**Recommendations of the SEC (Pulmonary) made in its 02th/26 meeting held on 17.02.2026 at CDSCO HQ New Delhi:**

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| **GCT Division** | | | |
| 1. | CT/181/25 Online Submission (53630)<br><br>BTZ-043 Quabodepistat (OPC167832) Delpazolid (LCB01-0371) Ganfeborole | M/s. Clinical Research Network India Private Limited | The firm presented phase IIC clinical study in India vide protocol no. PARADIGM4TB (UNITE4TB-01) (Phase IIB/IIC) version no. 2.0 dated 12 November 2024.<br><br>After detailed deliberation, the committee opined that the firm shall submit phase IIB safety data to CDSCO for further review by the committee. |
| 2. | CT/02/26 Online Submission (54047)<br><br>NNC0487-0111 B 0.80 mg/mL<br>NNC0487-0111 B 1.67 mg/mL<br>NNC0487-0111 B 3.35 mg/mL<br>NNC0487-0111 B 6.7 mg/mL<br>NNC0487-0111 B 13.4 mg/mL<br>NNC0487-0111 B 26.8 mg/mL | M/s. Novo Nordisk India Pvt. Ltd. | The firm presented phase IIIa clinical study protocol no. NN9490-8025, version no. 1.0 dated 09 October 2025.<br><br>After detailed deliberation, the committee opined that the firm shall submit phase II data for proposed IMP in patients with Obstructive Sleep Apnoea (OSA) to CDSCO for further review by the committee<br><br>Dr. Sushant Meshram and Dr. Rohit Kumar didn't participate in the discussion. |
| **Biological Division** | | | |
| 3. | BIO/CT18/FF/2025/52532<br><br>Benralizumab 30 mg/ml solution for injection in pre-filled syringe | M/s AstraZeneca Pharma India Limited | The firm did not attend the meeting. |
| **New Drugs Division** | | | |
| 4. | ND/CT/23/000074<br><br>Nerandomilast film coated tablets 9 mg and 18 mg | M/s Boehringer Ingelheim India Private Limited | The firm presented their proposal for grant of permission for Import and Marketing of the drug Nerandomilast film coated tablets 9 mg and 18 mg along with justification for local Phase III Clinical Trial waiver, before the committee.<br><br>The committee noted that there is no unmet medical need for the proposed indication as other drug to treat IPF and PPF are already approved in the country.<br><br>The committee further noted that the data |

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| | | | of Indian race patient presented by the firm is not adequate to address the ethnic variability.<br><br>After detailed deliberation committee did not agree for Phase-III CT waiver. |
| 5. | ND/MA/25/000147<br><br>Ensifentrine Inhalation suspension 3 mg/2.5ml | M/s Cipla Limited | In light of the earlier SEC recommendation dated 16.12.2025, the firm presented revised Phase-III clinical trial protocol of Ensifentrine Inhalation Suspension 3 mg /2.5 mL (Study code: CP/03/25 Protocol Version No: 2.0, dated 29.12.2025), before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial with Ensifentrine Inhalation Suspension 3 mg/ 2.5 mL as per the revised protocol presented by the firm.<br><br>The results of Phase III Clinical Trial should be submitted to CDSCO for further review by the committee.<br><br>Dr. Rohit Kumar didn't participate in the discussion |
| **SND Division** | | | |
| 6. | SND/MA/25/000174<br><br>Ivacaftor Tablets 75 mg and 150 mg | M/s MSN Laboratories Private Limited | Firm has presented the proposal for the manufacture and marketing permission of Ivacaftor tablets 75 mg and 150 mg along with BE study report (fasting and fed) of Ivacaftor tablets 150 mg and request for Phase-III clinical trial waiver.<br><br>The committee noted that the drug is proposed to be indicated for rare life threatening disease and there is an unmet medical need of the drug in the country. The drug Ivacaftor Tablets are approved in Europe & USA.<br><br>After detailed deliberation, the committee recommended for the grant of manufacturing and marketing permission of Ivacaftor Tablets 75mg and 150mg subject to the condition that the firm should conduct Phase-VI clinical trial. Further, firm should submit the detailed package insert along with dosing and administration information for the different |

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| | | | age groups considering the Indian population child weight.<br><br>Accordingly, firm should submit the revised proposed package insert to CDSCO for further review by the committee. |
| **FDC Division** | | | |
| 7. | FDC/MA/24/000149<br><br>Vilanterol trifenatate eq. to Vilanterol 12.5 mcg + Umeclidinium bromide eq. to Umeclidinium 31.25 mcg Metered dose inhalation | M/s Zydus Healthcare Limited | In light of earlier SEC recommendation dated 04.09.2024, the firm presented Phase III CT report before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC. |
| 8. | FDC/MA/25/000083<br><br>Salmeterol Xinafoate IP eq. to Salmeterol 25 mcg + Fluticasone Propionate IP 250 mcg Metered Dose Inhaler | M/s Lupin Limited | The firm presented their proposal for proposed FDC with Low Global Warming Potential (LGWP) Propellant (HFA 152a) in MDI before the committee.<br><br>Firm informed that the DMF of LGWP Propellant (HFA 152a) (manufactured by M/s Koura) is submitted to USFDA. However, the same is not yet approved.<br><br>Firm also informed that any product with LGWP Propellant (HFA 152a) in Pressurized MDI is also not yet approved anywhere in the world.<br><br>After detailed deliberation, the committee opined that the firm should present data w.r.t non-clinical data (Toxicity and Pharmacokinetics) and clinical data (Safety and Tolerability - Ciliary function, Airway sensitivity reactions) of LGWP Propellant (HFA 152a).<br><br>Accordingly, the firm should submit the above data to CDSCO for further review by the committee. |