

**Recommendations of the SEC (Pulmonary) made in its 71<sup>st</sup> meeting held on 06.06.2023 at CDSCO (HQ), New Delhi:**

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drug Division</b>			
1.	ND/CT/23/000029  ME-015 (Suplatast Tosilate) 100 mg Capsule	M/s. Syngene International Ltd.	<p>The firm presented the proposal for grant of permission to conduct the Phase IIa clinical trial of the drug ME-015 (Suplatast Tosilate) along with Phase IIa clinical trial study protocol before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should submit/ clarify for the following:</p> <ol style="list-style-type: none"> <li>1. While the drug is available in Japan for 25 years for other indications and not for the proposed indication ie, Cough related to IPF, reason as to why this study is proposed in India first instead of Japan or globally.</li> <li>2. Considering the ethnic variation among Indian and Japanese population, reason for not proposing to conduct a PK study before efficacy study.</li> <li>3. The firm should submit data of chronic toxicity &amp; teratogenicity study.</li> </ol> <p>Accordingly, the firm should submit the above mentioned details to CDSCO for further review by the committee.</p>
<b>FDC Division</b>			
2.	04-01/2022-DC (Misc. 47)  Chlorpheniramine Maleate IP 2mg + Phenylephrine HCl IP 5mg drop/ml	Nil	<p>In light of the earlier SEC recommendation dated 21.03.2023, the issue regarding use of the FDC of Chlorpheniramine Maleate IP 2mg + Phenylephrine HCL IP 5mg drop/ml was discussed before the committee along with specially invite expert (Pediatrician).</p> <p>The committee recommended that the FDC should not be used in children below 4 years of age and accordingly firm should mention warning in this regard on label and package insert.</p>

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3.	FDC/MA/22/000239  Glycopyrronium Bromide + Fluticasone Furoate + Vilanterol Trifenatate(50mcg/50mcg+100mcg/200mcg+25mcg/25mcg) Dry Powder for inhalation	M/s. Glenmark Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 29.09.2022, the firm presented the proposal before the committee.  After detailed deliberation, the committee reiterated its earlier recommendation. Accordingly, the firm should present the complete inhalation toxicity report before the SEC for further review of Phase III clinical trial protocol.
4.	FDC/MA/22/000091  Bilastine + Dextromethorphan Hydrobromide + Phenylephrine Hydrochloride (3.3mg+10mg+5mg) Syrup	M/s. Glenmark Pharmaceuticals	In light of the earlier SEC recommendation dated 21.03.2023, the firm presented the proposal before the committee along with Phase III clinical trial protocol.  After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III CT for acute cough only with the condition that the study should not include children below 12 years of age.
5.	FDC/MA/18/000028  Budesonide IP 400mcg + Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 12mcg inhalation preparation	M/s. Lupin Ltd.	In light of the earlier SEC recommendation dated 08.06.2021, the firm presented the proposal before the committee along with request for Phase III CT waiver.  After detailed deliberation, the committee reiterated its earlier recommendation on the same drugs for clinical trial where committee recommended for grant of permission to conduct the proposed Phase III clinical trial. The trial results should be presented before the committee for further review.
6.	FDC/MA/22/000311  Vilanterol Trifenatate eq. to Vilanterol 25mcg + Fluticasone Furoate 200mcg powder for inhalation	M/s. Malik Life Sciences Pvt. Ltd.	The firm did not turn up for the presentation.
7.	FDC/CT/23/000028  Glycopyrronium Ph.	M/s. Lupin Ltd.	In light of the condition mentioned in Form CT-23 dated 16.01.2023, the firm presented the Phase IV clinical trial protocol before the committee.

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	Eur 25mcg + Formoterol fumarate IP 12mcg + Budesonide IP 400mcg Inhalation Powder		After detailed deliberation, the committee recommended for conduct of the Phase IV clinical trial. Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
8.	FDC/MA/22/000409  Phenylephrine HCL 10 mg I.P. + Ebastine 10mg I.P. Tablets	M/s. Micro Labs Ltd.	The firm presented the proposal along with BE study protocol before the committee.  After detailed deliberation, the committee recommended for grant of permission for conduct of the BE study as per the protocol submitted by the firm. Accordingly, the firm should submit the BE study report to CDSCO for further review by the committee.
9.	FDC/MA/23/000035  Dextromethorphan Hydrobromide 10mg I.P. Phenylephrine Hydrochloride 5.0000mg I.P. Chlorpheniramine Maleate 2 mg I.P. tablets	M/s. Stedmen Pharmaceuticals Pvt. Ltd.	The firm presented the proposal along with justification for waiver of BE study.  After detailed deliberation, the committee recommended that the firm should submit the BE study protocol to CDSCO for further review by the committee.
10.	FDC/MA/23/000125  AmbroxolHCl 20mg+Dextromethorphan HBr 10mg+ Chlorpheniramine Maleate 2mg Syrup	M/s. Zuventus Healthcare Ltd.	The firm presented the proposal before the committee. The firm informed the committee that firm is already holding the product permission issued by the concerned State Licensing Authority.  After detailed deliberation, the committee recommended that the proposal may be considered for re-deliberation after CDSCO take the necessary action as the firm has already obtained the product license from State Licensing Authority.
11.	FDC/MA/23/000069  Indacaterol maleate eq. to Indacaterol 75mcg/150mcg + Budesonide IP 200mcg/400mcg Dry	M/s. Zydus	The firm presented the proposal before the committee along with request for manufacturing & marketing permission for the FDC for additional indication.  After detailed deliberation, the committee recommended for grant of permission to manufacture & market the FDC subject to

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	Powder for inhalation (capsules)		the condition that firm should conduct Phase IV clinical trial. Accordingly, firm should submit Phase IV clinical trial protocol to CDSCO for further review by the committee.
12.	FDC/MA/23/000068 Indacaterol Maleate eq. to Indacaterol 75mcg + Budesonide IP 200mcg Inhaler (metered dose inhaler)	M/s. Zydus	The firm presented the proposal before the committee along with request for manufacturing & marketing permission for additional indication. After detailed deliberation, the committee recommended for grant of permission to manufacture & market the FDC with condition to conduct the Phase IV clinical trial. Accordingly, firm should submit Phase IV clinical trial protocol to CDSCO for further review by the committee.
13.	FDC/MA/23/000149 DextromethaorphanHydrobromide 30mg I.P. + Chlorpheniramine Maleate 4mg I.P. + Methylparaben 5mg I.P. + Propylparaben 1mg I.P. Suspension	M/s. Lyrus Life Sciences Pvt. Ltd.	The firm presented the proposal before the committee along with BE study protocol. The committee noted that the product is already approved by this office on 23.06.2021 with Methyl paraben 10 mg.  After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. The firm should also submit the justification to CDSCO for adding Methyl paraben 5mg in the product. Accordingly, results of the study should be presented before the committee for review.
14.	FDC/CT/23/000039 Budesonide 80mcg USP + Formoterol Fumarate Dihydrate 4.5mcg USP Inhalation aerosol	M/s. Cipla Ltd.	The proposal was deferred for next meeting.
15.	FDC/MA/23/000157 Momentasone Furoate 80mg/160mg/320mg + Indacaterol 150mg/150mg/	M/s. Penta Kraft	The proposal was deferred for next meeting.

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	150mg Dry powder for Inhalation		
<b>GCT Division</b>			
16.	CT/21/23 Online Submission (36554)  PC945	M/s. PSI CRO	The firm presented the proposal for Phase III clinical trial before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial with the following conditions. 1. The firm should submit bi-annual safety data along with DSMB recommendations to CDSCO for further review by the committee. 2. The firm should include more govt. sites in the study.
17.	CT/127/22 Online Submission (34427)  (MED13506) IP (Tozorakimab)	M/s. AstraZeneca	In light of the earlier SEC recommendation dated 10.05.2023, the firm presented justification for not conducting Phase II clinical trial in India.  After detailed deliberation, the committee recommended that the firm should submit source of collection of presented data i.e. data presented on efficacy of test drug on other viral lung infection beyond Covid-19 infection and also submit details of published epidemic data on prevalence of proposed disease in India i.e. viral lungs infections/viral pneumonia vis a vis number of patients hospitalized for viral lung infection requiring supplement oxygen or requiring ventilation, for further review by the committee.
18.	CT/18/23 Online Submission (36387)  BLU-5937	M/s. IQVIA	The firm presented Phase III clinical trial protocol BUS-P3-02(CALM-2), version 1.0 dated 04-08-2022, before the committee.  After detailed deliberation, the committee recommended that the firm should submit justification for selection of 25mg BID and 50mg BID dose of test drug in the proposed trial for further review by the committee.
19.	CT/51/23 Online Submission (37455)	M/s. PPD	The proposal was deferred for next meeting.

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	Astegolimab (RO7187807)		