

Recommendations of the SEC (Oncology) made in its 26th/25 meeting held on 20.08.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	<p>SND/MA/25/000128</p> <p>Mercaptopurine Oral Suspension BP 20 mg/ml</p>	<p>Zydu Lifesciences Limited</p>	<p>Firm presented the BE study protocol in healthy, adult, human male subjects under fasting condition along with Phase III Clinical Trial Waiver before the committee.</p> <p>The committee noted that drug, Mercaptopurine is approved since 1953. Mercaptopurine oral suspension 20 mg/mL approved by USFDA in 2014, EMA in 2012 MHRA, UK in 2021.</p> <p>After detailed deliberation, the committee recommended to conduct the BE study with the presented BE protocol with the following changes: -</p> <p style="padding-left: 40px;">1. To include TPMT and NUDT 15 genotypic screening test at the time of screening.</p> <p>Accordingly, the revised protocol shall be submitted to CDSCO.</p> <p>Further, the committee did not consider the firm's request for Clinical Trial waiver and asked the firm to submit the BE study results along with proposal for follow up BE or modelling study in Paediatric Patients.</p>