injection 2.5mg in 5ml vial	M/s. Emcure Pharmaceuticals Limited	<p>In light of earlier SEC recommendations dated 24.08.2022, the firm presented specific justification for additional pack size along with Phase III clinical trial before the committee.</p> <p>It was informed by the firm that EribulinMesylate solution for injection 0.5mg/ml (2ml/vial intravenous route) is approved by CDSCO since 2016 for proposed indication.</p> <p>The committee noted that the proposed drug formulation is already approved in other country like United States, European Union, Japan and Canada for 1mg per 2ml pack size.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of EribulinMesylate solution for injection 2.5mg in 5ml vial (Additional Pack size) for proposed indications with waiver of clinical trial as this proposed formulation is patient and clinician convenience and administration of correct dose. However, the firm should fulfill the requirement of CMC data before approval.</p>

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3.	SND/MA/23/000138  Lenalidomide Capsules 10mg	M/s. Dr. Reddy's Laboratories Limited	<p>The firm presented their proposal for grant of permission for manufacture and marketing of Lenalidomide capsule 10mg with additional indication along with specific justification for Phase-III clinical trial before the committee.</p> <p>It was informed by the firm that Lenalidomide capsule 10mg is approved by CDSCO since 2007 for different indication.</p> <p>The committee noted that the Lenalidomide capsule 10mg already approved in other country like United States (in 2005), European Union (in 2007), and Australia (in 2007) for proposed indication.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of Lenalidomide capsule 10mg for proposed indications with waiver of Phase III clinical trial subject to condition that the firm should conduct Phase IV clinical trial study. However, the firm should fulfill the requirement of CMC data before approval.</p> <p>Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 03 months from date of approval of the drug for further review by the SEC committee.</p>
4.	SND/IMP/22/000088  Olaparib film coated tablet 100mg & 150mg (Additional Indication)	M/s. Astrazeneca Pharma India Limited	<p>In light of earlier SEC recommendations dated 23.02.2023, the firm presented specific justification for Phase III clinical before the committee.</p> <p>The committee noted that the Olaparib film coated tablet 100mg &amp; 150mg in already approved in 54 countries till date including in the US on 31<sup>st</sup> May 2023 and also approved in EU- Including Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland,</p>

**SEC (Oncology &Haematology) meeting dated 26.09.2023 & 27.09.2023**

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			<p>Portugal, Romania Slovak Republic, Slovenia, Spain, Sweden, Canada, Japan, Brazil, Singapore.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Olaparib film coated tablet 100mg &amp; 150mg (Additional Indication) with waiver of Phase-III clinical trial subject to condition that the firm should conduct Phase-IV clinical trial study on 300 population. However, the firm should fulfill the requirement of CMC data before approval.</p> <p>Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 03 months from date of approval of the drug for further review by the SEC Committee.</p>
<b>GCT Division</b>			
5.	<p>CT/61/23 Online Submission (37803)</p> <p>Hepcidin Mimetic Rusfertide (PTG-300)</p>	M/s. Medpace	<p>The firm presented Phase III clinical trial protocol No. PTG-300-11, amendment 2, 01 November 2022 before the committee.</p> <p>The committee noted that the sample size is very less for Indian population.</p> <p>After detailed deliberation, the committee recommended that the firm should submit sample size calculation for further review by the committee.</p>
6.	<p>CT/74/23 Online Submission (38096)</p> <p>Pegylated Factor VIII (BAX8551)</p>	M/s. IQVIA	The proposal was inadvertently added in the meeting and hence not deliberated.
7.	<p>CT/73/23 Online Submission (38090)</p> <p>MK-7684A (200 mg Vibostolimab and 200mg Pembrolizumab)</p>	M/s. MSD Pharmaceuticals	<p>The firm presented the Phase III clinical trial protocol No. MK-7684A PN 003 before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the protocol presented by the firm.</p>

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8.	CT/50/17 Online Submission (26894)  Lorlatinib (PF06463922) monotherapy versus Crizotinib monotherapy	M/s. Pfizer	The firm presented protocol amendment 08, dated 06 December 2022 for Protocol No. B7461006 before the committee.  After detailed deliberation, the committee recommended for approval of the proposed protocol amendment as presented by the firm.
9.	CT/159/22 Online Submission (26838)  ARV-471 Immediate Release Tablets 100 mg	M/s. Pfizer	The firm presented protocol amendment 02, dated 24 May 2023 for protocol No. C4891001 before the committee.  After detailed deliberation, the committee recommended for approval of the proposed protocol amendment as presented by the firm.
10.	CT/141/22 Online Submission (26866)  VAY736 (Ianalumab	M/s. Novartis	The firm presented their proposal to Waive off CT permission Condition (i) under clinical trial protocol number.: CVAY736O12301 as follow "submit safety data of 45 global subjects (including 08 subjects from the country) for review by the committee and once the data is reviewed by the committee trial might be continued in the country".  After detailed deliberation, the committee recommended to waive off the CT NOC Condition (i) of the CT permission.
11.	CT/148/21 Online Submission (26469)  Oregovomab	M/s. Star Genomics India Private Limited	The firm presented protocol amendment version 3.0 and version 4.0. for protocol no. QPT-ORE-005  After detailed deliberation, the committee recommended for approval of the amendment as presented by firm.
12.	CT/37/22 Online Submission (26441)  NBTXR3 Cetuximab	M/s. PRA	The firm presented protocol amendment 2, version 3.0 for protocol No. NANORAY-312  After detailed deliberation the committee recommended for approval of the amendment as presented by firm subject to the condition that: 1. Details of RT Techniques should be submitted to CDSCO. 2. Oral cavity tumors should be excluded from the study.

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13.	CT/111/22 Online Submission (25398)  Teclistamab	M/s. J&J	In light of earlier SEC recommendations dated 10.08.2023, the firm presented their proposal for protocol amendment vide protocol No. 64007957MMY3006, amendment 1, dated 16 Feb 2023 before the committee.  After detailed deliberation, the committee accepted the Justification and recommended for approval of the amendment as presented by firm.
14.	CT/87/23 Online Submission (38508)  NRC-2694 Tablets	M/s. Nacto Pharma Limited	The firm presented the Phase II clinical trial protocol No. NAT2694US before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the protocol presented by the firm.
15.	CT/84/22 Online Submission (27167)  Decitabine-tetrahydrouridine (NDec)	M/s. Nova Nordisk	The firm presented their proposal to increase the recruitment of additional patients for ongoing clinical study vide protocol No. NN7533-4470  After detailed deliberation, the committee recommended for approval for the increase in number of subjects from 15 to 45.
16.	CT/86/23 Online Submission (38577)  TK-112690	M/s. Biosphere Clinical Research	In light of earlier SEC recommendations dated 12.09.2023, the firm presented Phase IIa clinical trial protocol No. CLP-2690-0008, 1.0 dated 01-July-2023, adverse event reports of all previous studies and global regulatory status of the drug before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the study.
<b>New Drug Division</b>			
17.	ND/CT/23/000050  Entrectinib Capsules 100mg & 200 mg	M/s. Roche Products (India) Pvt. Ltd	In line with the earlier SEC recommendation dated 23.02.2023, the firm presented Phase IV clinical trial study protocol of drug Entrectinib capsules 100 mg & 200 mg before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial as per the protocol presented.