Recommendations of the SEC (Pulmonary) made in its 05th/26 meeting held on 21.04.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/41/26 Online Submission (55613) Benralizumab (MEDI-563)	M/s. PAREXEL International Clinical Research Private Limited	The firm presented phase III clinical study D3255C00004, Version 3.0 dated 02 Dec 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition. 1. The Principal Investigator shall be Paediatrician and the Co-Principal Investigator shall be pulmonologist. 2. More geographically distributed government site shall be included in the study.
2.	CT/17/26 Online Submission (54205) Bromhexine Hydrochloride Nasal Spray 2 mg/ml	M/s. Vivotech Research Lab Private Limited	Under Discussion.
FDC Division			
3.	FDC/MA/23/000338 Glycopyrrolate IP eq. to Glycopyrronium 25 mcg + Indacaterol Maleate eq. to Indacaterol 55 mcg Metered dose inhalation	M/s. Zydus Healthcare Limited	In light of earlier SEC recommendation dated 11.03.2025, the firm presented Phase III CT report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC.
4.	FDC/MA/25/000036 Glycopyrronium bromide eq. to Glycopyrronium 12.5 mcg + Formoterol Fumarate Dihydrate 6 mcg + Fluticasone Propionate 125 mcg Metered Dose Inhaler	M/s. Lupin Limited	In light of earlier SEC recommendation dated 09.04.2025, the firm presented Phase III CT report before the committee. After detailed deliberation, the committee opined that the firm should submit complete raw data for all outcomes of interest pertaining to both study groups i.e. treatment and reference group.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
			Accordingly, the firm should submit above data for further review by the committee.
5.	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 10.09.2025, the firm presented Phase III CT report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC for the indication “Symptomatic Treatment of Cough and Cold in adults”.
6.	FDC/MA/24/000097 Diphenhydramine Hydrochloride IP + Phenylephrine Hydrochloride IP (12.5 mg+5 mg)/ 5ml Syrup	M/s. Zydus Healthcare Limited	In light of earlier SEC recommendation dated 10.09.2025, the firm presented Phase III CT report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDCfor the indication“Symptomatic Treatment of Cough and Cold in adults”.