

Recommendations of the SEC (Pulmonary) made in its 75th meeting held on 05.09.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/23/000242 Glycopyrrolate IP eq. to Glycopyrronium + Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate + Budesonide IP (25mcg+ 20mcg + 500mcg) Inhalation Suspension (for Nebulization)	M/s. Glenmark Pharmaceuticals Ltd.	<p>The firm presented the proposal along with request for BE & Phase III clinical trial waiver before the committee.</p> <p>The committee noted that the FDC is approved by CDSCO in MDI and DPI form. However, the applied formulation is in Inhalation suspension (for Nebulization).</p> <p>After detailed deliberation, the committee opined the following:</p> <ol style="list-style-type: none"> 1. The firm has not presented published scientific literature in peer reviewed journal in support of FDC in Inhalation suspension dosage form. 2. The firm has not presented any in-vivo study data w.r.t. FDC in Inhalation Suspension dosage form. 3. No global data was presented w.r.t. the FDC in Inhalation Suspension dosage form. <p>In view of above, the firm should submit above data for further review by the committee.</p>
2.	FDC/MA/23/000232 Fluticasone Furoate 100mcg + Glycopyrronium Bromide IP eq. to Glycopyrronium 25mcg + Vilanterol Trifenatate eq. to Vilanterol 12.5mcg metered dose inhalation	M/s. Zydus Healthcare Limited	<p>The firm presented the proposal along with Phase III clinical trial protocol & requested for BE study waiver before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission for conducting the proposed Phase III clinical trial.</p> <p>The firm should submit Phase III clinical trial report for further review by the committee.</p>
GCT Division			
3.	CT/41/23 Online Submission (37160) Bemralizumab 100 mg	M/s. AstraZeneca	<p>The firm presented the proposal to conduct Phase III clinical trial, protocol No. D3251C00014, version 6.0, 06 Feb 2023 before the committee.</p>

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			After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as presented by the firm.
4.	CT/77/23 Online Submission (38215) Tezepelumab	M/s. AstraZeneca	The firm presented the proposal to conduct Phase III clinical trial, protocol No. D5180C00024, version 3.0, 28 Mar 2023 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as presented by the firm.
5.	CT/03/21 Online Submission (24390) Benralizumab	M/s. AstraZeneca	The firm presented the proposal for Phase III clinical trial protocol amendment, protocol No. D325BC00001, version 3.0, 10 Jan 2023 before the committee. After detailed deliberation, the committee recommended for approval for protocol amendment as presented by the firm subject to the condition that fresh ethics committee approval shall be obtained from respective ethics committee as there are too many changes.