

**Recommendations of the SEC (Pulmonary) made in its 09<sup>th</sup>/24 meeting held on 04.09.2024 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/90/24 Online Submission (44170)  PLN-74809	M/s. IQVIA RDS (India) Private Limited	The firm presented Phase 2b/3 clinical trial study protocol no. PLN-74809-IPF-206 version no. 2.2 dated 30 April 2024.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial with the condition that: <ol style="list-style-type: none"> <li>1. The firm should submit data of phase 2b part of the study to CDSCO for further review by the committee before proceeding to the phase 3 part of the study.</li> <li>2. In case of deterioration of condition of trial subject, background therapy should be provided as per unblinding and withdrawal criteria and investigator should be allowed to initiate the treatment as and when needed.</li> <li>3. More number of Govt. Sites should be included in the study.</li> </ol>
2.	CT/05/24 Online Submission (33761)  REGN3500 (Itepekimab) 300 mg (150 mg/mL) Solution	M/s. Sanofi Healthcare India Private Limited	The firm presented protocol amendment 01, version 01 dated 29 March 2024, protocol no. LTS18133. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/134/23 Online Submission (34418)  Budesonide/ Glycopyrronium/ for moterol fumarate pressurized inhalation suspension, DFP, HFO [Budesonide + Formoterol fumarate + Glycopyrronium (BGF MDI HFO)]	M/s. AstraZeneca Pharma India Limited	The firm presented protocol amendment version 2.0 dated 04 July 2024, protocol no. D5985C00002.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
<b>FDC Division</b>			
4.	FDC/CT/23/000078  Budesonide IP 200	M/s Cipla Limited	In light of earlier SEC recommendation dated 05.03.2024 and as per condition of Form CT-23 dated 25.08.2023, the

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	mcg + Formoterol Fumarate Dihydrate IP 6 mcg + Glycopyrronium (as Glycopyrrolate IP) 12.5mcg Inhaler		<p>firm presented Phase IV clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for conduct of the Phase IV clinical trial with the condition that “clinically significant ECG abnormality” should be defined in exclusion criteria.</p> <p>The firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.</p>
5.	FDC/MA/24/000128  Fluticasone Furoate 200mcg + Umeclidinium bromide eq. to Umeclidinium 62.5mcg + Vilanterol trifenate eq. to Vilanterol 25mcg dry powder for Inhalation in hard cellulose capsule	M/s Sun Pharma Laboratories Limited	<p>The firm presented the proposal before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should conduct Phase III CT study with the proposed FDC.</p> <p>Accordingly, the firm should submit Phase III clinical trial protocol to CDSCO for further review by the committee.</p>
6.	FDC/MA/24/000149  Vilanterol trifenate eq. to Vilanterol 12.5mcg + Umeclidinium bromide eq. to Umeclidinium 31.25 mcg Metered dose inhalation	M/s Zydus Healthcare Limited	<p>The firm presented the proposal along with Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial.</p> <p>Accordingly, the firm should submit Phase III clinical trial report to CDSCO for further review by the committee.</p>
7.	FDC/MA/24/000155  Vilanterol Trifenate eq. to Vilanterol 12.5mcg/ 12.5mcg + Umeclidinium bromide eq. to Umeclidinium 31.25mcg/31.25mcg + Fluticasone Furoate 50mcg/ 100mcg Metered Dose inhalation	M/s Zydus Healthcare Limited	<p>The firm presented the proposal along with Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial.</p> <p>Accordingly, the firm should submit Phase III clinical trial report to CDSCO for further review by the committee.</p>

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8.	FDC/CT/24/000059  Fluticasone Furoate 100mcg + Glycopyrrolate IP eq. to Glycopyrronium 50mcg + Vilanterol Trifenatate eq. to Vilanterol 25mcg Dry Powder for inhalation in capsules	M/s Zydus Healthcare Limited	In light of the condition mentioned in permission in Form CT-23 dated 22.02.2024, the firm presented the Phase IV clinical trial protocol before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct of the Phase IV clinical trial.  The firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
9.	04-01/2022-DC (Misc. 2) (Pt.1)  Montelukast Sodium IP eq. to Montelukast 10mg + Fexofenadine Hydrochloride IP 120mg tablets	M/s Sanofi India Limited	The firm presented the proposal for update in prescribing information for the FDC based on the updated company core data sheet (CCDS) version 7 dated 28.09.2023.  After detailed deliberation, the committee recommended for grant of approval for the proposed update in prescribing information as presented by the firm.
10.	04-01/2022-DC (Misc. 2) (Pt.1)  Pseudoephedrine Hydrochloride IP 120mg + Fexofenadine Hydrochloride IP 60mg extended release tablet	M/s Sanofi India Limited	The firm presented the proposal for update in prescribing information for the FDC based on the updated company core data sheet (CCDS) version 11 dated 28.09.2023.  After detailed deliberation, the committee recommended for grant of approval for the proposed update in prescribing information as presented by the firm.