Recommendations of the SEC (Pulmonary) made in its 07th/26 meeting held on 23.06.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/181/25 Online Submission (53630) BTZ-043 Quabodepistat (OPC167832) Delpazolid (LCB01-0371) Ganfeborole	M/s. Clinical Research Network India Private Limited.	In light of earlier SEC recommendation dated 17.02.2026, the firm presented phase IIC clinical study in India vide protocol no. PARADIGM4TB (UNITE4TB-01) version no. 2.0 dated 12 November 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/17/26 Online Submission (54205) Bromhexine Hydrochloride Nasal Spray 2 mg/ml	M/s. Vivotech Research Lab Private Limited.	The firm presented phase III clinical study protocol no.: VRL-CT-25-043, version no.: 1.0 dated 06-Nov-2025. After detailed deliberation, the committee opined that the firm shall submit the following for further review by the committee: 1. The Scientific rationale and proof of concept for conducting the proposed phase III study of Bromhexine Hydrochloride Nasal Spray 2 mg/ml formulation along with mechanism of action. 2. Local and Systemic Non-clinical Safety • Nasal irritation and local tolerability studies. • Assessment of effects on nasal epithelial integrity and mucociliary function. • Repeated-dose local toxicity studies where justified. • Systemic exposure assessment to determine whether additional systemic toxicity studies are required. 3. Pharmacology and Clinical data • Human data demonstrating local tolerability following intranasal administration. • Pharmacokinetic data, if measurable, including systemic absorption and exposure. • Pharmacodynamic evidence, where feasible, such as biomarkers demonstrating

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			TMPRSS2 inhibition or antiviral activity.
Biological Division			
3.	BIO/CT18/FF/2025/52532 Benralizumab 30 mg/ml solution for injection in pre-filled syringe	M/s. AstraZeneca Pharma India Limited.	The firm presented the Global Clinical Trial data for Benralizumab (30 mg/ml solution for injection in pre-filled syringe), where India was also a participating country and highlighted that the drug is proposed for a rare life threatening disease with a significant unmet medical need in the country. Further, it was also noted that this proposed indication has already been approved in US, Switzerland and Japan, etc. After detailed deliberation, the committee recommended for grant of approval for the following proposed additional indication subject to the condition that the firm conducts a PMS study in no fewer than 15 patients. • Hypereosinophilic Syndrome (HES): Benralizumab is indicated for the treatment of patients aged 12 years and older with hypereosinophilic syndrome without an identifiable non-haematologic secondary cause. Accordingly, the firm shall submit the report of PMS Study to CDSCO for further review.
4.	BIO/CT18/FF/2025/53800 Mepolizumab Solution for Injection 100 mg/mL	M/s. GlaxoSmithKline Pharmaceuticals Limited.	The firm presented a Global Clinical Trial data for Mepolizumab Solution for Injection 100 mg/mL, where India was also a participating country, for grant of approval for the following additional indication: • Chronic obstructive pulmonary disease (COPD): Indicated in adults as an add-on maintenance treatment for uncontrolled chronic obstructive pulmonary disease (COPD) characterized by raised blood eosinophils on a combination of an inhaled corticosteroid (ICS), a long acting beta 2 agonist (LABA) and a long acting muscarinic antagonist (LAMA).

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			After detailed deliberation, the committee noted that the clinical data generated in the Indian population lacks statistical and clinical significance. Further, the proposed indication is not a rare life threatening disease and there is no unmet medical need in the country. Accordingly, the committee did not consider the proposal and recommended for conduct of a Phase III Clinical Trial in a significant number of subjects.
SND Division			
5.	SND/MA/25/000036 SND/CT21/FF/2025/47827 Bilastine Nasal Spray 0.36 % w/v	M/s. Biodeal Pharmaceuticals Limited.	The firm presented their proposal for manufacture and marketing of Bilastine Nasal Spray 0.36% w/v for already approved indication along with pre-clinical data and Phase I and Phase II Clinical Trial protocol. The committee noted that Bilastine tablets 20 mg is already approved in India since 15.10.2019 for the Treatment of Allergic Rhino conjunctivitis. However, the proposed formulation, Bilastine Nasal Spray 0.36 % w/v is not approved anywhere in the world. Further, the committee observed that the firm could not justify the selection of proposed dose based on pre-clinical data. After detailed deliberation, the committee opined the firm should submit the animal pharmacology data, Proof of concept study data in animals, calculation of Human Equivalent Dose for conduct of First in Human studies and present it along with Phase I protocol before the committee.
FDC Division			
6.	FDC/MA/24/000128 Fluticasone Furoate 200 mcg + Umeclidinium bromide eq. to Umeclidinium 62.5 mcg + Vilanterol trifenatate eq. to Vilanterol 25 mcg dry powder for Inhalation in hard cellulose	M/s. Sun Pharma Laboratories Limited.	In light of earlier SEC recommendation dated 20.02.2025, the firm presented Phase III Clinical Trial report before the committee. The committee noted that the proposed FDC is already approved by CDSCO on 13.02.2026. After detailed deliberation, the committee recommended for grant of permission for

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	capsule		manufacturing and marketing of the proposed FDC with the condition to conduct Active PMS study. Accordingly, the firm should submit Active PMS protocol to CDSCO within 3 months of approval of the FDC for review by the committee.
7.	FDC/CT/24/000093 Glycopyrronium 50 mcg + Fluticasone Furoate 100 mcg + Vilanterol 25 mcg Powder for Inhalation	M/s. Glenmark Pharmaceuticals Limited.	In light of earlier SEC recommendation dated 11.03.2025 and as per condition of Form CT-23 dated 29.05.2024, 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.