**Recommendations of the SEC meeting to examine IND proposals, made in its 29th meeting held on 09.11.2022, 12:00 Noon at CDSCO, HQ New Delhi, through Webex (Video Conference):**

| Sr. No. | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| **New Drugs Division** | | | |
| 1. | F. No. IND/CT/22/000077<br><br>HRF-10071 tablet 120 mg | M/s Synapse Labs Pvt. Ltd. | The firm presented their proposal to conduct Phase I clinical trial alongwith preclinical data before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol subject to the condition that the additional exclusion criteria should be revised for COVID-19 screening in the study. |
| 2. | F. No. IND/CT/22/000076<br><br>HRF-10071 tablet 120 mg | M/s. Veeda Clinical Research Ltd. | The firm presented their proposal to conduct Phase IIa clinical trial alongwith preclinical data before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol subject to the condition that the exclusion criteria should not include “donation of blood (1 unit or 350 mL) within 3 months prior to receiving the first dose of the study medicine” in the protocol. |
| 3. | F. No. ND/CT/22/000064<br><br>AKP-11 Ointment | M/s ICBio Clinical Research Pvt. Ltd. | The firm presented their proposal to conduct Phase II clinical trial before the committee.<br><br>The committee noted that data presented by the firm was inadequate.<br><br>After detailed deliberation, the committee recommended that the firm should present the pre-clinical data as per the applicable guidelines and clinical study data before the committee for further consideration.<br><br>Accordingly, the firm should submit the data to CDSCO for further review by the committee. |

| Sr. No. | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| 4. | F. No. IND/CT/22/000013<br><br>GRC 54276 dihydrochloride | M/s Glenmark Pharmaceuticals Ltd. | The firm presented the Phase I protocol amendment before the committee.<br><br>After detailed deliberation, the committee recommended for grant of approval for the amendment in Phase I clinical trial protocol vide Protocol No. GRC 54276-101, Version 03 dated 18th Oct 2022. |
| 5. | F. No. IND/CT/19/000017<br><br>AT-10 7.5 mg,10 mg, 30 mg, 40 mg tablets | M/s IPCA Labs Limited | The firm presented the Phase I clinical trial report before the committee.<br><br>After detailed deliberation, the committee noted the results and recommended that the firm should submit the application for Phase II Clinical Trial. |