

Recommendations of the SEC (Pulmonary) made in its 61th meeting held on 07.07.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/CT/22/000037 Inhaled Itraconazole Dry Powder for inhalation 10 mg Capsule	M/s. Cipla Limited	In light of the earlier pre-submission meeting held on 25.02.2022 the firm presented proposal to conduct Phase II clinical trial for Inhaled Itraconazole Dry Powder for inhalation 10 mg Capsule. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase II clinical trial as per protocol presented.
FDC Division			
2.	FDC/CT/22/000022 Each actuation delivers: Glycopyrrolate IP 9.0mcg + Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 4.8mcg + Budesonide IP 160mcg metered Dose Inhaler	M/s. Zydus Healthcare Limited	The firm presented the Phase IV CT protocol before the committee as per the condition mentioned in permission dated 07.02.2022. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV CT study. The result of the study should be presented before the committee.
New Drug Division			
3.	ND/MA/21/000018 Revefenacin inhalation solution 175 mcg/3ml	M/s. Mylan Pharmaceuticals Pvt. Ltd.	In light of the earlier SEC recommendation dated 25.02.2022, the firm presented their proposal along with the revised Phase-III Clinical Trial Protocol including the CT NOC conditions before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase-III Clinical Trial Study as per revised Phase-III Clinical Trial Protocol (Protocol No. REVE-SGR-3001, Version 1.0, dated 03.03.2022).