

Recommendations of the SEC (Pulmonary) made in its 03rd/25 meeting held on 11.03.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/07/25 Online Submission (47473) Tezepelumab	M/s Astrazeneca Pharma India Limited	The firm presented phase III clinical study protocol no. D5241C00006 CSP version 1.0 dated 02 Dec 2024 and Local CSP Addendum IND-1 version 1.0 dated 03 Jan 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/130/24 Online Submission (46079) LY3502970	M/s Eli Lilly and Company India Pvt. Ltd.	The firm didn't turn up for presentation.
3.	CT/51/23 Online Submission (37415) MSTT1041A (Asteogolimab or RO7187807)	M/s PPD Pharmaceutical Development India Private Limited	The firm presented protocol amendment version 5.0 dated 08 November 2024 protocol no. GB44332. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
SND Division			
4.	SND/CT04/FF/2022/3 2439 Inhaled Itraconazole dry powder for inhalation 10 mg capsule (PUR1900)	M/s Cipla Limited	In light of the earlier SEC recommendation dated 07.07.2022, firm presented the Phase-II clinical trial report before the committee. After detailed deliberation, the committee accepted the phase-II clinical trial results and agreed to the firm's proposal to proceed with the 40mg dose of Inhaled Itraconazole dry powder for inhalation 10 mg capsules (PUR 1900) in Phase-III clinical trial and firm shall submit the Phase III protocol to CDSCO for taking further necessary action.
5.	SND/MA/25/000018 Ivacaftor Tablet 75 mg/150 mg (ORPHAN Drug)	M/s Pure & Cure Healthcare Private Limited	Firm has presented the proposal for the manufacture and market permission of Ivacaftor tablet 75 mg and 150 mg along with BE study protocol with Ivacaftor tablet 150 mg and request for Phase-III clinical trial waiver.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>Firm informed that Ivacaftor Tablets 75mg and 150 mg are approved by EMA and Ivacaftor tablets 150 mg and Ivacaftor oral granules 25mg, 50mg, 75mg are approved in USA and Canada.</p> <p>After detailed deliberation, the committee recommended for the grant of permission to conduct the BE study as per the protocol presented by the firm. After completion of the BE Study, firm shall submit the BE report to the CDSCO for taking further necessary action. Further the decision on the CT waiver will be taken after submission of the BE report.</p>
FDC Division			
6.	FDC/CT/24/000093 Glycopyrronium 50mcg, Fluticasone Furoate 100mcg and Vilanterol 25mcg Powder for Inhalation	Glenmark Pharmaceuticals Limited	<p>In light of the earlier SEC recommendation dated 04.12.2024, the firm presented the proposal along with revised Phase IV CT 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>
7.	FDC/MA/23/000338 Glycopyrrolate IP eq. to Glycopyrronium 25mcg + Indacaterol Maleate eq. to Indacaterol 55mcg Metered dose inhalation	M/s Zydus Healthcare Limited	<p>In light of the earlier SEC recommendation dated 05.11.2024, the firm presented the proposal along with Phase III CT protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial.</p> <p>Accordingly, the firm should submit the Phase III CT report to CDSCO for further review by the committee.</p>
8.	FDC/MA/23/000349 Vilanterol Trifenatate equivalent to Vilanterol 25mcg +	M/s Zydus Healthcare Limited	<p>In light of the earlier SEC recommendation dated 27.11.2024, the firm presented the proposal along with Phase III CT protocol before the committee.</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Umeclidinium Bromide equivalent to Umeclidinium 62.5mcg Powder for Inhalation		<p>After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial with subject to the condition that severe COPD patients with inspiratory flow rate of less than 30 liter per minute must be excluded from the study.</p> <p>Accordingly, the revised phase III CT protocol should be submitted to CDSCO for review.</p> <p>After approval from CDSCO, the firm should submit Phase III CT report to CDSCO for further review by the committee.</p>