**Recommendations of the SEC (IND) made in its 01st/26 meeting held on 09.01.2026 at CDSCO HQ New Delhi:**

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| **IND Division** | | | |
| 1. | IND/CT04/FF/2025/51088<br><br>13-Meta HCl for Injection, 50 mg/vial | M/s Cadila Pharmaceuticals Limited, | Firm presented the pre-clinical study data and phase-I clinical trial protocol vide no. CRSC25001, Version-01, dated 29.07.2025, before the committee.<br><br>After detailed deliberation, committee recommended for conduct of Phase-I clinical trial with the condition as below:<br><br>• Firm is required to present non-clinical pharmacological data with respect to metabolism and excretion of the drug, in each of the species studied.<br>• Constitute DSMB to evaluate the data before each dose escalation and in case of any DLT, report should be submitted to CDSCO.<br>• Firm is required to revise the study protocol to mention maximum or less dose to be given to subject at each next dose level.<br>• Firm is required to submit details of clinical site involved including facilities at the site like equipment, etc. along with accreditation status of clinical laboratory involved.<br><br>Accordingly, firm is required to submit DSMB constitution and revised CT protocol to CDSCO, for further review by the SEC. |
| 2. | IND/CT04/FF/2025/47184<br><br>Monoisoamyl 2, 3-dimercaptosuccinic acid (MiADMSA) 250 mg/vial | M/s Raptim Research Pvt. Ltd. | Firm presented preclinical study data to conduct Phase-I clinical study before the committee.<br><br>Committee noted that the firm has not presented the pre-clinical data in detail. Further, firm has not presented GLP compliance for the said study.<br><br>After detailed deliberation, committee recommended to submit the following:<br><br>• Preclinical animal study data generated under GLP as per NDCT |

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| | | | Rules, 2019.<br>• Firm is required to submit undertaking mentioning that the proposed drug has been discovered or developed in India and details of the sites involved.<br><br>Accordingly, firm is required to submit above mentioned data to CDSCO for further deliberation before the committee. |
| **FDC Division** | | | |
| 3. | FDC/MA/24/000072<br><br>Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg/15 mg + Ezetimibe IP 10 mg/5 mg Tablets | M/s Mankind Pharma Ltd. | In light of earlier SEC (IND) recommendation dated 27.12.2024, the firm presented the proposal for the FDC of Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg + Ezetimibe IP 10 mg Tablet along with justification before the committee along with scientific published literature, in-vivo animal studies including justification for dose selection in animal studies.<br><br>Committee noted that currently, there are limited drugs available for the treatment of the proposed indication and recommended the clinical development of the proposed FDC in stepwise manner.<br><br>After detailed deliberation, the committee recommended to conduct BA study with following groups:<br><br>1. Test group: FDC of Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg + Ezetimibe IP 10 mg Tablet.<br><br>2. Reference (R1) group: Ezetimibe IP 10 mg Tablet of innovator.<br><br>3. Reference (R2) group: Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg of innovator.<br><br>4. Reference (R3) group: Co-administration of Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Tablet and Ezetimibe IP 10 mg Tablet. |

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| | | | Accordingly, firm should submit BA study protocol to CDSCO for further review by the committee. |