Recommendations of the SEC (Pulmonary) made in its 14th/25 meeting held on 18.11.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2025/50486 Mepolizumab 100 mg/mL solution for injection in prefilled syringe (r-DNA origin)	M/s. Lupin Limited	The firm presented the proposal to conduct Phase I clinical trial titled, "A Double Blind, Randomized, Single-Dose, Single-Period, Two-Treatment, Parallel Comparative Pharmacokinetics and Pharmacodynamics Study of Lupin's Mepolizumab with US Licensed NUCALA (Mepolizumab) in Healthy, Adult, Human Subjects vide" Protocol No. LBC-P-203-24; Version No. 00; Dated: 27th May, 2025. The committee noted that the subject study has been approved abroad for export consideration. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial as per the protocol presented by the firm.
FDC Division			
2.	FDC/MA/25/000019 Acebrophylline 100 mg + Erdosteine 300 mg film coated bilayered tablet	M/s. Theon Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 20.02.2025, the firm presented the proposal along with BE study report under fasting condition before the committee. After detailed deliberation, the committee considered the BE study report and recommended to initiate Phase III clinical trial study for which permission is already granted by CDSCO. Accordingly, Phase III clinical trial report should be submitted to CDSCO for further review by the committee.
3.	FDC/CT/25/000047 Budesonide IP 160 mcg + Glycopyrrolate IP 9 mcg + Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 4.8 mcg Inhalation Aerosol	M/s. Macleods Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 18.06.2025 and as per condition of Form CT-23 dated 20.02.2025, the firm presented the revised Phase IV clinical trial protocol before the committee. After detailed deliberation, the

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			committee recommended for grant of permission to conduct the Phase IV clinical trial. Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
4.	FDC/MA/25/000210 Levosalbutamol Sulphate IP eq. to Levosalbutamol 0.63 mg/1.25 mg + Ipratropium Bromide IP eq. to Ipratropium Bromide (Anhydrous) 500 mcg/500 mcg + Budesonide IP 0.25 mg/0.5 mg In isotonic solution Inhalation Suspension (for Nebulization)	M/s. Glenmark Pharmaceuticals Ltd.	The firm presented the proposal before the committee. After detailed deliberation, the committee opined that: 1. The proposed three drug combination is not approved anywhere in the world. 2. The firm did not present any published literature. 3. As per GINA guideline, high dose ICS are recommended/ suggested. However, proposed FDC contains low dose. In view of above, the committee did not recommend for the approval of the proposed FDC.