Recommendations of the SEC (Pulmonary) made in its 67th meeting held on 08.02.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT/23/000002 Fluticasone Propionate HFA, MDI 110mcg ex-actuator dose (125 mcg ex-valve dose)	M/s Cipla Limited	The firm presented its proposal to conduct clinical trial to assess product functionality after repeated use of Fluticasone Propionate HFA pressurized metered dose inhaler 110mcg ex actuator dose (125 mcg ex Valve dose) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol.
2.	ND/MA/21/000181 Indacaterol (as acetate) 150mcg and Mometasone furoate 80/160/320mcg Dry powder for Inhalation (DPI)	M/s Glenmark Pharma. Ltd.	The firm has presented the proposal for conduct of the active surveillance study before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed active surveillance study with the drug as per the protocol presented & results of the study should be submitted to CDSCO for review by the committee.
3.	12-01/22-DC(pt-337) Bovine Lipid Extract suspension (Neosurf)	M/s. Cipla Limited	The firm presented its proposal for updating the prescribing information of the drug before the committee. After detailed deliberation, the committee recommended for grant of approval of updated prescribing information as presented by the firm along with the following precautions. In minimal invasive techniques (LISA or MIST), the volume of surfactant should be small. After installation of large volume surfactant (Bovine) which can initiate cough reflex, the chance of failure is high. But the advantages of LISA or MIST is much more than conventional surfactant therapy.
SND Division			
4.	SND/MA/21/000349 Pirfenidone Extended release Tablet 1200 mg	M/s Cipla Limited	The firm presented its proposal of manufacturing and marketing of Pirfenidone extended release tablet 1200 mg along with the results of the BE studies and with request for clinical trial

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			waiver. After detailed deliberation, the committee recommended that firm should conduct Phase III clinical trial. Accordingly, Phase III clinical trial protocol should be submitted for further review by the committee.
FDC Division			
5.	FDC/MA/20/000043 Blisatine10 mg + Montelukast 4mg orodispersible tablets	M/s. Synokem Pharmaceuticals Ltd.	The firm did not turn up for presentation.
6.	FDC/MA/22/000187 Fluticasone Furoate 200mcg + Vilanterol 25mcg Powder for inhalation	M/s. Sun Pharma Laboratories Ltd.	The firm did not turn up for presentation.
GCT Division			
7.	CT/127/22 Online Submission (34427) Tozorakimab	M/s. Astra Zeneca	The firm's proposal was re-deliberated in line with the earlier SEC recommendations held on 07 Dec, 2022 with reference to the protocol no-D9180C00001 before the committee. After detailed deliberation, the committee noted that in the presented data there is no available study for acute viral infection respiratory failure (ARDS) except for COVID-19 and recommended to conduct Phase II study for proposed indication.
8.	CT/163/22 Online Submission (35086) Tozorakimab	M/s. Astra Zeneca	The firm presented Phase III clinical trial protocol no- D9180C00008 before the committee. After detailed deliberation, the committee recommended to grant permission to conduct the study.
9.	CT/75/22 Online Submission (22082) Itepekimab	M/s. Sanofi	The applicant presented its proposal for protocol number: EFC16819, protocol amendment 01 version 1.0 dated 20 Sept 2022 before the committee. After detailed deliberation, the committee recommended for approval of proposed protocol amendment.