Recommendations of the SEC (Pulmonary) made in its 60th meeting held on 07.06.2022 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 Lvy Leaf Extract Cough Syrup	M/s. USV Pvt. Ltd.	In light of earlier SEC recommendation dated 29.03.2022, the firm presented patient safety data, details of concentration of saponin in the product and the details of countries in which the product is marketed, package insert & regulatory status before the committee. After detailed deliberation, the committee recommended for exemption from the "WARNING" label requirement for marketing of approved drug " Dried lvy Leaf Extract Cough syrup". Further, the committee opined that opinion from Phytopharmaceutical expert may be obtained.
2.	ND/MA/22/000027 Icatibant Injection 30mg/3ml (10mg/ml)	M/s. MSN Laboratories Pvt. Ltd.	In light of earlier SEC recommendations dated 29.03.2022, the opinion of expert in Internal Medicine was placed before the committee. The committee agreed with the opinion of Internal Medicine expert that the Bio-Equivalence of a compound similar to the innovator brand (not same) should be proven in-vivo. After detailed deliberation, the committee recommended that the firm should conduct BE study in suitable number of healthy subjects after getting the protocol approved and submit the results prior to the manufacturing and marketing approval.
FDC Division			
3.	FDC/IMP/19/000063 Budesonide 160 microgram + Formoterol Fumarate dihydrate 4.5 microgram Inhalation powder.	M/s AstraZeneca Pharma India Limited	In light of earlier SEC recommendation dated 26.02.2021 & 01.03.2021, the firm presented the justification for Phase III clinical trial study waiver before the committee. After detailed deliberation, the committee reiterated its earlier recommendation dated 26.02.2021 & 01.03.2021. Accordingly, the firm should submit Phase III CT protocol for review by the committee.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
4.	FDC/MA/21/000240 Fluticasone Furoate 100mcg/200mcg +Vilanterol Trifenatate eq. to Vilanterol 25mcg Dry Powder for inhalation	M/s. Glenmark Pharmaceuticals Ltd. India	The firm presented the justification for BE Study waiver along with in-vitro study data. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC with the condition that Active PMS study should be conducted. Accordingly, Active PMS study protocol should be submitted within 03 months for further review by the committee.
5.	FDC/MA/22/000091 Bilastine 3.3mg + Dextromethorphan Hydrobromide 10mg + Phenylephrine Hydrochloride 5mg Syrup	M/s Glenmark Pharmaceuticals	In light of earlier SEC recommendation dated 28.04.2022, the firm presented their proposal before the committee. The committee noted that Bilastine 3.3mg thrice a day is not yet approved. 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 consideration.
6.	FDC/MA/20/000029 Montelukast IP 4mg + Fexofenadine Hydrochloride IP 60mg Suspension	M/s. Synokem Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 01.10.2020, the firm presented their proposal before the committee. After detailed deliberation, the committee opined that the firm should submit justification on following points: 1. Rationality of proposed FDC alongwith international approval status. 2. Published supportive scientific literature on use of the drug in pediatric population. 3. Justification in light of standard therapeutic treatment guidelines. Accordingly, the firm should submit above data for review by the committee.
7.	FDC/MA/22/000141 Mometasone furoate eq. to 136mcg of Mometasone Furoate delivered dose from mouth piece 160mcg + Glycopyrronium bromide eq. to 46mcg	M/s. Lupin	The firm presented their proposal alongwith results of BE study which was conducted for export purpose. The committee noted that the proposed FDC was already approved in countries like EU, UK etc.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
	of Glycopyrronium delivered dose mouth piece 63mcg + Indacaterol acetate eq. to 114mcg of Indacaterol delivered dose from mouth piece 173mcg Inhalation powder		After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC with condition that Phase IV clinical trial should be conducted. Accordingly, Phase IV clinical trial protocol should be submitted within 03 months of approval for further review by the committee.
GCT Division			
8.	CT/133/21 Online Submission (28500) Dupilumab	M/s. Sanofi	In light of earlier recommendation dated 25.02.22, the firm presented their justification before the committee. After detailed deliberation, the committee reiterated the previous recommendation and 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 should 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. The firm should perform serum pregnancy test during screening visit and at every visit of women of child bearing potential as precautionary measures.
9.	CT/131/20 Online Submission (15960) Budesonide, Glycopyrronium	M/s. AstraZeneca	The firm presented protocol amendment version 3.0 dated 07/01/2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.