Recommendations of the SEC (Pulmonary) made in its 12th/24 meeting held on 27.11.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	GCT/PostAppr/2024/34868 Online Submission (34868) PC945 (Opelconazole) Nebuliser Suspension	M/s. PSI CRO Pharma Pvt. Ltd.	The firm presented protocol amendment 3.0 dated 10 June 2024 protocol No. PC-_ASP_006. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	GCT/PostAppr/2024/35782 Online Submission (35782) Tozorakimab (MEDI3506)	M/s. AstraZeneca Pharma India Limited	The firm presented protocol amendment version 3.0 dated 22 August 2024 protocol No. D9185C00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	GCT/PostAppr/2024/35763 Online Submission (35763) BI 1015550	M/s. IQVIA RDS (India) Private Limited	The firm presented protocol amendment version 3.0 dated 29 April 2024 protocol No. 1305-0031. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
New Drugs Division			
4.	ND-12011(13)/10/2024-eoffice Indacaterol 150mcg and Mometasone Furoate 80mcg/160mcg/320mcg	M/s. Glenmark Pharmaceuticals Ltd.	The firm has presented the active PMS study report as per the condition No. 9 of manufacture& market permission granted for the drug Indacaterol 150mcg and Mometasone Furoate 80mcg/160mcg/320mcg powder for inhalation (DPI), before the committee. After detailed deliberation, the committee considered the active PMS study report.
FDC Division			
5.	FDC/MA/23/000349 Vilanterol Trifenatate equivalent to Vilanterol 25mcg + Umeclidinium Bromide equivalent to Umeclidinium 62.5mcg Powder for Inhalation	M/s. Zydus Healthcare Limited	In light of the earlier SEC recommendation dated 05.12.2023, the firm presented BE study report as well as justification for Phase III CT waiver before the committee. After detailed deliberation, the committee considered the BE study report and opined that the firm needs to conduct Phase III clinical trial with the proposed

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			FDC. Accordingly, Phase III clinical trial protocol should be submitted to CDSCO for further review by the committee.
6.	FDC/MA/23/000232 Vilanterol Trifenatate eq. to Vilanterol 12.5mcg + Glycopyrronium IP eq. to Glycopyrronium 25mcg + Fluticasone Furoate Ph. Eur 100 mcg metered dose inhalation	M/s. Zydus Healthcare Limited	In light of earlier SEC recommendation dated 05.09.2023, the firm presented their proposal along with Phase III clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market for the proposed FDC.
7.	FDC/MA/21/000240 Fluticasone Furoate 100/200mcg Vilanterol Trifenatate Equivalent to Vilanterol 25mcg Dry powder for Inhalation in capsule	M/s. Glenmark pharmaceuticals	In light of earlier SEC recommendation dated 05.07.2023 and as per condition of Form CT-23 dated 06.07.2022, the firm presented the Active PMS report before the committee. After detailed deliberation, the committee noted and agreed the results of the report.