

Recommendations of the SEC (Pulmonary) made in its 01st/26 meeting held on 20.01.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Blood Product Division			
1.	BD PRO-11013(14)/89/2025-eoffice (Comp. No. 29565) Human α -1 Proteinase Inhibitor EP 1000 mg (Freeze Dried Powder)	M/s. Intas Pharmaceuticals Ltd.	<p>The firm has presented the proposal for grant of permission to manufacture and market Human Alpha-1 Proteinase Inhibitor EP 1000 mg (Freeze Dried Powder) (Domestic and Export purpose) with an indication for chronic replacement therapy of individuals having congenital deficiency of alpha1-P1 (alpha1-antitrypsin) with clinically demonstrable panacinar emphysema along with the justification for the Phase III clinical trial waiver before the committee.</p> <p>During the deliberation, committee noted that the drug Alpha 1-antitrypsin deficiency (AATD) induced emphysema is an orphan disorder. Further, the same drug is approved in USA since 1984 as an orphan drug.</p> <p>After detailed deliberation, the Committee has recommended for the grant of clinical trial waiver as it is falls under the definition of orphan drug of New Drugs and Clinical Trial Rules 2019 with subject to the following conditions:</p> <ol style="list-style-type: none"> 1) The drug should be prescribed by the pulmonologist and it shall be mentioned on the label, carton box and package insert. 2) The firm is required to conduct the phase IV study and submit the phase IV clinical trial protocol within 3 months from the date of approval. 3) The firm is also required to conduct genetic study with the drug. The firm shall submit an undertaking in this regard to CDSCO.
New Drug Division			
2.	ND/144/2025 eoffice Triprolidine hydrochloride and	M/s. Pfizer Limited	The firm presented proposal for updating the prescribing information from LPDCXT012020 into LPDCXT042025 and newly created Patient Information

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	codeine phosphate cough Syrup		<p>Leaflet-PLDCXT052025 for drug product, Codeine Phosphate 10 mg and Triprolidine Hydrochloride 1.2 mg Cough Syrup before the committee.</p> <p>The key changes in the proposed prescribing information are related to changes in the undesirable Gastrointestinal side-effects and patient counselling information.</p> <p>After detailed deliberation, the Committee recommended for grant of approval for the proposed updates in prescribing information as presented by the firm.</p>
3.	ND/MA/25/000002 Gefapixant Tablets 45 mg.	M/s. Exemed Pharmaceuticals	<p>In light of earlier SEC recommendation dated 13.05.2025, the firm presented the BE study report of Gefapixant Tablets 45 mg before the committee.</p> <p>Firm presented BE study report including safety parameters and statistical data for Bioequivalence study.</p> <p>After detailed deliberation, the committee considered the results of BE study presented by the firm and recommended for grant of permission to initiate Phase III clinical trial for New Drug Gefapixant Tablets 45 mg.</p> <p>The firm should submit Phase III clinical trial results to CDSCO for further review by the committee.</p>
SND Division			
4.	SND/MA/22/000352 Pretomanid Tablets 200 mg	M/s.Mylan Laboratories Limited	<p>The firm presented before the Committee Phase IV clinical trial report of Pretomanid Tablets 200 mg to fulfill the compliance requirements of permissions granted vide no. MF-FF-ND-62/2020 (New Drug Division) and requested for waiver to conduct further Phase IV Clinical trial.</p> <p>After detailed deliberation, the Committee recommended that the firm should submit and present the safety and efficacy data generated under the National TB Elimination Program (NTEP) for dosage regimen approved</p>

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			vide respective permission for further review by the Committee.
FDC Division			
5.	FDC/CT/24/000004 Fluticasone Furoate 100 mcg/200 mcg + Vilanterol Trifenatate eq. to Vilanterol 25 mcg/25 mcg dry powder for inhalation in capsule	M/s. Cipla Limited	In light of earlier SEC recommendation dated 06.02.2024, the firm presented Active PMS report before the committee. After detailed deliberation, the committee noted and agreed to the result of the Active PMS report.
6.	FDC/MA/24/000155 Vilanterol Trifenatate eq. to Vilanterol 12.5 mcg/12.5 mcg + Umeclidinium bromide eq. to Umeclidinium 31.25 mcg/31.25 mcg + Fluticasone Furoate 50 mcg/100 mcg Metered Dose inhalation	M/s. Zydus Healthcare Limited	In light of earlier SEC recommendation dated 04.09.2024, the firm presented Phase III clinical trial report before the committee. After detailed deliberation, the committee opined that the firm should submit data of randomly selected 5 patients from each centers for further review by the committee.
7.	FDC/MA/25/000120 Indacaterol acetate eq. to Indacaterol 75 mcg + Glycopyrronium Bromide Ph. Eur. eq. to Glycopyrronium 25 mcg + Mometasone Furoate IP 80 mcg Metered Dose Inhaler	M/s. Lupin Limited	In light of earlier SEC recommendation dated 10.11.2025, the firm presented the justification for PK study waiver before the committee. After detailed deliberation, the committee noted that firm did not submitted adequate justification/supporting data for PK study waiver. In view of above, the committee reiterated its earlier recommendation dated 10.11.2025.
8.	04-01/2022-DC (Misc. 2) (Pt.1), E. office No. 102650 Pseudoephedrine Hydrochloride IP 120 mg + Fexofenadine Hydrochloride IP 60 mg ER 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 12 dated 24.04.2025. After detailed deliberation, the committee recommended for grant of approval for the proposed update in prescribing information as presented by the firm with the condition that the treatment duration should not exceed 5 days.