Recommendations of the SEC (Pulmonary) made in its 63rd meeting held on 29.09.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	12-01/12-DC (Pt-9) Pirfenidone 200 mg tablets	M/s. Cipla	The firm presented their proposal for request for waiver of active surveillance study before the committee. After detailed deliberation, the committee reiterated its earlier recommendation and suggested that the firm needs to conduct active surveillance study. Accordingly protocol should be submitted for further review by the committee.
2.	ND/MA/22/000027 Icatibant Injection 30mg/3ml (10mg/ml)	M/s MSN Laboratories Ltd.	In light of earlier SEC Recommendations dated 08.03.2022, 29.03.2022 and 07.06.2022, the firm presented its justification for BE study waiver for Icatibant Injection 30mg/3ml (10mg/ml) vial before the committee. After detailed deliberation, the committee opined to produce the raw data of the invitro comparative evaluation report of Test drug vs Innovator drug product to CDSCO for further review by the committee.
FDC Division			
3.	FDC/MA/22/000239 Glycopyrronium Bromide 50mcg/50mcg + Fluticasone Furoate100mcg/ 200mcg +Vilanterol Trifenatate 25mcg/25mcg Dry Powder for inhalation.	M/s. Glenmark Pharmaceuticals Ltd.	The firm presented their proposal along with justification for CT and BE study waiver. After detailed deliberation, the committee recommended that the firm should conduct Phase-III CT and inhalation toxicity study and accordingly protocol for CT and toxicity report to be submitted to CDSCO for review by Committee.
4.	FDC/MA/20/000182 Chlorpheniramine Maleate 2mg/2mg + Noscapine 15mg/7mg Oral Liquids	M/s. Biological E Ltd.	In light of earlier SEC recommendation dated 26.02.2021, 01.03.2021 & 25.02.2022, the firm presented Phase-III CT report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC.
5.	FDC/MA/22/000203	M/s. Akums	The firm did not turn up for presentation.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Levosalbutamol Sulphate IP eq. to Levosalbutamol 0.25mg + + Ambroxol Hydrochloride IP 7.5mg + Guaiphenesin IP 12.5mg Oral drops		
6.	FDC/MA/20/000043 Blisatine 10mg + Montelukast 4mg Orodispersible tablets	M/s. Synokem Pharmaceutical Ltd.	The firm did not turn up for presentation.
7.	FDC/MA/21/000160 Indacaterol maleate eq. to Indacaterol 75mcg + Budesonide IP 200mcg Inhaler	M/s. Zydus Healthcare Ltd.	In light of earlier SEC recommendation dated 31.08.2021, the firm presented Phase-III CT report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC.
8.	FDC/MA/20/000029 Montelukast 4mg + Fexofenadine Hydrochloride 60mg Suspension	M/s. Synokem Pharmaceutical Ltd.	In light of earlier SEC recommendation dated 31.08.2022, the firm presented Phase-III CT study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase-III CT. The results of the study should be presented before the committee for review.
GCT Division			
9.	CT/63/22 Online Submission (33026) Mepolizumab	M/s. PPD	The applicant has presented Phase IIIA clinical trial protocol no. 208657 Amendment 6 dated 06/12/2021 before the committee. The committee noted that the study drug is already approved in the country for other indication. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IIIA study as presented.