

**Recommendations of the SEC (Pulmonary) made in its 10<sup>th</sup> meeting held on 03.10.2024 at CDSCO (HQ), New Delhi:**

| S. No               | File Name & Drug Name, Strength  | Firm Name   | Recommendations  |
|---------------------|--|---|--|
| <b>GCT Division</b> |  |   |  |
| 1.                  | CT/102/24<br>Online Submission<br>(43733)<br><br>Sutezolid, TBI-223,<br>Pretomanid,<br>Linezolid,<br>Bedaquiline,<br>Isoniazid, Rifampicin,<br>Pyrazinamide,<br>Ethambutol | M/s. B J Govt.<br>Medical College<br>Clinical Trial Unit              | The firm presented phase 2 clinical trial protocol no. A5409 Version No. 2.0 Protocol Date 21-MAR-2024.<br><br>After detailed deliberation, the committee opined that the firm should submit the following documents for further review by the committee.<br>1. Pharmacokinetic data for investigational new drug<br>2. Preclinical studies data<br>3. Phase-1 clinical study data |
| 2.                  | CT/106/24<br>Online Submission<br>(45012)<br><br>SAR443765 solution<br>for injection 165<br>mg/1.1 mL (150<br>mg/mL)   | M/s. Sanofi<br>Healthcare India<br>Private Limited                    | The firm presented phase 2 clinical trial protocol no. LTS17231 Version No. 1 Protocol Date 07-JUN-2024.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the phase 2 clinical trial as presented by the firm  |
| 3.                  | CT/106/23<br>Online Submission<br>(34664)<br><br>Tozorakimab<br>(MEDI3506)   | M/s. AstraZeneca<br>Pharma India<br>Limited                           | The firm presented protocol no. D9180C00012, amendment version 2.0 dated 12 Jun 2024.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.   |
| 4.                  | CT/21/23<br>Online Submission<br>(34868)<br><br>PC945<br>(Opelconazole)<br>Nebuliser Suspension<br>(PC945)   | M/s. PSI CRO<br>Pharma Pvt. Ltd.                                      | The firm did not turn up for presentation.   |
| 5.                  | CT/80/24<br>Online Submission<br>(43526)<br><br>Dex Pramipexole<br>dihydrochloride<br>monohydrate  | M/s. Parexel<br>International<br>Clinical Research<br>Private Limited | In light of earlier SEC recommendation 06.08.2024, the firm presented Phase III clinical study protocol No. : AR-DEX-22-02, India Specific Amendment 1 dated 17-SEP-2024.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.   |

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| 6.                  | CT/63/24<br>Online Submission<br>(43085)<br><br>Astegolimab<br>(RO7187807)  | M/s. PPD<br>Pharmaceutical            | In light of earlier SEC recommendation 04.07.2024, the firm presented Phase III clinical study protocol No. : GB43374 Version No. 2, Protocol Date 03-APR-2023.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial with the condition that<br>1. Any subject who received Investigational drug, found to be active tuberculosis should be excluded from the study and treated accordingly to National Tuberculosis Elimination Program (NTEP).<br>2. Protocol should include testing frequency for every 6 months for tuberculosis infection (Chest X-ray, Quantiferon and sputum test ) |
| 7.                  | CT/56/24<br>Online Submission<br>(42771)<br><br>Budesonide,<br>Glycopyrronium &<br>Formoterol Fumarate  | M/s. AstraZeneca                      | In light of earlier SEC recommendation 04.06.2024, the firm presented Phase III clinical study protocol No. : D5989C00001: CSP Version 2.0 dated 28 Jan 2024. Addendum IND-1, Version 1.0, 10 Jan 2024.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.   |
| <b>SND Division</b> |   |                                       |  |
| 8.                  | SND/MA/24/000018<br><br>Epinephrine tartrate<br>Injection IP<br>0.3mg/0.3ml &<br>0.15mg/0.3ml (Auto<br>injector) (Adrenaline<br>Injection IP) | M/s. Mylan<br>Laboratories<br>Limited | The firm presented their proposal for grant of permission to manufacture and marketing of Epinephrine tartrate Injection IP 0.3mg/0.3ml & 0.15mg/0.3ml (Auto injector) along with justification for BE waiver and clinical trial waiver.<br><br>The firm has informed that Epinephrine tartrate Injection IP 0.3mg/0.3ml & 0.15mg/0.3ml (Auto injector) is already approved in USA.<br><br>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Epinephrine tartrate Injection IP 0.3mg/0.3ml & 0.15mg/0.3ml (Auto injector) with different colour coding for                       |

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|-------|---------------------------------|-----------|------------------------|
|       |                                 |           | each applied strength. |