

Recommendations of the SEC (Endocrinology & Metabolism) made in its 09th/25 meeting held on 29.04.2025 at CDSCO HQ New Delhi:

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|----------------------------|---|------------------------------|--|
| GCT Division | | | |
| 1. | CT/33/25 Online Submission (48716) PF-06882961 (Danuglipron) | M/s Pfizer Limited | Firm did not turn up for the presentation. |
| 2. | CT/32/25 Online Submission (48717) PF-06882961-82 Danuglipron | M/s Pfizer Limited | Firm did not turn up for the presentation |
| Biological Division | | | |
| 3. | BIO/CT21/FF/2025/47384 Insulin Injection, Soluble (Neutral) IP 100IU/mL | M/s Regenix Drugs Ltd. | <p>The firm presented the proposal for grant of approval to manufacture and market Insulin Injection Soluble (Neutral) 100 IU/ml (rDNA origin) (10mL Vial ,3mL Cartridge, 3mL Cartridge in Disposable Pen) for the treatment of patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis based on the results of Phase III clinical trial conducted in India.</p> <p>After detailed deliberation, the committee recommended the firm to submit the following</p> <ol style="list-style-type: none"> 1) Complete trial data along with Type 1 and Type 2 patients participated in the trial. 2) Rationale of sample size calculation with both, type 1 and Type 2 diabetes subjects. 3) List of investigators along with concomitant medications used. 4) Details of management of hypoglycemia during the trial <p>Accordingly, the firm should submit the details to CDSCO for further deliberation before the committee.</p> |
| FDC Division | | | |
| 4. | FDC/CT/25/000014 Empagliflozin 5/10/12.5/25 (mg) + Metformin Hydrochloride (inextended release form)1000/1000/1000/1000 (mg) Tablets | M/s Zydus Healthcare Limited | <p>In light of the condition mentioned in permission Form CT-23 dated 13.12.2024, the firm presented the Phase IV CT protocol before the committee.</p> <p>The committee noted that firm has presented Phase IV CT protocol with Empagliflozin 10 (mg) + Metformin</p> |

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| | | | <p>Hydrochloride (in extended release form) 1000 (mg) Tablets and In case of additional glycemic control, Empagliflozin 25 mg + Metformin ER 1000 mg tablet may be given to the participant.</p> <p>After detailed deliberation, the committee recommended that the firm should conduct Phase IV clinical trial for all the strengths intended to be marketed and withdraw the remaining strengths from the permission.</p> <p>Accordingly, firm should submit Phase IV clinical trial protocol after clarification of remaining strengths to CDSCO. After approval from CDSCO, the firm should submit Phase IV clinical trial report for further review by the committee.</p> |