Recommendations of the SEC (Pulmonary) made in its 05th/24 meeting held on 21.05.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/18/23 Online Submission (32034) BLU-5937	M/s. IQVIA	The firm presented protocol amendment 1 dated 14 Dec 2023, protocol number BUS-P3-02 (CALM-2). After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm .
2.	CT/16/23 Online Submission (32206) BLU-5937	M/s. IQVIA	The firm presented protocol amendment 1 dated 15 Dec 2023, protocol number BUS-P3-01 (CALM-1) and increase in the number of subjects from 48 to 51. After detailed deliberation, the committee recommended for approval of protocol amendment and increase the number of subjects from 48 to 51 in india as presented by the firm.
3.	CT/110/23 Online Submission (32120) SAR443765	M/s. Sanofi	The firm presented protocol amendment 1, version 02 dated 01 Mar 2024, protocol number DRI16762. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm
4.	CT/133/21 Online Submission (32167) Dupilumab	M/s. Sanofi	The firm presented protocol amendment 03, version 01 dated 22 Jan 2024, protocol number LPS16676. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
5.	BIO/CT18/FF/2023/40504 Benralizumab 30mg solution for injection in Auto-injector	M/s. AstraZeneca Pharma India Limited	The firm presented their proposal for approval of Benralizumab solution for Injection 30 mg/ml in Auto-injector for the indication of "as an add-on maintenance treatment for severe asthma with an eosinophilic phenotype in adult patients" with request of local phase-III trial waiver. The committee has noted that Benralizumab solution for Injection 30 mg/ml in PFS has already been approved in India for the same indication.

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			The committee has also noted that Benralizumab solution for Injection 30 mg/ml in Auto-injector is approved in US, Great Britain, Europe, Singapore & Australia etc. After detailed deliberation, the committee has recommended for approval of Benralizumab solution for Injection 30 mg/ml in Auto-injector with waiver of phase III local clinical trial with condition to conduct the Phase IV clinical trial to generate more data in Indian population with respect to safety, functionality & reliability of auto-injector. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of approval for review by the committee.
SND Division			
6.	SND/MA/24/000061 Umeclidinium powder for inhalation 62.5mcg	M/s. Sun Pharma Labs Limited	The firm presented their proposal for grant of manufacture and marketing of Umeclidinium powder for inhalation 62.5mcg along with justification for waiver of Phase-III clinical trial and Bioequivalence study before the committee. The firm has informed that the proposed drug Umeclidinium powder for inhalation 62.5mcg is already in USA, UK, EU, Australia, Canada for Chronic obstructive pulmonary disease. Firm also informed that Umeclidinium is approved in India as part of FDC of fluticasone furoate, Umeclidinium and vilanterol (100mcg + 62.5mcg+25mcg) for same indication. After detailed deliberation, the committee opined to conduct bioequivalence study with pharmacokinetic endpoints for which firm should submit bioequivalence protocol to CDSCO for further review by the committee.

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FDC Division			
7.	FDC/MA/22/000203 Levosalbutamol Sulphate IP eq. to Levosalbutamol + Ambroxol Hydrochloride IP + Guaiphenesin IP 0.25mg + 7.5mg + 12.5mg Oral drops	M/s. Akums Drugs & Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 05.12.2023, the firm presented their proposal along with PK study report before the committee. After detailed deliberation, the committee considered the PK study report. Further, committee did not consider the request of clinical trial waiver. Accordingly, firm should submit Phase III clinical Trial protocol to the CDSCO for further review by the committee and one pediatrician should also be invited for deliberation in the next meeting.
8.	FDC/MA/24/000098 Noscapine IP 7mg/15mg + Chlorpheniramine Maleate IP 2mg/4mg + Phenylephrine Hydrochloride IP 5mg/10mg per 5mL Oral Liquids	M/s. Pure and Cure Healthcare Pvt. Ltd.	The firm presented their proposal along with justification for BE waiver & Phase III CT waiver before the committee. After detailed deliberation, the committee opined that: 1. The firm should submit rationality of proposed FDC along with international approval status. 2. The firm should submit justification on safety data of proposed FDC. 3. The firm should submit scientific literature available from peer reviewed journal in support of combining proposed FDC. Accordingly, the firm should submit above data to CDSCO for review by the committee and one pediatrician should also be invited for deliberation in the next meeting.
9.	FDC/MA/23/000242 Glycopyrrolate IP eq. to Glycopyrronium + Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate + Budesonide IP (25mcg+20mcg+500	M/s. Glenmark Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 05.03.2024, the firm presented the proposal along with Phase III CT study protocol before the committee. After detailed deliberation, the committee opined that: 1. The firm should include nebulization methodology with

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	mcg) Inhalation Suspension (for nebulization)		type of nebulizer & interface. 2. The firm should include subjects having exposure to biomass fuel smoke in the inclusion criteria. Accordingly, the revised Phase III CT study protocol should be submitted to CDSCO for further review by the committee.
10.	FDC/CT/23/000085 Formoterol Fumarate Dihydrate IP 12 mcg + Budesonide IP 400 mcg + Glycopyrrolate IP eq. to Glycopyrronium 25 mcg powder for inhalation in capsule	M/s. Penta Kraft	In light of earlier SEC recommendation dated 06.02.2024, the firm presented the revised Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee opined that: 1. Firm should revise Exclusion criteria w.r.t. to "Trial participants who are currently receiving triple drug treatment other than the study treatment." 2. Firm should submit statistical calculation for sample size of the participants. Accordingly, firm should submit revised Phase IV CT Protocol to CDSCO for further review by the committee.