Recommendations of the SEC (Pulmonary) made in its 66th meeting held on 10.01.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-01/22-DC(pt-337) Bovine Lipid Extract suspension (Neosurf)	M/s. Cipla Limited	The firm presented their proposal for updating the prescribing information of the drug before the committee. After detailed deliberation, the committee recommended that the proposal should be deliberated in the presence of Neonatologist.
SND Division			
2.	SND/MA/22/000331 Aviptadil Injection 15 UG/10 ml	M/s Zuventus Healthcare	The firm presented their proposal of manufacture and marketing permission of Aviptadil injection 15ug/10ml (15mcg) for additional indication as "For Acute Respiratory Distress Syndrome (ARDS)" alongwith some case studies, justification of proposed indication and local clinical trial waiver before the committee. The firm is already holding manufacturing and marketing permission in Form CT-23 (Permission No. MF-ND-52/2022 dated 29.04.2022) of Aviptadil injection 15mcg "For the treatment of patients with severe COVID-19 with Acute Respiratory Distress Syndrome (ARDS)". After detailed deliberation, the committee noted that the firm presented only some case studies where Aviptadil injection is used for ARDS induced by COVID-19 infection and the firm has not presented any clinical data for the proposed indication. In view above, the committee recommended that firm should submit the Phase III clinical trial protocol to CDSCO for further review by the committee.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
3.	FDC/MA/20/000043 Blisatine10 mg + Montelukast 4mg orodispersible tablets	M/s. Synokem Pharmaceuticals Ltd.	The firm did not turn up for presentation.
4.	FDC/IMP/22/000085 Budesonide 160mcg + Glycopyrronium 7.2mcg + Formoterol fumarate dehydrate 5mcg inhalation preparations	M/s. Astrazeneca	The firm presented their proposal along with justification for local Phase III CT waiver. The firm informed the committee that the product is already approved in various countries like U.S, EU, Australia, Japan etc. After detailed deliberation, the committee recommended for grant of permission to import and market the proposed FDC with condition to conduct Phase IV clinical trial study. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months from the date of approval for review by the committee.
5.	FDC/MA/22/000203 Levosalbutamol Sulphate IP eq. to Levosalbutamol 0.25mg + Ambroxol HCl IP 7.5mg + Guaiphenesin IP 12.5mg oral drops	M/s Akums	The firm presented their proposal along with justification for local Phase III CT waiver. The committee noted that the product is not yet approved in any country in proposed strength. After detailed deliberation, the committee recommended that the firm should initially conduct pK study and results of the study should be presented before the committee for further review.