Recommendations of the SEC (Pulmonary) made in its 10th/25 meeting held on 07.08.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/81/25 Online Submission (50182) Fluticasone furoate and vilanterol inhalation powder 100 mcg/25 mcg	M/s Veeda Clinical Research Limited	The firm presented phase III clinical study Protocol No.: SAN-1138 version no. 1.0 dated 12-FEB-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/86/25 Online Submission (50346) Dexpramipexole dihydrochloride monohydrate	M/s PAREXEL International Clinical Research Private Limited	The firm presented phase III clinical study protocol no.: AR-DEX-22-04 version no. 4.0, amendment 3 dated 03-MAR-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. Dr. Sushant didn't participate in the discussion.
3.	CT/89/25 Online Submission (50110) Verekitug (UPB-101)	M/s PAREXEL International Clinical Research Private Limited	The firm presented phase IIb clinical study protocol no. UPB-CP-06, version no. 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.
Biological Division			
4.	E-73057 Nirsevimab solution for Injection in pre-filled syringe 50 mg/ 100 mg	M/s Sanofi Healthcare India Pvt. Ltd	The firm presented the proposal for update in Package Insert dated November, 2024 (Source: USPI dated Aug 2024) for the changes in the Sections of Posology and Method of Administration, Special Warnings and Precautions for Use, Use in Specific Populations, Undesirable effects, Pharmacokinetic Properties and Patient Counselling Information of the drug product Beyfortus® (Nirsevimab solution for injection in pre-filled syringe 50 mg/ 100 mg) in line with US-PI update approval dated 22.08.2024. After detailed deliberation, the committee recommended for approval of updated package insert dated November, 2024 (Source: USPI dated Aug 2024) of the said drug product for the proposed

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			changes
5.	BIO/CT04/FF/2025/49062 Omalizumab solution for injection 150 mg/mL in pre-filled syringe	M/s Jeevan Scientific Technology Limited	The firm presented the proposal for grant of permission to conduct Phase I clinical trial titled "A phase 1, double-blind, balanced, randomized, two-treatment, two arm, single-period, single-dose, parallel, comparative pharmacokinetic and pharmacodynamic study of MP14 solution for injection 150 mg/mL in pre-filled syringe of CinnaGen Co., Iran comparing with Xolair®150 mg solution for injection in pre-filled syringe of Novartis Europharm Limited Vista Building Elm Park, Merrion Road Dublin 4 Ireland in normal, healthy, adult, human subjects under fasting conditions"; vide Protocol No.: 24-144, Version No. 01 date.: 07 Apr 2025 for export purpose. The committee noted that a Phase III clinical trial has been conducted in Iran and that the drug product is approved in the country of origin. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial as per the protocol presented by the firm.
New Drugs Division			
6.	ND/MA/25/000021 Revefenacin Inhalation solution 175 mcg/ 3ml	M/s BDR Pharmaceuticals International Pvt Ltd	In light of the earlier SEC recommendation dated 18.06.2025, the firm presented revised Phase-III CT protocol 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 with the condition that trial participant should continue the drug (LABA or LABA+ICS) during the clinical trial in the same dosage form as was being used prior to enrolment in the study.
7.	ND/MA/25/000017 Revefenacin Inhalation solution 175 mcg/ 3ml	M/s AKUMS DRUGS & PHARMACEUTICALS LIMITED	In light of the earlier SEC recommendation dated 18.06.2025, the firm presented revised Phase-III clinical trial protocol before the committee. After detailed deliberation, the committee

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			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.
FDC Division			
8.	FDC/CT/22/000001 Budesonide IP 400 mcg + Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 12 mcg + Glycopyrrolate IP eq. to Glycopyrronium 25 mcg Inhalation Powder	M/s Zydus Healthcare Limited	In light of earlier SEC recommendation dated 28.04.2022 and as per condition of Form CT-23 dated 02.11.2021, the firm presented Phase IV clinical trial report before the committee. After detailed deliberation, the committee noted and agreed to the result of the clinical trial report.
9.	FDC/MA/23/000270 Acebrophylline 100 mg + Erdosteine 300 mg film coated tablet	M/s Macleods 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 manufacturing and marketing of the proposed FDC.
10.	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.	The firm presented the proposal along with justification for BE and Phase III CT waiver before the committee. After detailed deliberation, the committee opined that Pediatrician may be invited in next meeting for wider discussion in the matter.