**Recommendations of the SEC (Endocrinology & Metabolism) made in its 07th/25 meeting held on 08.04.2025 at CDSCO (HQ), New Delhi:**

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| **GCT Division** | | | |
| 1. | CT/53/23<br><br>Online Submission (38019)<br><br>LY3437943 | M/s Eli lily and Company | The firm didn't turn up for presentation. |
| 2. | CT/60/22<br><br>Online Submission (38076)<br><br>Somapacitan | M/s Novo nordisk India Pvt Ltd | The firm presented protocol amendment version 10.0 dated 13 December 2024 protocol no. NN8640-4467.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.<br><br>Dr. Rajesh Khadgawat didn't participate. |
| **Biological Division** | | | |
| 3. | BIO/CT18/FF/2024/47125<br><br>Somatropin Injection (r-Human Growth Hormone injection) 15IU-5mg/1.5mL (3.33 mg/mL) | M/s. Sun Pharmaceuticals Industries Limited | The firm presented the proposal of additional strength of already approved product Somatropin Injection 15IU in liquid, cartridge presentation with the request for local clinical trial waiver.<br>The firm has obtained approval for 4IU in powder form in vial presentation<br>The firm presented the bioequivalence study conducted in China and committee noted that the product is approved in China, Philippines and Egypt.<br>The committee noted that the initially the drug was approved with the condition that the firm should conduct PMS study.<br>After detailed deliberation, the committee asked the firm to submit the PMS report conducted as part of the new drug permission for further deliberation. |
| 4. | File No. r-DNA-11016(13)/8/2024-eoffice(E-64487)<br><br>Velaglucerase alfa 400 units/vial powder for solution for | M/s Takeda Biopharmaceuticals India Pvt. Ltd | In light of the earlier SEC recommendation dated 11.06.2024 the firm presented the retrospective and prospective data of the subjects who participated in the study along with patient wise data regarding size reduction of organ – liver and spleen. |

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| | infusion | | After detailed deliberation, the committee noted that the firm has not presented the complete data and the committee recommended to submit the complete data assessed during the treatment including lifestyle management. |
| 5. | r-DNA-11016(13)/7/2025-eoffice<br><br>Idursulfase (r-DNA origin)-2 mg/ml | M/s Takeda Biopharmaceuticals India Pvt. Ltd | The firm didn't turn up for the presentation. |
| **BA/BE Division** | | | |
| 6. | BABE/CT05/FF/2024/45881<br><br>Vitamin D3 liposomal oral solution 60000IU/5ml. | M/s SpinoS Lifescience and Research Private Limited | The firm presented the Protocol No19-SEP-2024, Amendment No: 01, Date: 02 Dec 24, of the BA/BE study for Export purpose only.<br><br>After detail deliberation, the Committee opined that the firm should revise the exclusion criteria with respect to renal or liver impairment based on standard literature along with other exclusion parameters for further review by the SEC committee. |
| **SND Division** | | | |
| 7. | SND/CT/25/000002<br><br>Semaglutide Solution for injection in pre-filled pen 2 mg/1.5 ml, Semaglutide Solution for injection in pre-filled pen 4 mg/3 ml & Semaglutide Solution for injection in pre-filled pen 8 mg/3ml | M/s Biocon Pharma Limited | Under Discussion |
| **FDC Division** | | | |
| 8. | FDC/MA/24/000074<br><br>Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg/100mg + | M/s Eris Lifesciences Limited | In the light of earlier SEC recommendation dated 10.04.2024, the firm presented the proposal along with BE study report before the committee.<br><br>After detailed deliberation, the committee |

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| | Gliclazide IP (SR) 30mg/60mg + Metformin Hydrochloride IP (SR) 500mg/500mg film coated bilayered tablet | | recommended for grant of permission to manufacture and market the proposed FDC, after submission of data including dissolution data and justification for BE waiver for lower strength (Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg + Gliclazide IP (SR) 30mg + Metformin Hydrochloride IP (SR) 500mg) film coated tablet as per the BE Study guideline, with the condition that the firm should conduct Phase IV clinical trial.<br><br>Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of approval of the FDC for review by the committee. |
| 9. | FDC/MA/25/000039<br><br>Glimepiride IP 1mg/1mg/2mg/2 mg + Vildagliptin IP 100mg/100mg/100mg /100 mg + Metformin Hydrochloride IP (As Extended Release Form) 500mg/1000mg/500mg/1000mg mg Tablets | M/s Akums Drugs & Pharmaceuticals Limited | The firm presented the proposal along with BE study protocol before the committee.<br>After detailed deliberation, the committee recommended for grant of permission to conduct the BE study with fasting conditions.<br><br>Accordingly, the revised BE study protocol should be submitted to CDSCO for review.<br><br>Further, after approval from CDSCO the firm should submit BE study report along with Phase III CT protocol to CDSCO for further review by the committee. |