

**Recommendations of the SEC (Pulmonary) made in its 08<sup>th</sup>/24 meeting held on 06.08.24 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/80/24 Online Submission (43526)  Dexpramipexole dihydrochloride monohydrate	M/s. Parexel	The firm presented phase III clinical study protocol no. AR-DEX-22-02 Amendment 2 dated 20.02.2023.  After detailed deliberation, the committee opined that the firm shall submit following for further review of the committee:  (i) Phase –I study report including Pharmacokinetics data. (ii) Clinical study data of Phase-II conducted in adolescent patients (age 12 to 18 years). (iii) Chest X ray in the screening visit and criteria for exclusion of the subject to be defined.
2.	CT/21/23 Online Submission (33413)  PC945	M/s. PSI CRO	The firm presented protocol amendment 2 dated 21.02.2024 protocol no. PC_ASP_006  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/163/22 Online Submission (33414)  Tozorakimab (MEDI3506) 150 mg/mL	M/s. AstraZeneca	The firm presented protocol amendment version 3.0 dated 26.03.2024 protocol no. D9180C00008.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/65/24 Online Submission (43245)  Sisunatovir 50 mg capsules	M/s. Pfizer	The firm presented phase 1b clinical study protocol no. C5241009 Amendment 4 dated 11.03.2024.  After detailed deliberation, the committee opined that the firm shall submit following for further review of the committee in presence of one pediatric pulmonary expert:  (i) The diagnosis criteria for lower respiratory infection with either reference or guideline. (ii) Earlier study data of phase-I

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			<p>conducted in pediatrics including infants.</p> <p>(iii) Pharmacokinetic parameters should be included in protocol.</p>
5.	<p>CT/163/22 Online Submission (29315)</p> <p>Tozorakimab (MEDI3506) 150 mg/mL</p>	M/s. AstraZeneca Pharma India Limited	<p>In light of earlier SEC recommendation 05.12.2023, the firm presented protocol amendment version 2.0 dated 27.07.2023, Protocol no. D9180C00008 and Justification for amendment with respect to Echocardiography</p> <p>After detailed deliberation, the committee recommended for approval of protocol amendment including amendment with respect to Echocardiography as presented by the firm</p>
<b>Biological Division</b>			
6.	<p>r-DNA11016(13)/ 19/2024-eoffice</p> <p>Mepolizumab Powder for Solution for Injection (Brand Name: Nucala 100 mg)</p>	M/s. GlaxoSmithKline Pharmaceuticals Limited	<p>Firm presented the results of Phase-4 clinical study titled as- A Phase 4, open-label, single arm, 24-week, phase 4 study to evaluate the safety and efficacy of Mepolizumab 100 mg SC administered every 4 weeks in Indian Participants ages <math>\geq 12</math> years with severe eosinophilic Asthama requiring oral corticosteroid treatment to maintain asthma control (PRISM) vide Protocol No. 209682 amendment No. 4 dated 23.08.2022.</p> <p>After detailed deliberation, the committee recommended the firm to submit the detailed elaboration of AE's reported in the study for further evaluation by the committee.</p>
7.	<p>E-13980</p> <p>Benralizumab 30 mg/ml solution for Injection</p>	M/s. AstraZeneca Pharma India Limited	<p>Firm presented the proposal for revision in the package insert vide version 4.0 dated 10.02.2023 w.r.t. inclusion of instruction for self-administration of drug by patient/caregiver.</p> <p>The committee has noted that the PFS presentation of the drug is already approved for sub cutaneous route and proposed for self-administration of drug by patient/caregiver.</p> <p>After detailed deliberation, the committee recommended for approval of the revision in the package insert vide version 4.0 dated 10.02.2023 for inclusion of</p>

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			instruction for self-administration of drug by patient/caregiver.
8.	E-18281 Omalizumab Injection lyophilised	M/s. Veeda Clinical Research Limited	Firm presented the results of the Phase-1 clinical study titled as - “A Randomized, Double Blind, Two-Arm, Parallel Group, Single Dose Comparative PK, PD and Immunogenicity study comparing ADL-018 lyophilized powder with US-licensed Xolair lyophilized powder administered through subcutaneous route in healthy adult subjects” as per Protocol No.: OMA/2020/1772, Version 5.0 Date: 29.03.2022”.  After detailed deliberation committee noted the results of the study presented by the firm.
<b>SND Division</b>			
9.	SND/MA/22/000331  Aviptadil Injection 150µg/10ml	M/s. Zuventus Healthcare Limited	Firm presented their proposal for grant of permission for manufacture and marketing of Aviptadil injection 150mcg/10ml with additional Indication “as an add-on treatment to the Standard of Care in Acute Respiratory Distress Syndrome” along with Phase-III clinical trial protocol (Protocol No. ZUV/Aviptadil/08/2023, Version no. 1.0, dt 08.01.2024) before the committee. The firm has informed that they are already holding permission of manufacture and market of Aviptadil injection 15mcg/ml issued by the CDSCO on 29.04.2022 for treatment of patient with severe COVID-19 with acute respiratory distress syndrome (ARDS). After detailed deliberation, the committee recommended to conduct phase-III clinical trial as per protocol presented by the firm.
<b>FDC Division</b>			
10.	4-228/2014-DC  Terbutaline Sulphate 1.25mg + Acebrophylline 50mg + Guaiphenesin 50mg	M/s. Akums Drugs & Pharmaceuticals Ltd.	Firm did not turn up for the presentation.

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	per 5ml syrup		