Recommendations of the SEC (Pulmonary) made in its 13th meeting held on 04.12.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/130/24 Online Submission (46079) LY3502970	M/s. Eli lily	The firm presented phase 3 clinical study protocol no. J5P-MC-GZRA (ATTAIN-OSA) dated 08 Aug 2024. After detailed deliberation, the committee recommended that the firm should submit following for further review by the committee: 1.Pharmacokinetics data of 36mg dose generated by the firm 2. Justification for once daily dose of the drug 3.Study sites shall be geographically distributed 4.Firm shall generate India specific PK data of 36mg dose in statistically significant number of subjects. 5.Equal distribution of patients having Obesity and Overweight.
2.	CT/163/23 Online Submission (35978) Benralizumab	M/s. Fortrea	The firm presented protocol amendment version 9.0 dated 26 September 2024 protocol no. D3254C00001. After detailed deliberation, the committee opined proposal may be re-deliberated in upcoming SEC meeting alongwith complete information/ data.
Biological Division			
3.	BIO/CT04/FF/2024/45268 Nirsevimab	M/s Sanofi Healthcare India Pvt. Ltd.	The proposal may be re-deliberated in upcoming SEC meeting in presence of pediatrician.
4.	BIO/CT04/FF/2024/45742 Omalizumab 150mg/ml solution for injection	M/s Ecron Acunova Limited	The firm presented the protocol to conduct PK/PD study titled “An Open label, Randomized, Balanced, Two-treatment, Single Period, Parallel, Single dose, Subcutaneous administration, comparative pharmacokinetic study of ADL-018 Injection 150 mg/mL in a single dose pre-filled autoinjector Injection compared to ADL-018 150mg/mL in pre-filled syringe in normal, healthy, adult subjects under fasting conditions” vide Protocol No.

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			070-24 Version No:1, Final; 06 JUN 2024. After detailed deliberation, the committee recommended for approval to conduct the PK/PD study as per protocol presented by the firm.
5.	BIO/CT04/FF/2024/45717 Palivizumab solution for injection 50mg/0.5mL & 100 mg/mL	M/s AstraZeneca Pharma India Limited	The proposal may be re-deliberated in upcoming SEC meeting in presence of pediatrician.
6.	E-42499 Benralizumab 30mg	M/s AstraZeneca Pharma India Limited	The firm presented the final Clinical Study Report (CSR) version 1.0 dated 13 Jun 2024 for the Phase IV clinical study titled "A Post marketing, Phase 4, Multicentre, Prospective, Single-arm Study to Assess the Safety of Fasenra® (Benralizumab) in Adult Patients of Severe Asthma with Eosinophilic Phenotype in India" conducted as per Protocol No: D3250C00093, Version 1.0 dated 09 Mar 2022. After detailed deliberation, the committee noted the results of Phase IV study presented by the firm.
FDC Division			
7.	FDC/CT/24/000093 Glycopyrronium 50mcg, Fluticasone Furoate 100mcg and Vilanterol 25mcg Powder for Inhalation	Glenmark Pharmaceuticals Limited	In light of the condition mentioned in permission in Form CT-23 dated 29.05.2024, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee opined the following modification in the Phase IV CT protocol : 1. Efficacy should be included as co-primary efficacy endpoint. 2. Include ECG and blood sugar test in the assessment at the time of enrollment and end of the study. 3. Serum pregnancy test should be done at the time of randomization. Accordingly, revised Phase IV clinical trial protocol should be submitted to CDSCO for further review by the committee.

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8.	FDC/MA/24/000097 Diphenhydramine Hydrochloride IP + Phenylephrine Hydrochloride IP (12.5mg+ 5mg)/ 5ml Syrup	M/s Zydus Healthcare	In light of the earlier SEC recommendation dated 04.07.2024, the firm presented justification for Phase III CT waiver before the committee. After detailed deliberation, the committee reiterated its earlier recommendation dated 04.07.2024 and recommended that the firm should conduct Phase III CT study with the proposed FDC. Accordingly, the firm should submit Phase III clinical trial protocol to CDSCO for further review by the committee.
9.	FDC/MA/24/000096 Dextromethorphan Hydrobromide IP + Phenylephrine Hydrochloride IP (10mg + 5mg)/ 5ml Syrup	M/s Zydus Healthcare	In light of the earlier SEC recommendation dated 04.07.2024, the firm presented justification for Phase III CT waiver before the committee. After detailed deliberation, the committee reiterated its earlier recommendation dated 04.07.2024 and recommended that the firm should conduct Phase III CT study with the proposed FDC. Accordingly, the firm should submit Phase III clinical trial protocol to CDSCO for further review by the committee.