

**Recommendations of the SEC (Pulmonary) made in its 06<sup>th</sup>/24 meeting held on 04.06.2024 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/56/24 Online Submission (42771)  Budesonide, Glycopyrronium & Formoterol Fumarate	M/s. AstraZeneca	<p>The firm presented phase III clinical study protocol no D5989C00001 version 2.0 dated 28.01.2024 addendum IND-1, version 1.0, 10 January 2024.</p> <p>After detailed deliberation, the committee recommended that the firm should include following in the protocol.</p> <ol style="list-style-type: none"> <li>1. Safety assessment of the infections which are not due to hospitalized pneumonia. (Protocol needs to define about how they are going to assess non hospitalize respiratory tract infection including tuberculosis, bacterial and fungal as well as how frequently in terms of investigations).</li> <li>2. Composite end points should be defined in detail and uniform protocol for diagnosis and management should be provided to all the sites.</li> <li>3. Informed consent should be revised to include that “in case of chest pain suggestive of MI, the subject is allowed to visit nearby hospital”.</li> </ol> <p>Accordingly, the firm should submit revised protocol for further review by the committee.</p>
2.	CT/51/24 Online Submission (42648)  BMS-986278	M/s. BMS	<p>The firm presented phase III clinical study protocol no. IM027068 version 2.0 dated 01.12.2023.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the trial with the condition that the firm should include more geographically distributed government sites in the study.</p>
3.	CT/57/24 Online Submission (42785)	M/s. BMS	<p>The firm presented phase III clinical study protocol no. IM0271015, amendment 01 dated 01.12.2023.</p>

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	BMS-986278		After detailed deliberation, the committee recommended for grant of permission to conduct the trial with the condition that the firm should include more geographically distributed government sites in the study.
<b>FDC Division</b>			
4.	FDC/MA/23/000270  Acebrophylline 100mg + Erdosteine 300mg film coated tablet	M/s. Macleods	In light of earlier SEC recommendation dated 05.10.2023, the firm presented the proposal along with BE study report before the committee. After detailed deliberation, the committee opined that the firm should submit the following: 1. Comparative analysis of mean value of different laboratory test parameters with reference individual product and FDC. 2. Number of patients in which fluctuations occurred in the laboratory test parameter. Accordingly, the firm should submit above data to CDSCO for further review by the committee.
<b>BA/BE Division</b>			
5.	BABE/CT05/FF/2024 /42470  Guaifenesin and Dextromethorphan HBr Extended Release Tablets 1200 mg/60 mg	M/s. CliNovi Research Pvt. Ltd.	The firm presented the Protocol No.: CNR-004-24 ver. 00 dated 07.03.2024 & CNR-005-24 ver. 00 dated 07.03.2024 along with safety profile of the Fixed Dose Combination for BA/BE study for export purpose only.  The Committee observed that the proposed study is a Single dose BE study in healthy subjects for export purpose only. The said drug is approved in USA as OTC. Further, there are no specific safety concerns associated with this drug.  Therefore, after detailed deliberation, the Committee recommended for conduct of proposed BA/BE study only for export purpose.

