Recommendations of the SEC (Pulmonary) made in its 11th/25 meeting held on 22.08.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/98/25 Online Submission (49889) BTZ-04 Quabodepistat (OPC-167832) Delpazolid (LCB01-0371) Ganfeborole	M/s ICMR-National Institute For Research In Tuberculosis	The firm didn't turn up for the presentation.
2.	CT/18/23 Online Submission (40634) BLU-5937	M/s IQVIA RDS (India) Private Limited	The firm presented protocol amendment 3 dated 08 July 2025 protocol no. BUS-P3-02 (calm-2). After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm
New Drugs Division			
3.	ND/MA/25/000065 Revefenacin Inhalation solution 175 mcg/3 ml	M/s Sun Pharmaceutical Industries Limited	The firm presented the proposal for grant of permission to manufacture and market Revefenacin Inhalation solution 175mcg/3ml along with phase III Clinical Trial protocol (Protocol No ICR/25/004, Version No 2.0 dated 03.07.2025) and BE waiver before the committee. The firm presented Phase III CT protocol including study objectives, study endpoints, study design, inclusion criteria, exclusion criteria, clinical investigations, schedule of assessments and proposed study sites before the committee. After detailed deliberation, the committee recommended that firm should revise inclusion criteria so that subjects on triple therapy only shall be included in the study as per protocol presented by the firm and revised protocol shall be submitted to CDSCO.
FDC Division			
4.	FDC/MA/25/000155 Fluticasone Furoate 50 mcg + Umeclidinium Bromide eq. to Umeclidinium 31.25 mcg + Vilanterol	M/s Lupin Limited	The firm presented the proposal along with Phase III Clinical Trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III Clinical Trial with the following conditions:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Trifenatate eq. to Vilanterol 12.5 mcg Metered Dose Inhaler		1. Participant's age should be modified to ≥40 years with COPD. 2. More Government sites should be included and the sites should be geographically distributed. Accordingly, the revised Phase III Clinical Trial protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Phase III Clinical Trial report for further review by the Committee.
5.	FDC/CT/25/000075 Budesonide IP 200mcg + Glycopyrronium Bromide eq. to Glycopyrronium 12.5 mcg + Formoterol Fumarate Dihydrate IP 6 mcg Metered Dose Inhalers	M/s Lupin Limited	In light of the condition mentioned in permission in Form CT-23 dated 25.04.2025; the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial with condition that participant's age should be modified to ≥40 years with COPD. Accordingly, the revised Phase IV Clinical Trial protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Phase IV Clinical Trial report for further review by the Committee.