Recommendations of the SEC (Pulmonary) made in its 57th meeting held on 25.02.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-01/21-DC (Pt - 340) Dried Ivy Leaf Extract Cough Syrup	M/s. USV	The firm presented the proposal of switching of Dried Ivy Leaf Extract Cough Syrup from prescription to non prescription drug before the committee. After detailed deliberation, the committee recommended that the proposal should be examined in consultation with Phytopharmaceutical experts.
2.	ND/MA/21/000108 Lumacaftor and Ivacaftor tablet 100/125mg & 200/125mg	M/s. Laurus Lab	In light of the earlier recommendation of the SEC (Pulmonary) meeting held on 31.08.2021, the firm presented their proposal of BE Study result before the committee. The committee noted that the drug is proposed to be indicated for rare, life threatening disease and there is an unmet medical need of the drug in the country. The drug is approved by USFDA, Canada & Europe. After detailed deliberation, the committee recommended for grant of manufacturing and marketing permission of Lumacaftor and Ivacaftor tablet 100/125 & 200/125 mg subject to condition that the firm should conduct active post marketing surveillance for which protocol should be submitted to CDSCO within three months of approval of the drug.
3.	ND/CT-21/2021/28941 Indacaterol (as acetate) 150 mcg and mometasone furoate 80/160/320 mcg dry powder for inhalation (DPI)	M/s. Glenmark	In light of the earlier recommendation of the SEC (Pulmonary) meeting held on 07.12.2021, the firm presented their proposal along with the in vitro drug deposition study published data and results of GCT of the F.D.C conducted by other firm in which India was one of the participating countries before the committee. After detailed deliberation, the committee considered the local clinical trial waiver and recommended that the firm should submit the BA study results before the committee for further consideration.
4.	ND/IMP/21/000018	M/s. Mylan	In light of earlier SEC recommendation dated 07.04.2021, the firm presented their

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	Revefenacin inhalation solution 175 mcg/3ml		proposal along with revised Phase III CT protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study subject to condition that the firm should monitor evidence for development of glaucoma and urinary retention during follow up visits.
Biological Division			
5.	BIO/CT18/FF/2021/28908 Mepolizumab Solution for Injection	M/s. GSK	The firm presented the proposal for addition of two indications (a) Eosinophilic granulomatosis with polyangiitis (EGPA) and (b) Hypereosinophilic syndrome (HES). The firm presented the results of Phase III clinical trial conducted overseas (MIRRA study & FLARE study). The committee noted that the proposed indications are rare disease indications and are approved in USA, Europe, etc. After detailed deliberation, the committee recommended for grant of permission to market the drug for the aforesaid indications.
SND Division			
6.	SND/MA/21/000529 GlycopyrroniumPressurised Inhalation 35 mcg per actuation	M/s. Glenmark Pharmaceutical Ltd.	The firm didn't turn up for presentation.
FDC Division			
7.	FDC/MA/19/000072 Montelukast Sodium IP Eq. to Montelukast 4mg +Bilastine 10mg suspension	M/s. Synokem Pharmaceuticals	In light of earlier SEC recommendations dated 26.02.2021 & 01.03.2021, the firm presented Phase III clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC.
8.	FDC/MA/21/000169 Montelukast Sodium eq to Montelukast IP 10mg+ Bilastine20mg oro dispersible tablet	M/s. Akums Drugs and Pharmaceuticals	In light of earlier SEC recommendations dated 31.08.2021, the firm presented BE study report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and

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			marketing of the proposed FDC.
9.	FDC/CT/21/000072 Glycopyrronium Bromide + Fluticasone Furoate + VilanterolTrifenatate (50.0000 µg + 100 µg + 25µg) Inhalation Powder	M/s. JSS Medical Research Asia Pacific Private Limited	In light of earlier SEC recommendations dated 29.09.2021, the firm presented their proposal before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III clinical trial with the condition that inhalation toxicity study should be conducted and report to be submitted to CDSCO before initiating the Phase III clinical trial.
10.	FDC/MA/20/000133 Levosalbutamol Hydrochloride IP eq. to Levosalbutamol 1.25mg + Budesonide IP 0.5mg per 2ml Nebuliser Suspension.	M/s. Ahlcon Parenterals (India) Pvt. Ltd.	The firm didn't turn up for presentation.
11.	FDC/MA/20/000182 Chlorpheniramine Maleate 2mg/2mg+ Noscapine 15mg/7mg Oral Liquids	M/s. Biological E Ltd.	In light of earlier SEC recommendations dated 26.02.2021 & 01.03.2021, the firm presented Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III CT study.
GCT Division			
12.	CT/103/20 Online Submission (12755) Rilematovir	M/s. J&J	The firm presented the proposed protocol amendment to protocol no. 53718678RSV3001, amendment 1 dated 04-MAY-2021 before the committee. The committee noted that in application it is mentioned that the proposed study will not be conducted in neonates in India. After detailed deliberation, the committee recommended for grant of approval for the proposed protocol amendment.
13.	CT/165/21 Online Submission (29473) CSJ117	M/s. Novartis	The firm presented the proposed Phase IIb study protocol no. CCSJ117A12201C, Version 03 dated 21-JAN-2022 before the committee. After detailed deliberation, the committee

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			recommended for grant of permission to conduct the study with the following conditions: 1) The firm should perform QuantiFERON-TB Gold test during screening visit to exclude TB subjects from the study. 2) The firm should perform serum pregnancy test during screening of women of childbearing potential in the trial. Accordingly, the applicant should submit India specific protocol addendum to CDSCO.
14.	CT/108/21 Online Submission (15497) CSJ117	M/s. Novartis	In light of the CT NOC dated 22-Nov-2021 conditions no. (1) and (2) for the study protocol no. CCSJ117B12201, Version: 01 dated 29-JUN-2021, the firm presented justification to waive off the same before the committee. After detailed deliberation, the committee noted that the firm has complied with both conditions and hence recommended to waive off the said conditions. (Dr. S. H. Meshram did not participate in the deliberation)
15.	CT/133/21 Online Submission (28500) Dupilumab	M/s. Sanofi	The firm presented the proposed study protocol no. LPS16676, Version: 5.0 dated 28 JAN 2021 before the committee. **Risk versus benefit to the patients-** The safety profile of the investigational drug from various pre clinical and clinical phase studies was presented before the committee. **Innovation vis-a-vis existing therapeutic option-** In a population with moderate-to-severe asthma: to assess the effect of Dupilumab on preventing or slowing the rate of lung function decline by Week 52 (year 1) compared to placebo. **Unmet need** -The test drug may potentially provide alternative treatment option in patients with uncontrolled moderate to severe asthma. The committee noted that the test drug is not approved in India and there is no available data on test drug to use in pregnant women to inform any drug

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			associated risk. Human IgG antibodies are known to cross the placental barrier; therefore, test drug may be transmitted from the mother to the developing fetus. After detailed deliberation, the committee recommended for grant of permission to conduct the study with following conditions- 1. In India the study should be considered as Phase III and accordingly, only Phase III part of the proposed study is to be conducted in India. 2. The firm should perform QuantiFERON-TB Gold test during screening visit to exclude latent- TB subjects from the study. 3. Women of child bearing potential should be excluded from the study. The firm should perform serum pregnancy test during screening of women of child bearing potential in the trial. Accordingly, the applicant should submit India specific protocol addendum to CDSCO. (Dr. S. H. Meshram did not participate in the deliberation)