Recommendations of the SEC (Pulmonary) made in its 08th/26 meeting held on 08.07.2026 at CDSCO HQ New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/02/26 Online Submission (54047) NNC0487-0111 B 0.80 mg/mL NNC0487-0111 B 1.67 mg/mL NNC0487-0111 B 3.35 mg/mL NNC0487-0111 B 6.7 mg/mL NNC0487-0111 B 13.4 mg/mL NNC0487-0111 B 26.8 mg/m	M/s. Novo Nordisk India Pvt Ltd	In light of earlier SEC Recommendation dated 17.02.2026, the firm presented phase II study data for conducting the phase IIIa clinical study, vides protocol no. NN9490-8025, version no. 1.0 dated 09 October 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. Dr. Rohit Kumar didn't participate in the discussion.
2.	CT/73/26 Online Submission (56903) Benralizumab	M/s. Fortrea Development India Private Limited	The firm did not turn up for presentation.
Biological Division			
3.	E-138364 Benralizumab solution for injection in pre-filled syringe 30 mg/mL (Fasenra)	M/s. AstraZeneca Pharma India Ltd.	The firm presented the proposal for expansion of the warning statement under Condition No. 3 of Permission No. IMP/BIO/20/000097 dated 17.12.2020 for Benralizumab Solution for Injection in Pre-filled Syringe 30 mg/mL, seeking to revise the statement from "To be sold by retail on the prescription of a pulmonologist only" to "To be sold by retail on the prescription of a Registered Medical Specialist experienced in treating the diseases for which the drug is approved." After detailed deliberation, the committee did not agree to the firm's proposal and recommended that the existing warning statement remain unchanged.
SND Division			
4.	SND/MA/25/000018 Ivacaftor Tablets 75 mg and 150 mg	M/s. Pure & Cure Healthcare Pvt. Ltd.	Firm presented the proposal for the manufacture and marketing permission of Ivacaftor Tablets 75 mg and 150 mg for applied indication along with BE study report (fasting and fed) of Ivacaftor tablets

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			150 mg and requested waiver of Phase-III clinical trial. After detailed deliberation, the committee considered the BE study report. Further, the committee opined that more paediatric experts should be invited for further deliberation regarding the Phase-III clinical trial waiver.
5.	SND/CT18/FF/2025/50010 SND/IMP/25/000104 Mannitol Powder for Inhalation (Bronchial Challenge Airdol test kit)	M/s. Arna Pharma Private Limited	The firm presented proposal for grant of permission to Import and marketing of Mannitol powder for inhalation (Bronchial Challenge Airdol test Kit) for the indication for assessment of bronchial hyper responsiveness in adult and pediatric patients 6 years of age or older who do not have clinically apparent asthma with phase III clinical trial waiver. The Committee noted that, there is no unmet medical need of the product and opined that, firm should conduct clinical study to access safety and efficacy of product in Indian Population. After detailed deliberation the Committee did not recommended for phase III clinical trial waiver.
FDC Division			
6.	FDC/MA/25/000036 Glycopyrronium bromide equivalent to glycopyrronium 12.5 mcg + Formoterol Fumarate Dihydrate 6 mcg + Fluticasone Propionate 125 mcg Metered Dose Inhaler	M/s. Lupin Limited	In light of earlier SEC recommendation dated 21.04.2026, the firm presented raw data of Phase III CT report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC.
7.	FDC/CT/21/000076 Pseudoephedrine Hydrochloride IP 120 mg + Fexofenadine Hydrochloride IP 60 mg extended release tablet	M/s. Sanofi India Ltd.	In light of earlier SEC recommendation dated 07.12.2021and as per condition of Form CT-20 dated 19-03-2021, 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.