Recommendations of the SEC (Pulmonary) made in its 07th/24 meeting held on 04.07.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/63/24 Online Submission (43085) Astegolimab (RO7187807)	M/s. PPD Pharmaceutical	The firm presented Phase III clinical study protocol No. GB43374 version 2 dated 03 April 2023. After detailed deliberation, the committee opined that the firm should submit the following documents for further review by the committee: 1. Interim analysis report of both the parent studies. 2. Revised India specific protocol/addendum with respect to assessment of Tuberculosis.
Biological Division			
2.	E-10027 and E-10079 Palivizumab solution for injection 50mg/0.5mL & 100 mg/mL (Synagis)	M/s. AstraZeneca	The firm presented the proposal for waiver of Phase IV clinical study for the drug Palivizumab solution for injection 50mg/0.5mL & 100 mg/mL based on its extensive usage globally and the vast post-marketing experience & safety. Firm has also proposed to implement a robust pharmacovigilance in lieu of a Phase IV clinical study to monitor the safety in the Indian population. The committee has noted that the firm had been granted import and marketing permission for the said drug with local clinical trial waiver subject to the condition that firm shall conduct Phase IV study in India and accordingly shall submit the Phase IV protocol within 03 months of marketing authorization. After detailed deliberation, the committee has reiterated the earlier SEC recommendation dated 08.08.2023 and recommended to submit the Phase IV clinical study protocol. Accordingly, firm should submit the protocol to conduct Phase IV study.

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SND Division			
3.	SND/MA/24/000061 Umeclidinium powder for inhalation 62.5 mcg	M/s. Sun Pharma Labs Limited	In light of earlier SEC recommendations dated 21.05.2024, where in firm had been asked to conduct BE study with innovator product of Umeclidinium 62.5 mcg powder for inhalation approved by USFDA. In this regard, firm has presented guideline of EMA's step-wise approach to establish therapeutic equivalence for orally inhaled drug products along with following additional studies is support of BE waiver. 1. In-vitro in-silico study data 2. In-vitro performance test Aerodynamic Particle Size Distribution (APSD), single actuation contents (SAC) with innovator product After detailed deliberation, the committee noted that in-vitro performance test data with innovator product is found to be inconsistent in some interval. Therefore, the committee reiterated its earlier recommendation to conduct BE study with innovator product for which the firm should submit BE study protocol to CDSCO for review by the committee.
New Drugs Division			
4.	ND/MA/24/000058 Gefapixant tablets 45mg	M/s. Sun Pharmaceutical Industries Ltd.	The firm has presented the proposal for grant of permission to manufacture and marketing of Gefapixant tablets 45 mg, indicated in adults for the treatment of refractory or unexplained chronic cough, along with Bioequivalence study protocol and Phase III clinical trial before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study and Phase III clinical trial, with the following changes in inclusion criteria, a) at S.No. 1, aged 18-65 years instead

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			of aged 18 years or older, b) at S.No. 3, CT thorax instead of Chest X-ray or CT thorax. Other contents of the protocol remain same. Further, the firm should submit Bioequivalence study report to CDSCO for review by the SEC committee, before initiating the Phase III clinical trial.
FDC Division			
5.	FDC/CT/22/000022 Each actuation delivers: Glycopyrrolate IP 9mcg + Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 4.8mcg + Budesonide IP 160mcg suspended in inert propellant	M/s. Zydus Healthcare Limited	In light of earlier SEC recommendation dated 07.07.2022 and as per condition of Form CT-23 dated 07.02.2022, the firm presented Phase IV clinical trial report before the committee. After detailed deliberation, the committee noted and agreed to the result of the clinical trial report.
6.	FDC/MA/23/000242 Glycopyrrolate IP eq. to Glycopyrronium + Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate + Budesonide IP (25mcg+20mcg + 500mcg) Inhalation Suspension (for nebulization)	M/s. Glenmark Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 21.05.2024, the firm presented the proposal along with revised Phase III CT study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the revised protocol. Accordingly, the firm should submit Phase III clinical trial report to CDSCO for further review by the committee.
7.	FDC/MA/23/000270 Acebrophylline 100mg + Erdosteine 300mg film coated tablet	M/s. Macleods Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 04.06.2024, the firm presented the proposal before the committee. After detailed deliberation, the committee considered BE study report and recommended for initiating the Phase III clinical trial for which NOC was already issued to the firm on 20.12.2023 by CDSCO.

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8.	FDC/MA/23/000324 Formoterol Fumarate Dihydrate IP 6mcg + Glycopyrronium (as Glycopyrrolate) IP 12.5mcg Inhaler	M/s. Cipla Limited	In light of the earlier SEC recommendation dated 05.12.2023, the firm presented the proposal along with justification for BE and Phase III CT waiver before the committee. After detailed deliberation, the committee considered the request for BE and Phase III CT waiver and recommended for grant of permission for manufacturing and marketing of the FDC with the condition to conduct the Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of approval of the FDC for review by the committee.
9.	FDC/IMP/19/000049 Fluticasone Furoate 100mcg + Umeclidinium 62.5mcg + Vilanterol trifenatate 25mcg Powder for Inhalation	M/s.GlaxoSmithKline Pharmaceuticals Ltd.	The firm presented the proposal for update prescribing information for the FDC changes based on the updated Global Data Sheet (GDS) version 12 dated 06.03.2024. After detailed deliberation, the committee recommended for approval of the proposed update in prescribing information as presented by the firm.
10.	FDC/MA/24/000096 Dextromethorphan Hydrobromide IP + Phenylephrine Hydrochloride IP (10mg + 5mg)/ 5ml Syrup	M/s. Zydus Healthcare Limited	The firm presented the proposal along with justification for BE waiver & Phase III CT waiver before the committee. After detailed deliberation, the committee recommended that the firm should conduct Phase III CT study with the proposed FDC. Accordingly, the firm should submit Phase III clinical trial protocol to CDSCO for further review by the committee.
11.	FDC/MA/24/000097 Diphenhydramine Hydrochloride IP + Phenylephrine Hydrochloride IP (12.5mg+ 5mg)/ 5ml Syrup	M/s. Zydus Healthcare Limited	The firm presented the proposal along with justification for BE waiver & Phase III CT waiver before the committee. After detailed deliberation, the committee recommended that the firm should conduct Phase III CT study with the proposed FDC.

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			Accordingly, the firm should submit Phase III clinical trial protocol to CDSCO for further review by the committee.
12.	FDC/CT/24/000040 Indacaterol (as Indacaterol acetate) 150mcg + Glycopyrronium (As Glycopyrrolate IP) 50mcg + Mometasone FuroatelP 160 mcg inhalation powder in capsule	M/s. Cipla Limited	In light of the condition mentioned in permission (Form CT-23) dated 16.02.2024, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to 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.