Recommendations of the SEC (Pulmonary) made in its 06th/26 meeting held on 14.05.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/48/26 Online Submission (55855) Benralizumab	M/s. PAREXEL International Clinical Research Private Limited	The firm presented phase III clinical study protocol no. D3250C00024, version no. 3.0 dated 02 December 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/15/26 Online Submission (54599) Beclometasone Dipropionate + Formoterol Fumarate Dihydrate + Glycopyrronium	M/s. Cliantha Research Limited	The firm presented phase III clinical study protocol no. C2A06522, version no. 01 dated 16 January 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
New Drugs Division			
3.	ND/MA/25/000185 Gefapixant 45 mg Tablet	M/s. PURE & CURE HEALTHCARE Pvt. Ltd	The firm 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. The committee also recommended for grant of permission to conduct Phase III clinical trial with the condition that firm should revise the exclusion criteria to not include the asthma patients. Accordingly, the firm should submit the revised Phase III clinical trial protocol to CDSCO. Further, the firm should submit Bioequivalence study report to CDSCO for review by the committee, before initiating the Phase III clinical trial.
FDC Division			
4.	FDC/CT/23/000080	M/s. Zydus Healthcare	In light of earlier SEC recommendation dated 04.01.2024, the firm presented

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	Fluticasone Furoate 200 mcg + Vilanterol Trifenatate eq. to Vilanterol 25 mcg dry powder for inhalation in capsule	Limited	Active PMS report before the committee. After detailed deliberation, the committee noted and agreed to the result of the Active PMS report.
5.	FDC/MA/26/000009 Fluticasone Furoate 200 mcg + Umeclidinium 125 mcg + Vilanterol Trifenatate 50 mcg Inhalation Suspension (for nebulization)	M/s. Glenmark Pharmaceuticals Ltd.	The firm presented their proposal before the committee. After detailed deliberation, the committee considered the essentiality and desirability of the proposed FDC. Further, firm has not submitted the requisite protocols as per the applied FDC. Accordingly, the firm should submit revised protocols to CDSCO for further review by the committee.
6.	FDC/MA/26/000034 Levosalbutamol Sulphate IP eq. to Levosalbutamol 1.25mg + Sodium chloride IP 3% w/v per 4ml pulmule Inhalation solution (For nebulization)	M/s. Alkem Laboratories Ltd.	The firm presented their proposal along with request for BE waiver & Phase III CT waiver before the committee. After detailed deliberation, the committee opined the following: 1. The firm did not present scientific literature published in peer reviewed journals regarding rationality, essentiality and desirability of the proposed FDC. 2. There is no unmet need for the FDC. 3. The product is not approved internationally. Further, considering the potential risk of death and bronchospasm due to serious adverse events as per Prescribing information submitted by the firm, the committee noted that it is also unethical to conduct the study on human beings. Hence, the committee did not recommend for approval of the proposed FDC.
7.	FDC/MA/25/000068 Fluticasone Furoate 200 mcg + Umeclidinium 62.5 mcg + Vilanterol 25	M/s. Glenmark Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 13.05.2025, the firm presented Phase III CT report before the committee. After detailed deliberation, the committee recommended for grant of permission for

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	mcg Dry Powder for Inhalation		manufacturing and marketing of the proposed FDC.
8.	FDC/MA/26/000053 Salbutamol Sulphate IP eq. to Salbutamol 90mcg + Budesonide IP 80mcg Metered Dose Inhaler	M/s. Cipla Limited	The firm presented their proposal along with BA study report & Phase III CT waiver before the committee. The committee noted that the said FDC is already approved in the USA. However, no clinical safety and efficacy data was presented by the firm in Indian population. After detailed deliberation, the committee considered the request for BA/BE waiver. As regard to Phase III CT waiver was not considered and recommended to conduct Phase III CT study. Accordingly, the firm should submit Phase III CT protocol to CDSCO for further review by the committee.