

**Recommendations of the SEC (Pulmonary) made in its 09<sup>th</sup>/25 meeting held on 09.07.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drugs Division</b>			
1.	ND/IMP/24/000066 Olbas Oil 12 ml and 30 ml	M/s NK Healthcare Pvt.Ltd	Under Discussion.
<b>FDC Division</b>			
2.	FDC/CT/24/000019 Budesonide 160 mcg + Glycopyrronium 7.2 mcg + Formoterol fumarate dihydrate 5 mcg inhalation preparations	M/s AstraZeneca Pharma India Limited	In light of the earlier SEC recommendation dated 05.11.2024, the firm presented justification for sample size and duration of trial before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial.  Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
3.	FDC/MA/24/000096 Dextromethorphan Hydrobromide IP 10 mg + Phenylephrine Hydrochloride IP 5 mg) per 5 ml Syrup	M/s Zydus Healthcare Limited	In light of earlier SEC recommendation dated 11.06.2025, the firm presented Phase III CT protocol before the committee along with special invitee (Pediatrician).  After detailed deliberation, the committee opined that: <ol style="list-style-type: none"> <li>1. Patients below 18 years should be excluded from the study.</li> <li>2. Patients with pre-existing cardiovascular and respiratory disease should be excluded from the study.</li> </ol> Accordingly, the firm should submit revised Phase III CT study protocol to CDSCO for further review by the committee.
4.	FDC/MA/24/000097 Diphenhydramine Hydrochloride IP + Phenylephrine Hydrochloride IP (12.5 mg+ 5 mg)/ 5 ml Syrup	M/s Zydus Healthcare Limited	In light of earlier SEC recommendation dated 11.06.2025, the firm presented Phase III CT protocol before the committee along with special invitee (Pediatrician).  After detailed deliberation, the committee opined that: <ol style="list-style-type: none"> <li>1. Patients below 18 years should be</li> </ol>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>excluded from the study.</p> <p>2. Patients with pre-existing cardiovascular and respiratory disease should be excluded from the study.</p> <p>Accordingly, the firm should submit revised Phase III CT study protocol to CDSCO for further review by the committee.</p>
5.	<p>FDC/CT/25/000057</p> <p>Glycopyrronium (As Glycopyrrolate IP) 12.5 mcg + Formoterol Fumarate Dihydrate IP 6 mcg Inhaler</p>	M/s Cipla Limited	<p>In light of the condition mentioned in permission in Form CT-23 dated 05.03.2025; the firm presented the Phase IV clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial.</p> <p>Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.</p>
<b>GCT Division</b>			
6.	<p>CT/30/24 Online Submission (39709)</p> <p>BI 1015550</p>	M/s IQVIA RDS (India) Private Limited	<p>The firm presented phase-III protocol amendment version 5.0 dated 08 May 2025 protocol no. 1305-0031.</p> <p>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.</p>
7.	<p>CT/106/24 Online Submission (39940)</p> <p>SAR443765 solution for injection 165 mg/ 1.1 mL (150 mg/mL)</p>	M/s Sanofi Healthcare India Private Limited	<p>The firm presented for Increase in number of subjects from India 36 to 49 protocol no. LTS17231.</p> <p>After detailed deliberation, the committee recommended for approval of Increase in number of subjects from India 36 to 49 as presented by the firm.</p>
8.	<p>CT/77/25 Online Submission (50095)</p> <p>AZD6793 5 mg or 15 mg or 45 mg or Placebo Tablets</p>	M/s AstraZeneca Pharma India Limited	<p>The firm presented phase IIb clinical study protocol no. D7860C00006, CSP Version 1.0 dated 19 Mar 2025 and Local CSP Addendum IND-1: Version 1.0 dated 11 Apr 2025.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.</p>