Recommendations of the SEC (Pulmonary) made in its 02nd/24 meeting held on 06.02.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/22/000171 Online Submission (30715) BI 1015550	M/s. IQVIA	The firm presented protocol amendment version 3.0 dated 10 May 2023 and protocol amendment version 4.0 dated 21 september 2023 protocol No. 1305-0023. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/24/000005 Online Submission (41458) REGN3500 (Itepekimab) 300 mg (150 mg/mL) Solution	M/s. Sanofi Healthcare India Private Limited	The firm presented phase III clinical study protocol No. LTS18133 version No. 1 dated 24 october 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. (Dr. Naveed nazir shah did not participate in the deliberation).
BA/BE Division			
3.	File No. 12-09/2024/BA-BE/MISC-04/DC BABE/CT05/FF/2023 /38099 Levosalbutamol and Budesonide Inhalation 50 mcg +100 mcg	M/s. Macleods Pharmaceuticals Ltd, Mumbai-400059.	The firm presented their proposal alongwith the protocol of the BE study for export purpose only. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study as presented by the firm.
SND Division			
4.	SND-16044(ii)/ 1/ 2024-eoffice Bolus Nitroglycerin Use in sympathetic crashing acute pulmonary edema	IEC, AIIMS, Raipur	The firm presented their proposal to conduct academic clinical trial on bolus Nitroglycerin use in sympathetic crashing acute pulmonary edema (BoNUS): A randomized, open label, active comparator pilot study along with academic clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct academic clinical trial as per protocol presented by the firm.
5.	SND/IMP/23/0 00036	M/s. Dr. Reddy's	In light of earlier recommendation of SEC dated 21.09.2023, now the firm

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	12 SQ-HDM Sublingual lyophilisate tablet (SENSIMUNE) standardised allergen extract from house dust mites, *Dermatophagoides pteronyssinus and Dermatophagoides farinae* .	Laboratories	presented justification/clarification about the origin of the proposed product along with dosage regimen, duration of treatment and indication before the committee. The firm has informed that the drug product is of synthetic origin derived from natural source. The committee noted that the proposed drug already approved in more than 40 countries including Denmark, US and Japan etc. and such immunotherapy already approved in India for diagnostic purpose. After detailed deliberation, the committee recommended for grant of permission to import and marketing of 12 SQ-HDM Sublingual lyophilisate (SENSIMUNE) with clinical trial waiver subject to condition that the firm should conduct Phase-IV clinical trial. In addition to above, firm should fulfill the requirement of CMC data. Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within 03 months from date of approval for further review by the committee.
New Drug Division			
6.	12-1/22-DC (Pt-337) Bovine Lipid Extract Surfactant Suspension	M/s. Cipla Limited	The firm presented its proposal before the committee for updating the prescribing information without the provided precaution statement of 'In minimal invasive techniques (LISA or MIST), the volume of surfactant should be small. After installation of large volume surfactant (Bovine) which can initiate cough reflex, the chance of failure is high. But the advantages of LISA or MIST is much more than conventional surfactant therapy'. After detailed deliberation, the committee recommended for the grant of approval of updated prescribing information.

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FDC Division			
7.	04-74/2016-DC (Pt. AstraZeneca) Budesonide + Formoterol Fumarate Dihydrate 80/4.5mcg, 160/4.5mcg & 320/9mcg per dose Inhalation Powder	M/s. AstraZeneca Pharma India Limited	The firm presented the proposal for update prescribing information for said FDC, changes based on the updated company core data sheet (CCDS). After detailed deliberation, the committee recommended for grant of approval for the proposed update in prescribing information as presented by the firm. (Dr. Naveed nazir shah did not participate in the deliberation).
8.	FDC/CT/20/000070 Budesonide IP 400mcg + Glycopyrronium IP 25mcg + Formoterol Fumarate IP 12mcg Inhalation Powder	M/s. Cipla Limited	In light of earlier SEC recommendation dated 03.12.2020, the firm presented the Phase IV clinical trial report before the committee. After detailed deliberation, the committee recommended that the firm should reanalyze the results including different phenotypes of COPD patients as per GOLD guidelines 2023. Accordingly, revised Phase IV clinical trial report should be submitted to CDSCO for further review by the committee.
9.	FDC/MA/23/000173 Montelukast Sodium I.P. 10mg + Fexofenadine I.P. 180mg uncoated bilayered tablets	M/s. Synokem Pharmaceuticals Ltd.	The firm presented their proposal along with BE study report before the committee. After detailed deliberation, the committee considered the BE study report and recommended to initiate Phase III clinical trial study for which permission was already granted by CDSCO. The Phase III clinical trial report should be submitted to CDSCO for further review by the committee.
10.	FDC/CT/23/000078 Budesonide IP 200 mcg + Formoterol Fumarate Dihydrate IP 6 mcg +	M/s. Cipla Limited	The firm did not turn up for presentation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Glycopyrronium IP 12.5 mcg aerosol for inhalation		
11.	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 the condition mentioned in permission in Form CT-23 dated 28.07.2023, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee opined that Phase IV clinical trial protocol should include different phenotypes of COPD patients as per GOLD guidelines 2023. Accordingly, revised Phase IV clinical trial protocol should be submitted to CDSCO for further review by the committee.
12.	FDC/CT/24/000004 Fluticasone Furoate 100mcg/200mcg + Vilanterol Trifenatate eq. to Vilanterol 25mcg/25mcg dry powder for inhalation in capsule	M/s. Cipla Limited	In light of the condition mentioned in permission in Form CT-23 dated 28.07.2023, the firm presented the Active PMS protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct of the Active PMS study with the condition to include more government sites, which should be geographically distributed. The firm should submit the Active PMS study report to CDSCO for further review by the committee.