Recommendations of the SEC (Pulmonary) made in its 79th meeting held on 05.12.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/22/000203 Levosalbutamol Sulphate IP eq. to Levosalbutamol + Ambroxol Hydrochloride IP + Guaiphenesin IP 0.25mg + 7.5mg + 12.5mg Oral drops	M/s. Akums Drugs & Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 10.01.2023 & 21.03.2023, the firm presented the PK study report before the committee. After detailed deliberation, the committee opined that one Pediatrician should be invited in the next SEC meeting for deliberation in the matter.
2.	FDC/CT/23/000078 Budesonide IP 200 mcg + Formoterol Fumarate Dihydrate IP 6 mcg + Glycopyrronium IP 12.5 mcg aerosol for inhalation	M/s. Cipla Limited	The firm didn't turn up for presentation.
3.	FDC/MA/23/000324 Formoterol Fumarate Dihydrate IP 6mcg + Glycopyrronium (as Glycopyrrolate) IP 12.5mcg Inhaler	M/s. Cipla Limited	The firm presented their proposal along with justification for CT and BE waiver before the committee. After detailed deliberation, the committee recommended that the firm should conduct the BE study with innovator product as a reference product and clinical trial waiver was not considered at this stage. Accordingly, the BE protocol should be presented before the committee for review.
4.	FDC/MA/23/000338 Glycopyrrolate IP eq. to Glycopyrronium 25 mcg + Indacaterol Maleate eq. to Indacaterol 55 mcg Metered dose inhalation	M/s. Zydus Healthcare Limited	The firm presented their proposal along with BE protocol & justification for CT waiver before the committee. After detailed deliberation, the committee recommended that the firm should conduct BE study and clinical trial waiver was not considered at this stage. Accordingly, the result of the BE study should be presented before the committee for review.
5.	FDC/MA/23/000349 Vilanterol Trifenatate	M/s. Zydus Healthcare Limited	The firm presented their proposal along with BE study protocol & justification for CT waiver before the committee.

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	equivalent to Vilanterol 25mcg + Umeclidinium Bromide equivalent to Umeclidinium 62.5mcg Dry Powder Inhaler in capsule		After detailed deliberation, the committee recommended that firm should conduct BE study and clinical trial waiver was not considered at this stage. Accordingly, the result of the BE study should be presented before the committee for review and further consideration of the clinical trial waiver.
GCT Division			
6.	CT/146/23 Online Submission (40530) AZD4604 Inhalation powder 0.2 mg/ 1.0 mg/ Placebo(SD3FL inhaler, 60 doses)	M/s. AstraZeneca	The firm presented Phase 2a clinical trial Protocol no. D8210C00003. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
7.	CT/134/23 Online Submission (40341) Budesonide, Glycopyrronium, and Formoterol Fumarate (BGF) Delivered by MDI HFO	M/s. AstraZeneca	The firm presented Phase III clinical trial Protocol no. D5985C00002. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
8.	CT/51/23 Online Submission (29648) Astegolimab	M/s. PPD	The firm didn't turn up for presentation.
9.	CT/163/22 Online Submission (29315) Tozorakimab (MEDI3506) 150 mg/mL	M/s. AstraZeneca	The firm presented protocol amendment version 2.0 dated 27 July2023, Protocol no. D9180C00008. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm. However, the proposed amendment with respect to Echocardiography was not accepted by the committee.
BA/BE Division			
10.	File No. 12-09/ 2023 / BA-BE/MISC-38/DC BABE/CT05/FF/2023 /39352 Probenecid Oral Suspension 100mg/ml	M/s. Vayam Research Solutions Limited	The firm presented their proposal before the committee. After detailed deliberation, the committee opined that the proposal should be deliberated in SEC (Analgesic and Rheumatology) meeting.