Recommendations of the SEC (Pulmonary) made in its 08th/25 meeting held on 18.06.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/58/25 Online Submission (49063) BI 1291583	M/s IQVIA RDS (India) Private Limited	The firm presented phase III clinical study protocol no. 1397-0014 version 1.0 dated 29 Jan 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1 More geographically distributed government sites shall be included in the study. 2. The sputum examination for TB test shall be conducted on every visit.
2.	CT/21/23 Online Submission (39357) PC945 (opelconazole) Nebuliser Suspension (PC945)	M/s PSI CRO Pharma Pvt. Ltd.	The presented for waive off condition no.1 safety data and DSMB Recommendations protocol no. PC_ASP_006. After detailed deliberation, the committee recommended for approval of waiver off condition no.1 safety data and DSMB Recommendations protocol no. PC_ASP_006 as presented by the firm.
New Drugs Division			
3.	ND/MA/25/000017 Revefenacin Inhalation Solution 175 mcg / 3 ml	M/S Akums Drugs & Pharmaceuticals Limited	The firm presented the proposal for grant of permission to manufacture and market Revefenacin Inhalation solution 175mcg/3ml along with phase III Clinical Trial protocol before the committee. After detailed deliberation, committee recommended that subjects who are only on LAMA monotherapy should not be included in the trial. Accordingly, firm should submit revised CT protocol to CDSCO for further review by the committee
4.	ND/MA/25/000021 Revefenacin Inhalation Solution 175 mcg / 3 ml	M/s BDR Pharmaceuticals International Pvt Ltd	The firm presented the proposal for grant of permission to manufacture and market Revefenacin Inhalation solution 175mcg/3ml along with phase III Clinical Trial protocol before the committee. After detailed deliberation, committee recommended that firm should include patients who are on LABA + LAMA

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			treatment in addition to patients who are on LABA+LAMA+ICS therapy with the replacement of existing LAMA as per the randomization. Accordingly, firm should submit revised CT protocol to CDSCO for further review by the committee.
5.	ND/MA/24/000069 Revefenacin Inhalation Solution 175 mcg / 3 ml	M/s. Zydus Healthcare Limited	Already uploaded on website.
6.	ND/MA/24/000177 Revefenacin Inhalation Solution 175 mcg / 3 ml	M/s. Cipla Limited	The firm's proposal was re-deliberated for grant of permission to manufacture and market Revefenacin Inhalation solution 175 mcg/ 3 ml along with phase III Clinical Trial protocol before the committee. After detailed deliberation, committee recommended that subjects on LAMA monotherapy, SABA + SAMA and treatment naive should not be included in the trial. Accordingly, firm should submit revised CT protocol to CDSCO
FDC Division			
7.	FDC/CT/25/000047 Budesonide IP 160 mcg + Glycopyrrolate IP 9 mcg + Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 4.8 mcg Metered Dose Inhalation Aerosol	M/s Macleods Pharmaceuticals Ltd.	In light of the condition mentioned in permission in Form CT-23 dated 19.02.2025; the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee opined that the firm should modify the study title, study objective, inclusion criteria and include test for blood eosinophil count at screening and applicable subsequent visit. Accordingly, the firm should submit scientifically structured revised Phase IV clinical trial protocol to CDSCO for further review by the committee.
8.	FDC/MA/25/000120 Indacaterol acetate eq. to Indacaterol 75 mcg + Glycopyrronium	M/s Lupin Limited	The firm presented the proposal along with Phase III CT protocol before the committee. After detailed deliberation, the committee

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	Bromide Ph. Eur. eq. to Glycopyrronium 25 mcg + Mometasone Furoate IP 80 mcg Metered Dose Inhaler		opined that the firm should submit the following: 1. Essentiality and desirability of the proposed FDC as higher strength of the FDC is already approved as DPI. 2. Detail report regarding amount of drug reaching to the lung tissue. Accordingly, the firm should submit the above data to CDSCO for further review by the committee.