

**Recommendations of the SEC (Pulmonary) made in its 72<sup>nd</sup> meeting held on 05.07.2023 at CDSCO HQ New Delhi:**

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>Biological Division</b>			
1.	BIO/CT18/FF/2023/35930  Palivizumab 50mg/0.5mL & 100 mg/ 1mL solution for injection	M/s AstraZeneca Pharma India Limited	The proposal was deferred for next SEC meeting.
<b>SND Division</b>			
2.	SND/MA/23/000149  Selexipag for injection 1800 mcg/vial (Lyophilized powder for injection)	M/s. MSN Laboratories Ltd.	<p>The firm presented the proposal of manufacture and marketing permission of Selexipag for injection 1800 mcg/vial (Lyophilized powder for injection) for already approved indication along with therapeutic rationale and justification for clinical trial and BA/BE waiver, before the committee.</p> <p>The committee observed that the Pulmonary Arterial Hypertension (PAH) is a serious, life threatening, rare disease, for which there is unmet medical need in the country and Selexipag is already approved in USA, EU and designated as orphan drug. Further, Selexipag tablets 200mcg/400mcg/600mcg/800mcg/1000mcg/1200mcg/1400mcg/1600mcg are already approved in India.</p> <p>After detailed deliberation, the committee considered clinical trial and BA/BE waiver for the applied drug product and recommended for grant of permission to manufacture and market Selexipag for injection 1800 mcg/vial (Lyophilized powder for injection) for already approved indication subject to conditions as mentioned below:</p> <ol style="list-style-type: none"> <li>1. The applied drug product i.e. Selexipag for injection 1800 mcg/vial (Lyophilized powder for injection) should be used only in patients who are already under treatment with Selexipag tablets, but temporarily unable to take oral therapy due to any serious condition or stage of hospitalization. This should be highlighted in the package insert.</li> </ol>

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			<p>2. The firm should conduct a Phase-IV clinical trial of the drug product. Accordingly, firm should submit Phase-IV clinical trial protocol within six months from the date of approval of the drug product to CDSCO for further review by the committee.</p> <p>3. The drug product permission and prescribing Information should include following “warning”:  <b>“To be sold by retail on the prescription of a Cardiologist /Pulmonologist only”</b></p> <p>4. Use of this injectable “only in cases who are already on this drug in tablet form” should be highlighted.</p>
<b>FDC Division</b>			
3.	FDC/MA/22/000311  Vilanterol Trifenatate eq. to Vilanterol 25mcg + Fluticasone Furoate 200mcg powder for inhalation	M/s. Malik Life Sciences Pvt. Ltd.	<p>In light of the condition mentioned in Form CT-23 dated 06.02.2023, the firm presented the Active PMS study protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for conduct of the Active PMS study, with the condition to include atleast 50% of the sites and subjects from government sites.</p> <p>The firm should submit the Active PMS Study report to CDSCO for further review by the committee.</p>
4.	FDC/MA/23/000173  Montelukast Sodium I.P. 10mg + Fexofenadine I.P. 180mg uncoated bilayered tablets	M/s. Synokem Pharmaceuticals Ltd.	<p>The firm presented the proposal before the committee along with BE study protocol and phase III clinical trial study protocol.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the BE study and Phase III clinical trial.</p> <p>The firm should present the results of BE study for review by the committee before initiation of the Phase III clinical trial study.</p>
5.	FDC/MA/23/000153  Montelukast Sodium I.P. 10mg +	M/s. Exemed Pharmaceuticals	<p>The firm presented the proposal before the committee along with BE study protocol and phase III clinical trial study protocol.</p>

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	Fexofenadine I.P. 180mg uncoated bilayered tablets		After detailed deliberation, the committee recommended for grant of permission to conduct the BE study and phase III clinical trial. The firm should present the results of BE study for review by the committee before initiation of the Phase III clinical trial.
6.	FDC/MA/23/000154  Montelukast Sodium I.P. 10mg + Bilastine 40mg Tablets	M/s. Exemed Pharmaceuticals	The firm presented the proposal before the committee along with BE study protocol and phase III clinical trial study protocol.  After detailed deliberation, the committee recommended for grant of permission to conduct the BE study and phase III clinical trial. The firm should present the results of BE study for review by the committee before initiation of Phase III clinical trial.
7.	FDC/MA/22/000304  Each capsule contains: - Indacaterol (as acetate) equivalent to Indacaterol 150 mcg + Glycopyrrolate IP equivalent to Glycopyrronium 50 mcg + Mometasone Furoate IP 160 mcg Dry Powder for inhalation	M/s. Glenmark Pharmaceuticals	In light of the condition mentioned in Form CT-23 dated 24.04.2023, the firm presented the Phase IV clinical trial protocol before the committee.  After detailed deliberation, the committee recommended for conduct of the Phase IV clinical trial.  The firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
8.	FDC/MA/21/000240  Fluticasone Furoate + Vilanterol Trifenatate eq. to Vilanterol (100mcg/200mcg+25 mcg/25mcg)	M/s. Glenmark Pharmaceuticals Ltd. India.	In light of the condition mentioned in Form CT-23 dated 06.07.2022, the firm presented the Active PMS Study protocol before the committee.  After detailed deliberation, the committee recommended for conduct of the Active PMS Study.  The firm should submit the Active PMS study report to CDSCO for further review by the committee.

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<b>GCT Division</b>			
9.	CT/51/23 Online Submission (37455) Asteogolimab (RO7187807)	M/s. PPD	The firm presented the proposal of grant of permission to conduct phase III clinical trial with protocol No. GB44332, version 2 dated 16-Sept-2022 before the committee. After detailed deliberation, the committee recommended for conduct of the study subject to the condition that at least 50% sites & subjects should be from the Govt. sites.
10.	CT/62/22 Online Submission (23593)  SAR440340/ REGN3500/ Itepekimab	M/s. Sanofi	The proposal was deferred for next SEC meeting.
11.	CT/131/20 Online Submission (25565)  Budesonide, Glycopyrronium, and Formoterol Fumarate	M/s. Astra Zeneca	The proposal was deferred for next SEC meeting.
<b>Medical Device Division</b>			
12.	IMP/MD/2023/92837  Antiviral Nasal Spray (Brand Name: Viraleze™ Antiviral Nasal Spray)	M/s. Clini Experts Services Private Limited	The proposal was deferred for next SEC meeting.