

Recommendations of the SEC (Investigational New Drugs) made in its 02nd/25 meeting held on 28.02.2025. at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
IND Division			
1.	IND/CT/23/000021 AUR-108 Indication: Relapsed Advanced Lymphoma (ASHA-1) (Re-Deliberation)	M/s Aurigene Oncology Limited	In light of previous SEC meeting dated 07.10.24 firm has re-deliberated proposal for Phase I study protocol AUR-108-101 version 3.0 dated 30.07.24 to SEC meeting for approval to include Chronic Lymphocytic Leukemia (CLL) patients in the study. After detailed deliberations the committee recommended that: <ol style="list-style-type: none"> 1. The firm needs to submit additional toxicological study data performed by the firm in support of the proposed new indication. 2. The firm needs to submit in-vitro study data in support of the proposed new indication. 3. The firm needs to revise the study protocol with respect to following: 4. The firm needs to revise the inclusion criteria to define the second line and third line treatment for study drug. 5. The firm needs to define whether single line treatment or combination of already approved treatment is used for said study. Accordingly, firm should submit the proposal for further review by the committee.
2.	E-Receipt-71300 Nafithromycin Tablet 400 mg	Wockhardt Ltd.	Firm has presented the proposal for approval of revised prescribing information (date of revision 01/2025), specimen artwork of the carton and labels of Nafithromycin Tablets 400 mg (MIQNAF) before the committee. After detailed deliberation, the committee recommended that the firm should revise the Prescribing Information and label as follows :- <ol style="list-style-type: none"> 1. The indication in revised prescribing information should be in-line with the indication mentioned in manufacturing and marketing permission issued by CDSCO.

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			<p>2. Warning statement “For supply only to Medical colleges/ Tertiary care Hospitals/ District Hospitals” should be mentioned in prescribing information and labels.</p> <p>3. The labels shall be revised to include word “Schedule H1 prescription Warning” instead of “Schedule H prescription Drug Warning” in draft labels as per the condition of manufacturing and marketing permission.</p> <p>Accordingly, firm need to submit the revised copy of prescribing information, specimen artwork of the carton and labels to CDSCO for further action in the matter.</p>
Biological Division			
3.	BIO/CT04/FF/2024/4774 NM8074	M/s Ablenio Sciences Pvt. Ltd.	<p>In light of the earlier SEC recommendation dated 11.11.2024, the firm presented clinical parameters of patients enrolled in the study along with justification for the new dose regime in cohort 3.</p> <p>After detailed deliberation committee recommended for approval of the revised protocol No. NM8074-PNH-103, Version 3.0 dated 01 Aug 2024, as presented by the firm.</p>