Recommendations of the SEC (Pulmonary) made in its 74th meeting held on 21.08.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/22/000239 Glycopyrronium Bromide + Fluticasone Furoate + Vilanterol Trifenatate (50mcg/50mcg + 100mcg/200mcg+ 25mcg/25mcg) Dry Powder for inhalation	M/s. Glenmark Pharmaceuticals Ltd.	In light of earlier recommendation of SEC dated 29.09.2022, the firm presented their proposal along with Phase III clinical trial protocol and justification for inhalation toxicity study before the committee. After detailed deliberation, the committee opined that the firm should submit supportive documents/ scientific literature w.r.t safety of the dose of Fluticasone Furoate (200mcg) in three drug combination in uncontrolled asthma. Accordingly, the firm should submit above data for further review by the committee.
2.	FDC/MA/23/000206 Indacaterol Maleate Eq. to Indacatero l55mcg + Glycopyrronium bromide Eq. to Glycopyrronium 25mcg inhalation powder	M/s. Lupin Ltd.	The firm presented their proposal along with request for Phase III clinical trial & BE study waiver before the committee. After detailed deliberation, the committee noted that: 1) The firm did not present any justification / supportive scientific literature for introduction of new delivery system. 2) No global data was produced regarding the combination in MDI form. 3) Issue of solvent in the FDC in MDI form was also not presented by the firm. 4) The firm did not present any data w.r.t actual clinical response and stability of FDC in MDI form. 5) There is no unmet need. In view of above, the firm should submit above data for further review by the committee.
3.	FDC/MA/23/000201 Combi kit for Macitentan 10mg + Tadalafil 20mg Tablets	M/s. MSN laboratories Pvt. Ltd.	The firm presented their proposal before the committee along with justification for Phase III clinical trial & BE study wavier. After detailed deliberation, the committee recommended for grant of permission for

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			manufacturing and marketing of the FDC subject to condition that the firm should conduct Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 03 months of approval for review by the committee.
4.	FDC/MA/23/000152 Fluticasone Furoate 100mcg + Glycopyrronium Bromide eq. to Glycopyrronium 50mcg + Vilanterol Trifenatate eq. to Vilanterol 25mcg Inhalation Powder	M/s. Lupin Ltd.	The firm presented their proposal before the committee along with Phase III clinical trial report and justification for BE study wavier. The firm informed the committee that the proposed Phase III clinical trial study is conducted by CRO M/s JSS Medical Research Asia Pacific Private Limited and M/s Lupin Ltd. is the sponsor of the study. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC, subject to condition that the firm should conduct Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 03 months of approval for review by the committee.
5.	FDC/MA/23/000163 Glycopyrronium Bromide + Vilanterol Trifenatate (50µg Ph.Eur + 25µg) Inhalation Powder	M/s. Lupin Ltd.	The firm presented their proposal before the committee along with Phase III clinical trial report conducted by CRO M/s JSS Medical Research Asia Pacific Private Li mited and justification for BE study wavier. The firm informed the committee that the proposed Phase III clinical trial study was conducted by CRO M/s JSS Medical Research Asia Pacific Private Li mited and M/s Lupin Ltd. was the sponsor of the study. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the

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			proposed FDC, subject to condition that the firm should conduct Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 03 months of approval for review by the committee.
6.	FDC/CT/21/000071 Glycopyrronium Bromide + VilanterolTrifenatate eq. to Vilanterol (50µg + 25µg) Inhalation Powder	M/s.JSS Medical Research Asia Pacific Private Limited	In light of earlier recommendation of SEC dated 25.02.2022, the firm presented their proposal along with Phase III clinical trial report before the committee. The firm informed the committee that the proposed Phase III clinical trial study is conducted by CRO M/s JSS Medical Research Asia Pacific Private l Limited and M/s Lupin Ltd. is the sponsor of the study. After detailed deliberation, the committee recommended for grant of permission to manufacturing and marketing of the FDC to sponsor (M/s Lupin Ltd.) subject to condition that the firm should conduct Phase IV clinical trial.
7.	FDC/CT/21/000072 Glycopyrronium Bromide + Fluticasone Furoate + Vilanterol Trifenatate (50 µg + 100 µg + 25 µg) Inhalation Powder	M/s.JSS Medical Research Asia Pacific Private Limited	In light of earlier recommendation of SEC dated 29.09.2021& 25.02.2022, the firm presented their proposal along with Phase III clinical trial report before the committee. The firm informed the committee that the proposed Phase III clinical trial study is conducted by CRO M/s JSS Medical Research Asia Pacific Private Limited and M/s Lupin Ltd. is the sponsor of the study. After detailed deliberation, the committee recommended for grant of permission to manufacturing and marketing of the FDC to sponsor (M/s Lupin Ltd.) subject to condition that the firm should conduct Phase IV clinical trial.
GCT Division			

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8.	CT/18/23 Online Submission (36387) BLU-5937	M/s. IQVIA	The firm presented Phase III CT study protocol No. BUS-P3-02 (CALM-2), version 1.0 dated 04-08 -2022. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III CT study.
9.	CT/29/23 Online Submission (36625) Benralizumab (Medi-563)	M/s. Labcorp	The firm presented Phase III CT study protocol No. D3254C00001. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III study with subject to condition that at least 50% subjects shall be enrolled from Government sites.
10.	CT/77/23 Online Submission (38215) Tezepelumab	M/s. AstraZeneca	The firm didn't turn up for presentation.