

Recommendations of the SEC (Pulmonary) made in its 3rd/24 meeting held on 05.03.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/141/21 Online Submission (27767) MEDI3506	M/s. AstraZeneca	The firm presented the protocol amendment No. 2.0 (version 3.0) dated 23 Jun 2023, protocol No. D9180C00003. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
2.	BIO/CT18/FF/2023/4 1110 Nirsevimab solution for injection 50 mg/100 mg	M/s. Sanofi Healthcare India Pvt. Ltd.	The firm presented the proposal for grant of permission to import and market Nirsevimab solution for injection in prefilled syringe 50mg and 100mg with local clinical trial waiver under unmet medical need indicated for the prevention of Respiratory Syncytial Virus (RSV) lower respiratory tract disease in: <ul style="list-style-type: none"> • Neonates and infants born during or entering their first RSV season. • Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season <p>The committee noted that the drug is approved in several countries globally including USA, UK, Canada and EU.</p> <p>After detailed deliberation, the committee recommended for grant of permission for import and marketing Nirsevimab solution for injection in prefilled syringe 50mg and 100mg with local clinical trial waiver subject to the condition that the firm should conduct Phase-IV study for assessing the efficacy and safety in Indian population.</p> <p>Accordingly, the firm should submit the protocol to conduct Phase-IV study within 3 months of approval of marketing authorization.</p>
FDC Division			
3.	FDC/MA/23/000153	M/s. Exemed Pharmaceuticals	In light of earlier SEC recommendation dated 05.10.2023, the firm presented their

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	Montelukast Sodium IP eq. to Montelukast 10mg + Fexofenadine Hydrochloride IP 180mg tablets		proposal along with Phase III clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC with the condition that “The drug causes drowsiness & dizziness and should not be consumed while driving and other skilled jobs.” Accordingly, the firm should mention the said warning on package insert/Promotional Literature of the drug product.
4.	FDC/MA/23/000212 Vilanterol Trifenatate eq. to Vilanterol 25mcg + Fluticasone Furoate 200mcg powder for inhalation in capsule	M/s. Biodeal Pharmaceuticals Pvt. Ltd.	The firm presented their proposal along with justification for BA/BE waiver before the committee. The committee noted that the BA/BE waiver is already considered for the proposed FDC with the condition to conduct Active PMS study. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC with the condition that Active PMS study should be conducted. Accordingly, Active PMS study protocol should be submitted within 03 months for further review by the committee.
5.	FDC/MA/23/000242 Glycopyrrolate IP eq. to Glycopyrronium + Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate + Budesonide IP (25mcg+20mcg+500 mcg) Inhalation Suspension (for nebulization)	M/s. Glenmark Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 05.10.2023, the firm presented their proposal along with the justification before the committee. The committee noted that the proposed FDC is not approved as Inhalation suspension (for nebulization). After detailed deliberation, the committee recommended that the firm should conduct Phase III clinical trial. Accordingly, the firm should submit Phase III clinical trial protocol to CDSCO for review by the committee.
6.	FDC/MA/23/000313 Bilastine IP 3.3mg/5ml +	M/s. Kingston Aqua Industries Pvt. Ltd.	The firm did not turn up for presentation.

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	Dextromethorphan hydrobromide IP 10mg/5ml + Phenylephrine hydrochloride IP 5mg/5ml syrup		
7.	FDC/CT/23/000078 Budesonide IP 200 mcg + Formoterol Fumarate Dihydrate IP 6 mcg + Glycopyrronium IP 12.5 mcg inhaler	M/s. Cipla Limited	In light of the condition mentioned in permission in Form CT-23 dated 25.08.2023, the firm presented the request for Phase IV clinical trial waiver before the committee. After detailed deliberation, the committee did not consider the request for Phase IV CT waiver. Accordingly, the firm should present Phase IV clinical trial protocol before the committee.
8.	FDC/MA/24/000045 Vilanterol Trifenatate equivalent to Vilanterol 25mcg + Umeclidinium Bromide equivalent to Umeclidinium 62.5mcg Dry Powder Inhaler in capsule	M/s. Sun Pharma Laboratories Limited	The firm presented the proposal along with comparative BA study protocol & justification for CT waiver before the committee. After detailed deliberation, the committee recommended that firm should conduct BA study and clinical trial waiver was not considered at this stage. Accordingly, the result of the BA study should be presented before the committee for further review of waiver of clinical trial study.
9.	FDC/CT/24/000014 Glycopyrronium Bromide eq. to 50mcg Glycopyrronium 63mcg + Vilanterol Trifenatate eq. to 25mcg Vilanterol 40mcg powder for inhalation in capsule	M/s. Lupin Limited	In light of the condition mentioned in permission in Form CT-23 dated 15.11.2023, 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.