

Recommendations of the SEC (Pulmonary) made in its 07th/25 meeting held on 11.06.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/16/23 Online Submission (39270) BLU-5937	M/s IQVIA RDS (India) Private Limited	The firm presented protocol amendment 2 dated 25 February 2025 protocol no. BUS-P3-01 (CALM -1). After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/18/23 Online Submission (39292) BLU-5937	M/s IQVIA RDS (India) Private Limited	The firm presented protocol amendment 2 dated 24 March-2025 protocol no. BUS-P3-02 (CALM-2). After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
3.	E-74568 Omalizumab for injection	M/s. Reliance Life Sciences Pvt Ltd	The firm presented the CSR of Phase IV study titled “Prospective, multi-center, open-label, single-arm, clinical study to evaluate safety and efficacy of OmaliRel™ in patients with moderate to severe persistent asthma” conducted vide Protocol No. RLS/RES/2020/02 Version 2.0, dated 20 Aug 2020. After detailed deliberation, the committee noted the results of the Phase IV study presented by the firm.
New Drugs Division			
4.	ND/IMP/24/000066 Olbas Oil 12 ml and 30 ml	M/s NK Healthcare Pvt.Ltd	The firm did not turn up for the presentation
SND Division			
5.	SND/MA/25/000057 Umeclidinium 62.5 mcg Powder for Inhalation in Capsule,	M/s Pure & Cure Healthcare Pvt. Ltd	The firm presented their proposal for grant of manufacture and marketing of Umeclidinium 62.5 mcg Powder for Inhalation in Capsule along with BE Study protocol and justification for waiver of Phase-III clinical trial study before the committee.

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			<p>The firm has informed that the proposed drug Umeclidinium powder for inhalation 62.5mcg is already approved in USA, UK, EU, Australia, Canada for the applied indication.</p> <p>Firm also informed that Umeclidinium is approved in India as part of FDC of fluticasone furoate, Umeclidinium and vilanterol (100mcg + 62.5mcg+25mcg) for same indication.</p> <p>After detailed deliberation, the committee opined to revise the Bioequivalence study protocol by including the subjects of the age group more than 45 years and not recommended for the Phase-III clinical trial waiver.</p> <p>Therefore, firm should submit the revised BE Protocol and Clinical trial protocol to CDSCO for further review by the committee</p>
FDC Division			
6.	FDC/MA/24/000096 Dextromethorphan Hydrobromide IP 10mg + Phenylephrine Hydrochloride IP 5mg per 5ml Syrup	M/s Zydus Healthcare Limited	<p>In light of earlier SEC recommendation dated 04.12.2024, the firm presented the proposal along with Phase III CT protocol before the committee.</p> <p>After detailed deliberation, the committee opined that Pediatrician may be invited in next meeting for wider discussion in the matter.</p>
7.	FDC/MA/24/000097 Diphenhydramine Hydrochloride IP + Phenylephrine Hydrochloride IP (12.5mg+ 5mg)/ 5ml Syrup	M/s Zydus Healthcare Limited	<p>In light of earlier SEC recommendation dated 04.12.2024, the firm presented the proposal along with Phase III CT protocol before the committee.</p> <p>After detailed deliberation, the committee opined that Pediatrician may be invited in next meeting for wider discussion in the matter.</p>
8.	FDC/MA/25/000056 Budesonide IP 200 mcg + Glycopyrronium 25 mcg (As Glycopyrrolate IP) +	M/s Cipla Limited	<p>The firm presented their proposal along with request for BE & Phase III CT waiver before the committee.</p> <p>After detailed deliberation, the committee opined the following: 1. The product is not approved</p>

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	Formoterol Fumarate (As Formoterol Fumarate Dihydrate IP) 12 mcg capsule		<p>internationally.</p> <ol style="list-style-type: none"> 2. There is no unmet need for the proposed FDC. 3. Individual drugs are already available in the market. <p>In view of above, the firm needs to generate data regarding reduction of risk of TB/Pneumonia in COPD patients with the proposed FDC in Indian population.</p> <p>Accordingly, study protocol should be submitted to CDSCO for further review by the committee.</p>