Recommendations of the SEC (Pulmonary) made in its 09th/26 meeting held on 15.07.2026 at CDSCO HQ New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/79/26 Online Submission (57094) Deupirfenidone	M/s. IQVIA RDS (India) Private Limited.	The firm presented phase III clinical study protocol no. LYT-100-2025-301 version no. 2.0 dated 27-MAR-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that more government sites shall be included in the study.
2.	CT/87/26 Online Submission (57359) LY3537031	M/s. Clinical Trials Eli Lilly and Company India Pvt. Ltd.	The firm presented phase II clinical study protocol no. J2S-MC-GZMV version no. a dated 27-APR-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that more government sites shall be included in the study.
3.	CT/73/26 Online Submission (56903) Benralizumab	M/s. Fortrea Development India Private Limited.	The firm presented phase III clinical study protocol no. D3250N00036 CSP version no. 1.0 dated 04-DEC-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
FDC Division			
4.	FDC/MA/26/000001 Glycopyrrolate IP eq. to Glycopyrronium 25 mcg + Formoterol fumarate dihydrate IP eq. to Formoterol fumarate 20 mcg + Budesonide IP 0.5mg per 2 ml pulmule Inhalation suspension (For nebulization)	M/s Alkem Laboratories Ltd.	The firm presented the proposal along with in-vitro data & BE study protocol (under fasting condition) before the committee. The committee noted that the proposed FDC is already approved by this Directorate on 22.10.2025. After detailed deliberation, the committee recommended to conduct BE study. Accordingly, the firm should submit BE study report to CDSCO for further review by the committee.
5.	FDC/MA/26/000065 Dextromethorphan Hydrobromide IP 10 mg + Chlorpheniramine	M/s. Akums Drugs and Pharmaceuticals Ltd.	The firm presented the proposal along with BE study protocol (under fasting condition) & phase III CT waiver before the committee. After detailed deliberation, the committee

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	Maleate IP 2 mg + Phenylephrine Hydrochloride IP 5 mg Lozenges		recommended for grant of permission to conduct the BE study. Accordingly, the firm should submit BE study report to CDSCO for further review by the committee. As regard to Phase III clinical trial decision may be taken after review of BE study results.
6.	FDC/CT/26/000047 Fluticasone Furoate 100mcg + Glycopyrronium IP eq. to Glycopyrronium 50 mcg + Vilanterol Trifenatate equivalent to Vilanterol 25 mcg Powder for Inhalation in hard cellulose capsule	M/s. Sun Pharma Laboratories Limited	In light of the condition mentioned in permission in Form CT-23 dated 18.03.2026; 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. Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
7.	FDC/CT/26/000050 Fluticasone Furoate 100 mcg/200 mcg/400 mcg + Umeclidinium Bromide eq. to Umeclidinium 62.5 mcg/125 mcg/250 mcg + Vilanterol Trifenatate eq. to Vilanterol 25 mcg/50 mcg/100 mcg Inhalation Suspension (for nebulization)	M/s. Glenmark Pharmaceuticals Ltd.	The firm presented the proposal along with BA study protocol before the committee. The committee noted that Test-2 (Fluticasone Furoate 200 mcg, Umeclidinium 125 mcg and Vilanterol 50 mcg Inhalation Suspension) and Test-3 (Fluticasone Furoate 400 mcg, Umeclidinium 250 mcg and Vilanterol 100 mcg Inhalation Suspension) products are not yet approved. After detailed deliberation, the committee recommended to conduct BA study and submit the BA study report to CDSCO for further review by the committee to take necessary action in the matter.