Recommendations of the SEC (Pulmonary) made in its 12th/25 meeting held on 10.09.2025 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/98/25 Online Submission (49889) BTZ-043 Quabodepistat (OPC-167832) Delpazolid (LCB01-0371) Ganfeborole	M/s. ICMR-National Institute For Research In Tuberculosis	The firm presented phase 2B/2C protocol no: PARADIGM4TB (UNITE4TB-01) version 2.0 dated 12-Nov -2024. After detailed deliberation, the committee opined that the firm shall submit the following for further review by the committee: 1. Source of IMP and its manufacturing sites. 2. Details of Phase I & II (2A & 2B) safety data. 3. Regulatory status of the IMP (Globally). 4. Details of composition of DSMB committee.
SND Division			
2.	SND/MA/23/000296 Roflumilast Tablets 250 mcg	M/s. MSN Laboratories Private Limited	Firm has presented their proposal for the grant of Permission to Manufacture and Marketing of Roflumilast Tablets 250 mcg indicated as starting dose in already approved indication. Firm informed that, the proposed additional dose is a starting dose, for the first 4 weeks of treatment only and is not therapeutic dose. The committee noted that, Roflumilast Tablets 250 mcg is approved in USA as starting dose, for the first 4 weeks of treatment only and further the dose increased to 500 mcg once daily for continued treatment. Roflumilast Tablets 500 mcg is approved in India. After detailed deliberation, the committee recommended to manufacture and Market

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			Roflumilast Tablets 250 mcg for usage up to 4 weeks followed by 500 mcg dose in already approved indication subject to the condition that, firm should conduct Active PMS study for which protocol shall be submitted to CDSCO within three months for review by the committee.
3.	SND/MA/25/000144 Sodium Chloride Nebuliser Solution BP 3% w/v	M/s. Zydus Healthcare Limited	The firm presented the proposal for grant of permission to manufacture and market Sodium Chloride Nebuliser Solution 3% w/v along with Package insert and justification for Clinical trial waiver before the Committee. After detailed deliberation, the committee accepted the justification of Clinical trial waiver and recommended grant of permission to manufacture and market Sodium Chloride Nebuliser Solution 3% w/v, subject to the condition that the firm should conduct a Phase IV clinical study. Further, the Committee also opined to revise and present the Package insert i.e. posology and method of dosage administration, contradiction, warning for further review by the Committee Accordingly, the firm should submit Phase IV study protocol to CDSCO within three months of approval.
4.	SND/MA/25/000174 Ivacaftor Tablets 75 mg and 150 mg	M/s.MSN Laboratories Private Limited	The firm didn't turn up for presentation.
FDC Division			
5.	FDC/MA/23/000242 Glycopyrrolate IP eq. to Glycopyrronium + Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate +	M/s Glenmark Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 04.07.2024, the firm presented Phase III clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission for

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	Budesonide IP (25 mcg+ 20 mcg+ 500 mcg) Inhalation Suspension (for nebulization)		manufacturing and marketing of the proposed FDC.
6.	FDC/MA/24/000096 Dextromethorphan Hydrobromide IP 10 mg + Phenylephrine Hydrochloride IP 5 mg) per 5 ml Syrup	M/s Zydus Healthcare Limited	In light of earlier SEC recommendation dated 09.07.2025, the firm presented their proposal along with revised Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial. Accordingly, the firm should submit the Phase III CT report to CDSCO for further review by the committee.
7.	FDC/MA/24/000097 Diphenhydramine Hydrochloride IP + Phenylephrine Hydrochloride IP (12.5 mg+ 5 mg)/ 5 ml Syrup	M/s Zydus Healthcare Limited	In light of earlier SEC recommendation dated 09.07.2025, the firm presented their proposal along with revised Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial. Accordingly, the firm should submit the Phase III CT report to CDSCO for further review by the committee.
8.	FDC/MA/24/000227 Bilastine 10 mg + Montelukast Sodium IP eq. to Montelukast 4 mg per 5 mL oral solution	M/s. Ravenbhel Healthcare Pvt. Ltd	In light of earlier SEC recommendation dated 07.08.2025, the firm presented justification for BE and Phase III CT waiver before the committee along with special invitee (Pediatrician). The committee noted that the said FDC is already approved in suspension and orodispersible tablets i.e., • Bilastine 10 mg + Montelukast Sodium IP eq. to Montelukast 4 mg per 5 ml suspension on 11.03.2022.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			• Bilastine 10 mg + Montelukast Sodium IP Eq. to Montelukast 4mg Orodispersible tablet on 09.05.2022. After detailed deliberation, the committee considered the request for BE and Phase III CT waiver and recommended for grant of permission for manufacturing and marketing with the condition to conduct the Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of approval of the FDC for review by the committee.