Recommendations of the SEC (Pulmonary) made in its 69th meeting held on 05.04.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2022/ 32804 Tezepelumab Solution for injection 210 mg	M/s. Astrazeneca Pharma India Limited	In light of earlier SEC recommendations dated 04.11.2022, the firm presented the additional data for justification of clinical trial waiver for import & marketing of the drug Tezepelumab Solution for Injection (210mg) intended for subcutaneous administration for the indication as an add-on maintenance treatment in patients with severe asthma aged 12 years and older. After detailed deliberation, the committee reiterated the earlier SEC recommendation that the firm should conduct Phase III study in India initially in adult patients for consideration of the proposed indication in adult patients. Accordingly, the firm should submit Phase III study protocol for further review and should submit interim data after completion of six months of Phase III clinical trial for further deliberation.
SND Division			
2.	SND/MA/21/000349 Pirfenidone Extended Release Tablets 1200mg	M/s Cipla Ltd.	The firm presented the proposal of manufacturing and marketing of Pirfenidone Extended Release Tablets 1200mg along with the results of single dose and multiple dose bioequivalence studies along with the request for local clinical trial waiver. After detailed deliberation, the committee reiterated its earlier recommendation of SEC held on 08.02.2023 i.e the firm should conduct Phase III clinical trial. The firm should submit Phase III clinical trial protocol accordingly.
FDC Division			
3.	FDC/MA/20/000043 Bilastine10mg + Montelukast 4mg Orodispersible tablets	M/s. Synokem Pharmaceuticals Ltd.	As per the condition mentioned in Form CT-23, the firm presented Phase IV clinical trial study protocol before the committee. After detailed deliberation, the committee recommended for conducting the Phase IV clinical trial.
4.	04-01/2022-DC (Misc. 47)	Nil	The proposal was deferred and will be deliberated in upcoming SEC before experts along with one pediatrician.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Chlorpheniramine Maleate IP 2mg+Phenylephrine HCl IP 5mg drop/ml		
5.	FDC/MA/23/000034 Paracetamol 160mg + Phenylephrine HCl 5mg + Chlorpheniramine maleate 1mg Oral liquid/ suspension	M/s. Stedman	The firm presented its proposal alongwith justification for dosage of FDC. The committee observed that: 1. Safety profile data was not presented. 2. Published supportive scientific literature on use of the drug in pediatric population for proposed strengths was not presented. 3. Justification in light of standard therapeutic treatment guidelines should be presented. 4. Rationality of the proposed FDC along with international approval status should be presented. After detailed deliberation, the committee recommended that the firm should submit above documents to CDSCO for review by the committee and one pediatrician should also be invited for deliberation in the next meeting.
6.	FDC/MA/23/000032 Dextromethorphan HBr 10mg + Phenylephrine HCl 5mg + Chlorpheniramine Maleate 1mg syrup	M/s. Stedman	The firm presented its proposal alongwith justification for dosage of FDC. The committee observed that: 1. Safety profile data was not presented. 2. Published supportive scientific literature on use of the drug in pediatric population for proposed strengths was not presented. 3. Justification in light of standard therapeutic treatment guidelines should be presented. 4. Rationality of the proposed FDC along with international approval status should be presented. After detailed deliberation, the committee recommended that the firm should submit above documents to CDSCO for review by the committee and one pediatrician should also be invited for deliberation in the next meeting.
7.	FDC/MA/20/000029 Montelukast IP 4mg + Fexofenadine	M/s. Synokem Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 29.09.2022, the firm presented the Phase III CT report before the committee.

SEC (Pulmonary) meeting dated 05.04.2023

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Hydrochloride IP 60mg Suspension		After detailed deliberation, the committee considered the clinical trial report and recommended for grant of permission to manufacture & market the FDC. Further, the committee recommended that the firm should update CDSCO with the PMS/PSUR of the drug within 6 months of its marketing as per requirements under NDCT Rules, 2019.
GCT Division			
8.	CT/168/22 Online Submission (35220) BI 1015550	M/s IQVIA RDS	The firm presented its proposal for Phase III clinical study for protocol no: 1305-0014 (FIBRONEERTM-IPF) version 2.0 dated 26-July-2022 before the committee. After detailed deliberation, the committee opined that the presentation of the firm was not adequate w.r.t. long term toxicology data, pharmacological data etc. and presented two different studies (35220 and 35282) in one presentation. The firm was not ready with two separate presentations at this time. The committee also opined that the firm has selected only 5 private trial sites, also they are not covering patient populations from PAN India. The firm should include equal numbers of Government clinical trial sites. Accordingly, the committee recommended for the proposal to be deferred for next meeting.
9.	CT/171/22 Online Submission (35282) BI 1015550	M/s IQVIA RDS	The firm presented its proposal for Phase 3 clinical study for protocol no: 1305-0023 (FIBRONEERTM-ILD) version 2.0 dated 26-July-2022 before the committee. After detailed deliberation, the committee opined that the presentation of the firm was not adequate w.r.t. long term toxicology data, pharmacological data etc. and presented two different studies (35220 and 35282) in one presentation. The firm was not ready with two separate presentations at this time. The committee also opined that the firm has selected only 5 private trial sites, also they are not covering patient populations from PAN India. The firm should include equal numbers of Government clinical trial

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			sites. Accordingly, the committee recommended for the proposal to be deferred for next meeting.