

**Recommendations of the SEC (Pulmonary) made in its 56<sup>th</sup> meeting held on 07.12.2021 at CDSCO HQ New Delhi:**

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drugs Division</b>			
1.	12-01/21-DC (Pt - 340) Dried Ivy Leaf Extract Cough Syrup	M/s. USV	The firm didn't turn up for presentation.
2.	ND/MA/21/000181 Indacaterol (as acetate) and Mometasonefuroate Dry Powder for Inhalation (DPI) in Capsules 150mcg/80mcg, 150mcg/160mcg & 150 mcg/ 320mcg.	M/s. Glenmark Pharma Ltd	The firm presented their proposal for conduct of BA Study along with justification for local clinical trial waiver before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the BA study as per protocol presented and results of BA study should be presented before the committee.  The committee also recommended that the firm should also conduct clinical trial in Indian patient for which protocol should be submitted.
<b>Biological Division</b>			
3.	BIO/CT04/FF/2021/2 8329 Mepolizumab solution for injection	M/s. GSK	The firm presented the clinical trial protocol before the committee.  After detailed deliberation, the committee recommended for grant of permission for the conduct of the PMS (active surveillance) study.  The firm shall omit the word Phase IV from the study title and protocol and accordingly submit the revised protocol to the CDSCO for consideration.
<b>SND Division</b>			
4.	SND/MA/21/000529 Glycopyrrnium Pressurized Inhalation 35 mcg per actuation	M/s. Glenmark Pharmaceuticals	The firm presented their proposal for conduct of BA Study of Glycopyrrnium Pressurized Inhalation 35 mcg per actuation along with justification for local clinical trial waiver before the committee.  After detailed deliberation, the committee opined that firm needs to submit further justification along with supportive documents for selection of proposed dose of 70mcg for the applied drug product i.e. two puffs of Glycopyrrnium Pressurized

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			Inhalation 35 mcg, vis-à-vis approved dose of the drug.
<b>FDC Division</b>			
5.	FDC/MA/21/000124 Each actuation delivers: Glycopyrrolate IP + Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate + Budesonide IP (9.0mcg+4.8mcg+160mcg) metered Dose Inhaler	M/s. Zydus Healthcare Limited	In light of earlier SEC recommendation dated 07.07.2021 firm presented the BE study report before the committee.  After detailed deliberation, the committee recommended for grant of manufacturing and marketing permission of the proposed FDC with the condition that phase IV clinical trial should be conducted and protocol should be submitted with in 3 months of approval.
6.	FDC/CT/21/000076 Pseudoephedrine Hydrochloride 120mg + Fexofenadine Hydrochloride 60mg extended release tablet	M/s. Sanofi India Ltd.	The firm presented their proposal along with phase IV clinical trial protocol.  The committee noted that the proposed sample size is 106 only which is not justified.  After detailed deliberation, the committee recommended for grant of permission for conduct of the proposed phase IV clinical trial study with the condition that firm should increase the sample size with proper justification and accordingly revised protocol should be submitted to CDSCO.
<b>GCT Division</b>			
7.	CT/103/20 Online Submission (12755) Rilematovir	M/s. J&J	The firm's proposal is deferred to the next meeting as the proposal should be deliberated along with hematologist, neonatologist and a pediatrician.
8.	CT/141/21 Online Submission (28721) MEDI 3506	M/s. AstraZeneca	The firm presented their proposal for phase III clinical study before the committee. <b>Assessment of risk vs. Benefit to the patients:</b> The safety profile of the study drugs from preclinical toxicology studies including repeat dose toxicity study and phase I & II clinical study data justify the conduct of the trial. <b>Innovation vis-à-vis Existing Therapeutic option:</b> The purpose of the study is to evaluate the effect of 2 dose regimens of

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			<p>MEDI3506 as add on to SoC compared with SoC plus placebo on the rate of moderate to severe COPD exacerbations in former smokers.</p> <p><b>Unmet Medical need in the country:</b> The test drug may potentially provide treatment in patients with Symptomatic Chronic Obstructive Pulmonary Disease (COPD) with a history of COPD Exacerbations (OBERON)".</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study subject to the condition that patient should be followed up for at least one year after completion of the study.</p>
9.	CT/55/20 Online Submission (13310)  C21	M/s. QED	<p>The firm presented the clinical trial protocol amendment VP-C21-005, Version 7.0 dated 15 Sep 2021.</p> <p>After detailed deliberation, the committee recommended for approval of the protocol amendment with condition that the subjects already on anti fibrotic agents Nintedanib/ Pirfenidone and responding to treatments should not be included in the study.</p>
<b>Medical Device Division</b>			
10.	IMP/MD/2021/44614  Cytosorb (Polymer Based Adsorbent Cytosorb 300ml Device)	M/s. Biocon Biologics Limited	<p>The firm presented their proposal before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of import permission in MD-27 for restricted use under emergency situation to treat patients of 18 years of age or older with confirmed COVID-19 admitted to the ICU with confirmed or imminent respiratory failure by reducing proinflammatory cytokine levels, which may ameliorate a cytokine storm due to the overabundance of pro-inflammatory cytokines and, in turn, provide clinical benefit to such patients.</p> <p>However for other indication, proposal needs to be discussed with nephrologist and hepatologist.</p>