

Recommendations of the SEC (Pulmonary) made in its 03rd/26 meeting held on 17.03.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
BABE Division			
1.	BABE/CT05/FF/2025/52977 Riociguat extended-release tablets 3 mg and 4.5 mg	M/s Azidus Laboratories Limited	Firm presented the BA/BE study Protocol No. AZBE092519 Version No. 1.0 Protocol Date 30-OCT-2025 for export purpose only before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BABE study for export purpose only, with condition to submit updated ICF in vernacular language covering financial compensation and medical management.
Biological Division			
2.	BIO/CT18/FF/2025/52532 Benralizumab 30 mg/ml solution for injection in pre-filled syringe	M/s. AstraZeneca Pharma India Limited	The firm did not attend the meeting.
New Drug Division			
3.	ND/MA/24/000069 Revefenacin Inhalation solution 175 mcg/3ml	M/s. Zydus Healthcare Limited	In light of earlier SEC recommendation dated 09.04.2025, the firm presented Phase III Clinical trial report for manufacture and marketing of new drug Revefenacin Inhalation solution 175 mcg/3ml before the committee. After detailed deliberation, the committee recommended for the grant of permission for manufacturing and marketing of drug Revefenacin Inhalation solution 175 mcg/3ml.

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4.	ND/17/2026-eoffice Bosentan Tablets 62.5 mg and Bosentan Tablets 125 mg	M/s. Cipla Limited	The firm presented proposal for update in Prescribing Information of drug, Bosentan Tablets 62.5 mg and 125 mg (Date of revision: 04.12.2025) before the committee. After detailed deliberation, the committee recommended for update in prescribing Information, as presented by firm.
SND Division			
5.	SND/MA/25/000144 Sodium Chloride Nebuliser Solution BP 3% W/V	M/s. Zydus Healthcare Limited	In light of earlier recommendation dated 10.09.2025, the firm presented the proposed Package insert for Sodium Chloride Nebuliser Solution 3% w/v before the Committee. After detailed deliberation, the committee accepted the presented package insert for Sodium Chloride Nebuliser Solution 3% w/v
FDC Division			
6.	FDC/MA/23/000349 Vilanterol Trifenatate equivalent to Vilanterol 25mcg + Umeclidinium Bromide equivalent to Umeclidinium 62.5mcg Powder for 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.
7.	FDC/MA/24/000045 Vilanterol Trifenatate equivalent to Vilanterol 25mcg + Umeclidinium Bromide equivalent to Umeclidinium 62.5mcg Dry Powder Inhaler in capsule	M/s. Sun Pharma Laboratories Limited	In light of the earlier SEC recommendation dated 05.03.2024, the firm presented the proposal along with Phase III CT Protocol and BA study report. Committee noted that BA study does not meet the criteria for Umeclidinium, the test formulation is showing lower %T/R ratio for Cmax (~65%). For AUC0- 24, %T/R ratio is slightly lower

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			<p>(~20%), whereas the AUC_{0-t} is comparable to reference formulation. For Vilanterol, the test formulation is showing higher %T/R ratio for AUC_{0-t} (~28%). For AUC₀₋₂₄, %T/R ratio is slightly higher (~24%), whereas the C_{max} is comparable to reference formulation. However, firm has presented the justification stating that though the product was not bioequivalent but it is therapeutically efficacious & safe.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial.</p> <p>Accordingly, the firm should submit the Phase III CT report for review by the committee and to take further decision on the BA study report.</p>
8.	FDC/MA/24/000155 Vilanterol Trifenatate eq. to Vilanterol 12.5mcg/12.5mcg + Umeclidinium bromide eq. to Umeclidinium 31.25mcg/31.25mcg + Fluticasone Furoate 50mcg/100mcg Metered Dose inhalation	M/s. Zydus Healthcare Limited	<p>In light of earlier SEC recommendation dated 20.01.2026, the firm presented data of randomly selected 5 patients from each centers for Phase III CT report before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC.</p>