Recommendations of the SEC (Pulmonary) made in its 15th/25 meeting held on 16.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/168/25 Online Submission (53265) PF-07275315 Solution for Injection	M/s Pfizer Limited	The firm presented phase II/ III clinical study Protocol No.: C4531031, Final Protocol Amendment 1 dated 23 October 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. Quantification of COPD must be done using High Resolution Computed Tomography (HRCT) Scan. 2. ECHO (2D) should be done in patients to rule out pulmonary arterial Hypertension. 3. Firm shall submit phase II study safety data to CDSCO before initiation to conduct phase III study.
2.	CT/140/25 Online Submission (52120) LY3537031	M/s Clinical Trials Eli Lilly and Company India Pvt. Ltd	In light of earlier SEC recommendations dated 14.10.2025, The firm presented Phase II protocol no.: J2S-MC-GZMR version no. a dated 01-AUG-2025. Now the firm presented: 1. Preclinical data in an asthmatic model along with proof-of-concept to justify the conduct of the proposed clinical trial. 2. Scientific rationale for the proposed Phase II study supported by Phase I study data generated in asthmatic patients. 3. Supporting data and relevant literature on the use of the product as an add-on therapy in asthmatic patients. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.

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Medical Devices Division			
3.	MED-14/20/2025-eoffice AI-driven mHealth app	Dr. Ajish K. Abraham, Professor of Electronics and Acoustics, All India Institute of Speech and Hearing, Mysuru	The applicant presented their proposal for conducting Field Validation Studies of the applied device, i.e. AI-based mHealth App for hypernasality prediction in children, in the presence of ENT specialists. After detailed deliberation, the committee recommended for consideration of the proposed study vides BioRRAP Reg. no. ALL 37022025 subject to the condition that all statutory guidelines pertaining to data privacy and protection shall be considered and taken care of during the course of the study.
Biological Division			
4.	BIO/CT18/FF/2022/32804 Tezepelumab Solution for Injection (Tezspire 210 mg)	M/s AstraZeneca Pharma India Limited	In light of the earlier SEC recommendations dated 04.11.2022 & 05.04.2023, the firm presented the additional data for justification of clinical trial waiver for import & marketing of the drug Tezepelumab Solution for Injection (210 mg) intended for subcutaneous administration for the indication as an add-on maintenance treatment in patients with severe asthma aged 12 years and older. The committee noted the results of Phase III studies (DESTINATION, NAVIGATOR and DIRECTION study) presented by the firm and found that INDIA is not one of the participant countries in any of these global studies. Further, the committee also noted the updates of ongoing Global Clinical Study presented by firm for the indication Severe Chronic Obstructive Pulmonary Disease (EMBARK study) where India is one of the participating country. Further, the committee also noted that there is no unmet need and no significant therapeutic advancement of the proposed drug over the current standard of care. After detailed deliberation, the committee reiterated the earlier SEC recommendations that the firm should

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			conduct Phase III study in India initially in adult patients for consideration of the proposed indication in adult patients. Accordingly, the firm should submit Phase III study protocol for further review and should submit interim data after completion of six months of Phase III clinical trial for further deliberation.
New Drugs Division			
5.	ND/MA/25/000147 Ensifentrine inhalation suspension 3 mg/2.5ml	M/s Cipla Limited	The firm presented the proposal for grant of permission to manufacture and market of product Ensifentrine Inhalation Suspension 3mg/2.5mL with Phase III Clinical Trial protocol (Study code: CP/03/25 Protocol Version No: 1.0, dated 11-Sep-2025) and justification for BE study waiver before the committee. After detailed deliberation, the committee agreed for waiver of BE study and recommended to revise the Phase III CT protocol to include the following: 1. The firm should have DSMB (Data Safety and Monitoring Board) for monitoring of trial. 2. The trials sites should be geographically distributed throughout the country. 3. Study duration shall be increased to atleast 24 weeks. Accordingly, firm should submit the revised Phase III CT protocol to CDSCO for further review by the committee.
SND Division			
6.	SND/MA/24/000150 Levodropropizine Tablet 60mg	M/s Macleods Pharmaceuticals Limited	The firm presented their proposal for grant of permission to manufacture and marketing of Levodropropizine Tablet 60 mg along with BE study report before the committee. The firm has informed that Levodropropizine oral syrup (30 mg/5 ml) was approved in India since 2005 and Levodropropizine Tablet 60 mg is approved in Italy, Korea, Philippines & Poland. The firm also informed that proposed daily dose of Levodropropizine

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			Tablet 60 mg is three times a day i.e. 180 mg, which is equivalent to the approved daily dose of Levodropropizine oral syrup (30 mg/5 ml) i.e. 10 ml, three times a day. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Levodropropizine Tablet 60mg for applied indication with condition to conduct post marketing surveillance (PMS) study. Accordingly, the firm should submit PMS study protocol to CDSCO within 03 months from date of approval of the drug product for further review by the committee.
FDC Division			
7.	FDC/MA/24/000211 Vilanterol trifenatate eq. to Vilanterol 25 mcg + Umeclidinium bromide eq. to Umeclidinium 62.5 mcg + Fluticasone Furoate 200 mcg powder for Inhalation in capsule	M/s Zydus Healthcare Limited	In light of earlier SEC recommendation dated 20.02.2025, the firm presented Phase III clinical trial report before the committee. After detailed deliberation, the committee considered the BE study waiver and recommended for grant of permission for 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.