

Recommendations of the SEC (Pulmonary) made in its 06th/25 meeting held on 28.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/102/24 Online Submission (43733) Sutezolid, TBI-223, Pretomanid, Linezolid, Bedaquiline, Isoniazid, Rifampicin, Pyrazinamide, Ethambutol	M/s B J Govt. Medical College Clinical Trial Unit	In light of earlier SEC Recommendation dated 09.01.2025, the firm presented phase 2 clinical trial protocol no. A5409 version no. 2.0 dated 21-MAR-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1.Cardiac evaluation at every visit. 2. Objective assessment of neuropathy nerve conduction studies in subject with comorbidities or moderate severe grade neuropathy.
2.	CT/20/25 Online Submission (47881) Tozorakimab (MEDI3506) Solution for injection 150mg/mL	M/s AstraZeneca Pharma India Limited	The firm presented phase IIb clinical study Protocol No.: D9181C00002, Version 1.0 dated 26 Nov 2024 and Local CSP Addendum IND-1: Version 1.0, dated 20 Feb 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/80/24 Online Submission (38492) Dexpramipexole tablets for oral use	M/s PAREXEL International Clinical Research Private Limited	The firm presented protocol amendment 2 India Specific dated 12-March-2025 and Increase in the number of subjects in India from 50 to 80 protocol no.AR - DEX-22-02. After detailed deliberation, the committee recommended for approval of protocol amendment and increase in the number of subjects in India from 50 to 80 as presented by the firm.
4.	CT/39/25 Online Submission (49088) Dexpramipexole tablets for oral use	M/s PAREXEL International Clinical Research Private Limited	The firm presented phase III clinical study protocol no. AR-DEX-22-01, India Specific amendment 1 dated 03 March 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.

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5.	CT/110/23 Online Submission (38952) SAR443765	M/s Sanofi Healthcare India Private Ltd.	The firm presented protocol amendment 2 version 1 dated 27 Feb 2025 protocol no.: DR116762. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
6.	CT/51/24 Online Submission (38269) BMS-986278	M/s Bristol-Myers Squibb India Private Limited	The firm presented protocol amendment 3 version 1.0 dated 24 December 2024 protocol no. IM027068. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
7.	CT/134/23 Online Submission (39105) Budesonide, Glycopyrronium, and Formoterol Fumarate (BGF) Delivered by MDI HFO	M/s AstraZeneca Pharma India Limited	The firm presented protocol (CSP) amendment version 3.0 dated 07 April 2025 protocol no. D5985C00002. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
New Drugs Division			
8.	ND/MA/24/000058 Gefapixant Tablets 45 mg	M/s Sun Pharma Laboratories	In light of earlier recommendations dated 04.07.2024, the firm presented the BE study report of Gefapixant Tablets 45 mg before the committee. 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. Accordingly, the firm should submit Phase III clinical trial results to CDSCO for further review by the committee.
FDC Division			
9.	FDC/MA/25/000053 Glycopyrronium 100mcg + Vilanterol 50 mcg + Fluticasone Furoate 200 mcg Inhalation Suspension	M/s Glenmark Pharmaceuticals Ltd	The firm presented their proposal along with request for BE study waiver before the committee. After detailed deliberation, the committee opined that the firm should submit data/research evidence and published scientific literature in peer reviewed

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			<p>journal to support that double dose of nebulizer is equivalent to half dose of MDI/DPI.</p> <p>Accordingly, the firm should submit the above data to CDSCO for further review by the committee.</p>