Recommendations of the SEC (Pulmonary) made in its 11th meeting held on 05.11.2024 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	GCT/PostAppr/2024/35045 Online Submission (35045) LYT-100	M/s. Novotech Clinical Research India Private Limited	The firm presented protocol amendment version 6 dated 13 August 2024 protocol no. LYT-100-202 2-204. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
2.	r-DNA-11016(13)/21/2024-eoffice Mepolizumab Powder for Solution for Injection	M/s GSK Pharmaceuticals Ltd.	In continuation to the earlier SEC recommendation dated 06.08.2024, firm presented the detailed information related to AE's and SAE's reported in the Phase-IV study of Mepolizumab vide protocol No. 209682 amendment No. 04 dated 23.08.2022. The committee reviewed the AE and SAE in detail and the committee reviewed the 3 SAEs in detail out of which one subject (Subject ID-134) discontinued from the study due to protocol deviation. After detailed deliberation, the committee noted the results of the study.
3.	BIO/CT18/FF/2024/44555 Benralizumab 30 mg/ml solution for Injection	M/s AstraZeneca Pharma India Limited	The firm presented the proposal for approval of additional indication i.e, treatment of adult patients with Eosinophilic granulomatosis with polyangiitis (EGPA) for the already approved drug Benralizumab 30 mg/ml solution for Injection with waiver of the local clinical trial. The firm is claiming that proposed indication comes under the category of rare and life-threatening disease and unmet need in the country. The firm presented the result of Phase III global clinical trial conducted in North America , Japan & Western Europe. The committee has noted that the proposed additional indication is approved in US, EU, Russia and New Zealand.

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			After detailed deliberation, the committee has recommended to submit following information for further review by the committee: (1) Phenotype specific response (2) Dosing in EGPA (3) Clinical data beyond 52 weeks (4) The applied indication may be suitably modified by mentioning for the treatment of relapsing & refractory disease of EGPA.
New Drugs Division			
4.	ND/MA/24/000069 Revefenacin Inhalation solution 175 mcg/3ml	M/s Zydus Healthcare Limited	The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Revefenacin Inhalation solution 175 mcg/3ml with Phase III clinical trial protocol and BE study waiver before the committee. The committee deliberated in detail the need to follow GOLD 2024 guidelines and ensure categorization of COPD as per the latest guidelines. The committee also recommended the firm to submit an active controlled clinical trial design considering the ethical issues w.r.t. moderate to very severe COPD patients. The firm is requested to submit the revised protocol for further evaluation by the committee.
FDC Division			
5.	FDC/CT/20/000056 Fluticasone Furoate 100mcg + Umeclidinium 62.5mcg + Vilanterol trifenatate 25mcg powder for inhalation	M/s. GlaxoSmith Kline Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 07.12.2022 and as per condition of Form CT-23 dated 18.05.2020, 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.
6.	FDC/MA/23/000206 Indacaterol Maleate eq. to Indacaterol 55mcg + Glycopyrronium bromide eq. to Glycopyrronium 25mcg inhalation aerosol	M/s. Lupin Ltd.	In light of the earlier SEC recommendation dated 07.11.2023, the firm presented the proposal along with BE study report wherein BE study is failed to meet the primary end point criteria since 42% of enrolled subjects could not inhale MDI dose properly leading to inadequate number of subjects to get reliable results as power of study found to be significantly lower i.e. 26%

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			and current BE study could not be achieved to the targeted power. In view of above, the firm presented the revised BE study protocol by increasing the number of subjects from 38 to 50 to improve reliability and conduct the study with same CRO with the improved protocol by implementing the learning from current study with more vigorous trainings before product administration. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study as per the revised BE protocol and clinical trial waiver was not considered at this stage. Accordingly, the result of the BE study should be submitted to CDSCO for further review by the committee.
7.	FDC/MA/23/000338 Glycopyrrolate IP eq. to Glycopyrronium 25mcg + Indacaterol Maleate eq. to Indacaterol 55mcg Metered dose inhalation	M/s Zydus Healthcare Limited	In light of the earlier SEC recommendation dated 05.12.2023, the firm presented BE study report as well as justification for Phase III CT waiver before the committee. After detailed deliberation, the committee considered the BE study report and opined that the firm needs to conduct Phase III clinical trial with the proposed FDC. Accordingly, Phase III clinical trial protocol should be submitted to CDSCO for further review by the committee.
8.	FDC/CT/24/000019 Budesonide 160mcg + Glycopyrronium 7.2mcg + Formoterol fumarate dihydrate 5mcg inhalation preparations	M/s AstraZeneca Pharma India Limited	In light of the earlier SEC recommendation dated 24.04.2024, the firm presented justification for sample size and duration of trial before the committee. After detailed deliberation, the committee did not consider the justification and reiterated its earlier recommendation. Accordingly, the firm should submit revised Phase IV CT protocol to CDSCO for further review by the committee.

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9.	FDC/MA/24/000198 Levocetirizine Hydrochloride IP 2.5mg + Montelukast Sodium IP eq. to Montelukast 5mg per 5mL syrup	M/s Ravenbhel Healthcare Pvt. Ltd.	The firm presented the proposal along with justification for BE and Phase III CT waiver before the committee. The committee noted that similar FDC i.e. Montelukast 4mg + Levocetirizine 2.5mg syrup and Levocetirizine dihydrochloride 2.5mg + Montelukast 5mg dispersible tablet is already approved by CDSCO. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC with the condition to conduct the Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of approval of the FDC for review by the committee.