Recommendations of the SEC (Pulmonary) made in its 4th/24 meeting held on 24.04.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/30/24 Online Submission (42109) BI 1015550	M/s. IQVIA	The firm presented Phase III clinical study protocol number 1305-0031, version 2.0 dated 22 September 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm.
2.	CT/29/23 Online Submission (31560) Benralizumab (Medi-563)	M/s. Fortrea Development	The firm presented protocol amendment version 8.0 dated 12 June 2023 protocol number D3254C00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
3.	BIO/CT18/FF/2023/40504 Benralizumab 30mg solution for injection	M/s. AstraZeneca Pharma India Limited	The firm did not turn up for presentation.
FDC Division			
4.	FDC/MA/23/000313 Bilastine IP 3.3mg/5ml + Dextromethorphan hydrobromide IP 10mg/5ml + Phenylephrine hydrochloride IP 5mg/5ml syrup	M/s. Kingston Aqua Industries Pvt. Ltd.	The firm did not turn up for presentation.
5.	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 condition mentioned in permission in Form CT-20 dated 29.11.2023, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee opined that the firm should conduct Phase IV CT study in statistically significant number of subjects and the duration of the trial should be at least 52 weeks. Accordingly, firm should submit revised Phase IV CT protocol to CDSCO for

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			further review by the committee.
6.	FDC/MA/23/000154 Montelukast Sodium I.P. 10mg + Bilastine 40m g Tablets	M/s. Exemed Pharmaceuticals	In light of earlier SEC recommendation dated 05.10.2023, the firm presented their proposal along with Phase III clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC for the management of severe Allergic Rhinitis in adults for maximum duration of 4 weeks with the condition that "The drug causes drowsiness & dizziness and should not be consumed while driving & other skilled jobs." Accordingly, the firm should mention the said warning on package insert/Promotional Literature of the drug product.
7.	FDC/CT/20/000091 Glycopyrrolate and Formoterol Fumarate Inhalation 9 mcg and 4.8 mcg 4.8mcg+9.0mcg	M/s. Zydus Healthcare Limited	In light of earlier SEC recommendation dated 01.03.2021 and as per condition of Form CT-23 dated 14.08.2020, 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.
8.	FDC/CT/20/000070 Budesonide IP 400mcg + Glycopyrronium IP 25mcg + Formoterol Fumarate IP 12mcg Inhalation Powder 400mcg + 25mcg + 12mcg	M/s. Cipla Limited	In light of earlier SEC recommendation dated 06.02.2024 and as per condition of Form CT-23 dated 17.07.2020, 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.