Recommendations of the SEC (Pulmonary) made in its 77th meeting held on 05.10.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/23/000153 Montelukast Sodium I.P. 10mg + Fexofenadine I.P. 180mg uncoated bilayered tablets	M/s. Exemed Pharmaceutical	In light of earlier SEC recommendation dated 05.07.2023, the firm presented BE study report. After detailed deliberation, the committee considered the BE study report and recommended to initiate Phase III clinical trial for which permission has already been granted by CDSCO. The Phase III clinical trial report should be submitted to CDSCO for further review by the committee.
2.	FDC/MA/23/000154 Montelukast Sodium I.P. 10mg + Bilastine 40mg Tablets	M/s. Exemed Pharmaceutical	In light of earlier SEC recommendation dated 05.07.2023, the firm presented BE study report. After detailed deliberation, the committee considered the BE study report and recommended to initiate Phase III clinical trial for which permission has already been granted by CDSCO. The Phase III clinical trial report should be submitted to CDSCO for further review by the committee.
3.	FDC/MA/23/000242 Glycopyrrolate IP eq. to Glycopyrronium + Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate + Budesonide IP (25mcg+20mcg+500 mcg) Inhalation Suspension (for nebulization)	M/s. Glenmark Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 05.09.2023, the firm presented their proposal along with request for BE & Phase III clinical trial waiver and justification, supporting literatures and in-vitro study data before the committee. After detailed deliberation, the committee opined the following: 1. To demonstrate lungs deposition of the triple drug combination in inhalation suspension (for nebulization) 2. The firm should present in-vitro study data for triple drug combination with all the three drug individually in inhalation suspension (for nebulization) 3. The firm should present internationally peer review journals & approval status of the three drug combination in inhalation suspension (for nebulization)

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			In view of above, the committee recommended that the firm should present the documents/justification on aforesaid points before the SEC for further review.
4.	FDC/MA/22/000340 Vilanterol Trifenatate eq.to Vilanterol 12.5mcg+Glycopyrrolate IP eq. to Glycopyrronium 25mcg + Fluticasone Furoate50mcgMetered Dose Inhaler.	M/s. Zydus Heathcare Limited	In light of earlier SEC recommendation dated 07.12.2022, the firm presented their proposal along with Phase III clinical trial study report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC.
5.	FDC/MA/23/000270 Acebrophylline 100mg + Erdosteine 300mg film coated tablet	M/s. Macleods Pharmaceutical Ltd.	The firm presented its proposal along with BE study and Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study and Phase III clinical trial study with the condition that BE study report should be presented before the SEC prior to initiation of the Phase III clinical trial study.
6.	FDC/MA/23/000286 Fluticasone Furoate 200mcg + Glycopyrronium IP eq. to Glycopyrronium 50mcg + Vilanterol Trifenatate eq. to Vilanterol 25mcg powder for inhalation in capsule	M/s. Zydus Healthcare Limited	The firm presented the proposal along with Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission for conducting the proposed Phase III clinical trial. The firm should submit Phase III clinical trial report to CDSCO for further review by the committee.