Recommendations of the SEC (Pulmonary) made in its 04th/25 meeting held on 09.04.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/51/24 Online Submission (38269) BMS-986278	M/s Bristol Myers Squibb India Private Limited	The firm didn't turn up for presentation.
2.	CT/146/23 Online Submission (38110) AZD4604 Inhalation powder 0.2 mg, AZD4604 Inhalation powder 1.0 mg	M/s Astrazeneca Pharma India Limited	The firm presented protocol (CSP) amendment version 3.0 dated 31 Oct 2024 protocol no: D8210C00003. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
3.	r-DNA-11016(11)/11/2024-eoffice Benralizumab 30 mg/mL Prefilled Syringe	M/s. AstraZeneca Pharma India Ltd.	The firm presented the proposal for the revision in prescribing information based on EU SmPC for Benralizumab 30 mg/mL Prefilled Syringe with respect to changes in Section 4.8 Undesirable effects and 5.1 Pharmacodynamic properties. After detailed deliberation, the committee recommended for approval of the proposed changes in revised prescribing information version 5.0 dated 24 Mar 2023 as presented by the firm.
New Drug Division			
4.	ND/MA/24/000069 Revefenacin Inhalation solution 175 mcg/3ml	M/s. Zydus Healthcare Limited	In light of the earlier SEC recommendation dated 05.11.2024, the firm presented revised Phase-III protocol with active controlled clinical trial design before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial with new drug Revefenacin Inhalation solution 175 mcg/3ml as per the revised protocol presented.
5.	ND/18/2025-eoffice Bosentan 62.5 mg/125 mg oral tablets	M/s. Cipla Limited	The firm has presented the Active Surveillance study report of Bosentan 62.5 mg/125mg oral tablets in patients

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			with pulmonary arterial hypertension (PAH), before the committee. After detailed deliberation, the committee reviewed the results of Active Surveillance study of Bosentan 62.5 mg/125mg oral tablets and accepted results of the study. Further, the committee opined that the firm should submit PSUR data for next 2 years at 6 months interval. Accordingly, the firm should submit PSUR data to CDSCO for next 2 years at 6 months interval**.**
6.	ND/MA/24/000177 Revefenacin Inhalation solution 175 mcg/3ml	M/s. Cipla Limited	The firm has presented the proposal for grant of permission to manufacture and market Revefenacin Inhalation solution 175 mcg/3ml along with BE study waiver and phase III Clinical Trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III Clinical Trial as per the protocol presented.
FDC Division			
7.	FDC/MA/25/000041 Vilanterol Trifenatate Eq. to Vilanterol 25mcg + Umeclidinium Bromide Eq. to Umeclidinium 62.5 mcg. Dry Powder Inhalation	M/s Pure & Cure Healthcare Pvt. Ltd.	The firm presented the proposal along with BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to Conduct BE study. Accordingly, the firm should submit the BE study report along with phase III CT protocol to CDSCO for further review by the committee.
8.	FDC/MA/25/000045 Bilastine IP 10mg/20mg + Acebrophylline 200mg/200mg (As sustained release) film	M/s Ravenbhel Healthcare Pvt Ltd.	The firm presented the proposal before the Committee. After detailed deliberation, the committee noted that- 1. The firm did not present scientific literature published in peer reviewed journal regarding rationality, essentiality

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	coated bilayered tablet.		and desirability of proposed FDC. 2. The proposed FDC is not recommended in any standard therapeutic guidelines. 3. There is no unmet need of the FDC. 4. The firm did not present any proof of concept study in support of significant clinical need of the FDC in the proposed indication. 5. The product is not approved internationally. In view of above, the committee did not recommend for the approval of the proposed FDC.
9.	FDC/MA/25/000036 Glycopyrronium bromide equivalent to glycopyrronium12.5mcg + Formoterol Fumarate Dihydrate 6 mcg + Fluticasone Propionate 125 mcg Metered Dose Inhaler	M/s Lupin Limited	The firm presented the proposal along with phase III CT protocol before the committee. After detailed deliberation, the committee recommended to conduct Phase-III CT study with proposed FDC. Accordingly, the firm should submit Phase III CT report to CDSCO for further review by the committee.