

**Recommendations of the SEC (Pulmonary) made in its 78<sup>th</sup> meeting held on 07.11.2023 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>FDC Division</b>			
1.	FDC/MA/22/000091 Bilastine 3.3mg/5ml + Dextromethorphan Hydrobromide 10mg/5ml + Phenylephrine Hydrochloride 5mg/5ml syrup	M/s. Glenmark Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 06.06.2023, the firm presented their 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 proposed FDC should not be given in children below 12 years of age for more than 7 days. Accordingly, the firm should mention the said warning on label and package insert/Promotional Literature of the drug product.
2.	FDC/MA/22/000297 Vilanterol trifenate eq. to Vilanterol 12.5mcg + Glycopyrrolate IP eq. to Glycopyrronium 25mcg metered dose inhalation	M/s. Zydus Healthcare Ltd.	In light of earlier SEC recommendation dated 04.11.2022, the firm presented their proposal along with Phase III clinical trial report before the committee.  After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC.
3.	FDC/MA/23/000032 Dextromethorphan Hydrobromide IP 10mg/5ml + Phenylephrine Hydrochloride IP 5mg/5ml + Chlorpheniramine Maleate IP 1mg/5ml syrup	M/s. Stedman Pharmaceuticals Pvt. Ltd.	In light of the earlier SEC recommendation dated 05.04.2023, the firm presented their proposal along with the rationality and justification for the proposed FDC.  After detailed deliberation, the committee noted that rationality, justification in light of standard therapeutic treatment guidelines, safety profile data& published supportive scientific literature on use of the drug in pediatric population for proposed strengths was not adequately presented by the firm.  Therefore, the committee reiterated its earlier recommendation dated 05.04.2023 and also opined that the firm should submit structured Phase III clinical trial protocol as per NDCT Rules, 2019 for

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			further review.
4.	FDC/MA/23/000034 Paracetamol 160mg + Phenylephrine HCl 5mg + Chlorpheniramine maleate 1mg Oral liquid suspension	M/s. Stedman Pharmaceuticals Pvt. Ltd.	In light of the earlier SEC recommendation dated 05.04.2023, the firm presented their proposal along with the rationality and justification for the proposed FDC.  After detailed deliberation, the committee noted that rationality, justification in light of standard therapeutic treatment guidelines, safety profile data & published supportive scientific literature on use of the drug in pediatric population for proposed strengths was not adequately presented by the firm.  Therefore, the committee reiterated its earlier recommendation dated 05.04.2023 and also opined that the firm should submit structured Phase III clinical trial protocol as per NDCT Rules, 2019 for further review.
5.	FDC/MA/23/000206 Indacaterol Maleate Eq. to Indacaterol 55mcg + Glycopyrronium bromide Eq. to Glycopyrronium 25mcg inhalation powder	M/s. Lupin Ltd.	The firm presented their proposal along with justification for BE waiver & Phase III CT waiver before the committee. Further, the firm also presented the BE study protocol before the committee.  After detailed deliberation, the committee did not consider the justification for waiver of the BE study & Phase III CT study. The committee after detailed deliberation recommended to conduct BE study as per the presented BE study protocol.  Accordingly, the firm should submit BE study report to CDSCO for further review by the committee.
<b>GCT Division</b>			
6.	CT/106/23 Online Submission (39320)  Tozorakimab (MEDI3506) 150mg/mL or Placebo Solution for injection (2mL pre-filled)	M/s. AstraZeneca	The firm presented Phase III clinical trial protocol No. D9180C00012 version 1.0.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as per the proposed protocol presented by firm.

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	syringe)		(Dr. Naveednzir did not participated in the deliberation)
7.	CT/110/23 Online Submission (39527)  SAR443765	M/s. Sanofi	The firm presented Phase II clinical trial protocol No. DRI16762 version 1.0.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as per the protocol presented by the firm
8.	CT/127/ 22 Online Submission (28712)  Tozorakimab (MEDI350)	M/s. AstraZeneca	The firm presented protocol amendment version 2.1 dated 19May 2023 protocol No. D9185C00001.  After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by firm