Recommendations of the SEC (Pulmonary) made in its 05th/25 meeting held on 13.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/130/24 Online Submission (46079) LY3502970	M/s. Eli Lilly and Company India Pvt. Ltd	In light of earlier SEC Recommendation dated 04.12.2025, the firm presented phase 3 clinical study protocol no. J5P-MC-GZRA (ATTAIN- OSA) dated 08 Aug 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that India specific addendum with respect to fundus examination at beginning midway and end shall be submitted.
2.	CT/163/23 Online Submission (35978) Benralizumab	M/s. Fortrea Development India Private Limited	In light of earlier SEC Recommendation dated 04.12.2025, the firm presented protocol amendment version 9.0 dated 26 September 2024 protocol no. D3254C00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
3.	BIO/CT18/FF/2024/44555 Benralizumab 30mg/mL solution for injection	M/s. AstraZeneca Pharma India Limited	In light of earlier SEC recommendation dated 05.11.2024, the firm presented additional data on phenotype-specific response from the Phase III global trial, dosing, clinical data beyond 52 weeks, and aligning the proposed indication with EMA along with a request for waiver of local clinical trial. The committee noted that the proposed indication is approved in 52 countries, including the US, EU, UK, Japan, and Australia. The committee also noted that the proposed additional indication falls under the rare and life-threatening disease category, with an unmet medical need. After detailed deliberation, the committee recommended approval of the additional indication: "Benralizumab is indicated as an add-on treatment for adult patients with relapsing or refractory eosinophilic

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			granulomatosis with polyangiitis (EGPA)."
New Drug Division			
4.	ND/MA/25/000017 Revefenacin inhalation solution. 175 mcg /3ml	M/s AKUMS DRUGS & PHARMACEUTICALS LIMITED	Under Discussion.
5.	ND/MA/25/000002 Gefapixant Tablets 45mg.	M/s Exemed Pharmaceuticals	The firm has presented the proposal for grant of permission to manufacture and marketing of Gefapixant tablets 45 mg, indicated in adults for the treatment of refractory or unexplained chronic cough, along with Bioequivalence study protocol and Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study and Phase III clinical trial. Further, the firm should submit Bioequivalence study report to CDSCO for review by the committee, before initiating the Phase III clinical trial.
6.	ND/MA/25/000021 Revefenacin Inhalation Solution 175 mcg / 3 ml	M/s BDR Pharmaceuticals International Pvt Ltd	Under Discussion.
SND Division			
7.	SND/CT/25/000022 12 SQ-HDM SublingualLyophilisate (Sensimune)	M/s Dr. Reddy's Laboratories Limited	The firm presented the proposal for grant of permission to conduct Phase IV clinical trial vide protocol No. DRL/SMUNE/2025, Version:1.0, dated 21 February 2025 before the committee. After detailed deliberation, the committee opined to revise the protocol as below- 1) 'Observational' word to be removed from the protocol. 2) Sample size to be increased based on statistical analysis. 3) Endpoints to be defined in the protocol. 4) Study centres should be selected to represent geographical distribution

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			and inclusion of 50% Government CT sites. 5) Respiratory quotient (RQ) and Life Quality (LQ) to be included. Accordingly, the firm should submit revised protocol to CDSCO.
FDC Division			
8.	FDC/CT/25/000036 Indacaterol maleate eq. to Indacaterol 75mcg/150mcg + Budesonide IP 200mcg/400mcg Dry Powder for inhalation (capsules)	M/s Zydus Healthcare Limited	In light of the condition mentioned in permission in Form CT-23 dated 22.09.2023, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct of the Phase IV clinical trial. Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
9.	FDC/MA/25/000068 Fluticasone Furoate 200 mcg + Umeclidinium 62.5 mcg + Vilanterol 25 mcg Dry Powder for Inhalation	M/s Glenmark Pharmaceuticals Ltd.	The firm presented their proposal along with Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial study with condition that: 1. Study should be conducted on subjects with uncontrolled asthma. 2. More Government sites should be included and the sites should be geographically distributed. Accordingly, the revised Phase III CT Protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Phase III CT report for further review by the committee.