Recommendations of the SEC (Pulmonary) made in its 13th/25 meeting held on 14.10.2025 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/140/25 Online Submission (52120) LY3537031	M/s Clinical Trials Eli Lilly and Company India Pvt. Ltd.	The firm presented Phase II protocol no.: J2S-MC-GZMR version no. a dated 01-AUG-2025. After detailed deliberation, the committee opined that the firm should submit the following information for further review by the committee: 1. Preclinical data in an asthmatic model along with proof-of-concept to justify the conduct of the proposed clinical trial. 2. Scientific rationale for the proposed Phase II study supported by Phase I study data generated in asthmatic patients. 3. Supporting data and relevant literature on the use of the product as an add-on therapy in asthmatic patients.
Biological Division			
2.	BIO/CT04/FF/2025/50889 Sotatercept 45 mg and 60 mg	M/s MSD Pharmaceuticals Private Limited	The firm presented the proposal for grant of permission to conduct a Phase IV clinical trial titled "A Phase 4, Prospective, Open-label, Single-Arm Study to Evaluate the Safety of Sotatercept in Adults with Pulmonary Arterial Hypertension (PAH) in India" vide Protocol No. MK7962-037 dated 23.05.2025. After detailed deliberation, the committee recommended for the conduct of clinical trial as per the protocol presented by the firm with the condition that clinical trial sites should be geographically distributed including Government sites.
SND Division			

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
3.	SND/MA/25/000174 Ivacaftor Tablets 75 mg and 150 mg	M/s.MSN Laboratories Private Limited	The firm did not turn up for the presentation.
FDC Division			
4.	FDC/CT/23/000028 Glycopyrronium Ph. Eur 25 mcg + Formoterol fumarate IP 12 mcg + Budesonide IP 400 mcg Inhalation Powder in Capsule	M/s. Lupin Ltd.	In light of earlier SEC recommendation dated 06.06.2023 and as per condition of Form CT-23 dated 16.01.2023, the firm presented Phase IV clinical trial report before the committee. After detailed deliberation, the committee noted that data collected from multisite study is not uniform. Accordingly, firm should submit the compiled data to CDSCO for further review by the committee.
5.	FDC/CT/23/000091 Fluticasone Furoate 100 mcg + Glycopyrronium Bromide eq. to Glycopyrronium 50 mcg + Vilanterol Trifenatate eq. to Vilanterol 25 mcg Inhalation Powder in capsule	M/s. Lupin Ltd.	In light of earlier SEC recommendation dated 04.01.2024 and as per condition of Form CT-23 dated 26.09.2023, the firm presented Phase IV clinical trial report before the committee. After detailed deliberation, the committee noted and agreed to the result of the clinical trial report.
6.	FDC/CT/24/000014 Glycopyrronium Bromide (eq. to 50mcg of Glycopyrronium) 63 mcg + Vilanterol Trifenatate (eq. to 25 mcg Vilanterol) 40 mcg Powder for Inhalation in Capsule	M/s Lupin Limited	In light of earlier SEC recommendation dated 05.03.2024 and as per condition of Form CT-23 dated 15.11.2023, the firm presented Phase IV clinical trial report before the committee. After detailed deliberation, the committee noted and agreed to the result of the Clinical trial report.
7.	FDC/MA/24/000250 Fluticasone Furoate BP	M/s Malik Life Sciences Pvt. Ltd.	The firm did not turn up for the presentation.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	200 mcg + Umeclidinium Bromide Eq. to Umeclidinium 62.5 mcg + Vilanterol Trifenatate Eq. to Vilanterol 25 mcg Powder for Inhalation in Capsule		
8.	FDC/MA/25/000053 Glycopyrrolate IP eq. to Glycopyrronium 100 mcg + Vilanterol Trifenatate eq. to Vilanterol 50 mcg + Fluticasone Furoate 200 mcg Inhalation Suspension	M/s Glenmark Pharmaceuticals Ltd.	The firm did not turn up for the presentation.