**Recommendations of the SEC (Endocrinology & Metabolism) made in its 109th meeting held on 04.12.2023 at CDSCO (HQ), New Delhi:**

| S.No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| **SND Division** | | | |
| 1. | SND/MA/23/000030 Cholecalciferol Oral Suspension 400 IU/5ml (Additional Indication & Additional Dosage Form ) | M/s. Stedman Pharma Private Limited | The firm didn't turn up for presentation. |
| 2. | SND/MA/23/000032 Cholecalciferol Oral Suspension 800 IU/5ml (Additional Indication & Additional Dosage Form ) | M/s. Stedman Pharma Private Limited | The firm didn't turn up for presentation. |
| 3. | SND/MA/23/000029 Cholecalciferol Oral Drops 400IU/ml | M/s. Stedman Pharma Private Limited | The firm didn't turn up for presentation. |
| 4. | SND/MA/21/000302 Nano Carrier Entrapped Vitamin D3 Oral Dispersion 400IU (Additional Dosage form) | M/s. Pulse Pharmaceuticals Pvt. Ltd. | In light of earlier SEC recommendations dated 25.11.2021,the firm presented clinical trial report for the Nano Carrier Entrapped Vitamin D3 Oral Dispersion 60000IU.<br>After detailed deliberation, the committee opined that clinical trial report should be forwarded to all the experts to give their final opinion. |
| **FDC Division** | | | |
| 5. | FDC/MA/22/000320 Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin + Glimepiride IP + Metformin Hydrochloride IP (ER) 100mg/100mg + 1mg/2mg + 1000mg/1000mg film coated tablet | M/s. Sun Pharma Laboratories Ltd. | In light of earlier recommendation dated 24.11.2022, the firm presented their proposal along with BE study report wherein the product is bioequivalent with the innovators products in respect for Sitagliptin and Metformin, however not bioequivalent with the innovator product in respect of Glimepride component and the firm has presented revised BE study protocol before the committee.<br>After detailed deliberation, the committee recommended for BE study.<br>Accordingly, the firm should submit the results of BE study along with clinical trial study results to CDSCO for further review by the committee. |
| 6. | FDC/MA/23/000089 Dapagliflozin Propanediol monohydrate eq to Dapagliflozin 5mg/5mg/10mg/10mg | M/s. Exemed Pharmaceuticals | In light of earlier recommendation dated 18.05.2023 &19.05.2023 the firm presented their proposal along with BE study report and justification for CT waiver.<br>After detailed deliberation, the committee |

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| | + Linagliptin 5mg/5mg/5mg/5mg + Metformin HCl eq to Metformin (as extended release) 500mg/1000mg/500mg/ 1000mg tablets | | considered the BE study report.<br>Further, committee did not consider the request of clinical trial waiver..<br>Accordingly, firm should submit Phase III clinical Trial protocol to the CDSCO for further review by the committee. |
| 7. | FDC/MA/23/000220<br>Metformin HCl IP (As extended release form) 500mg/1000mg + Glimepiride IP 1mg/1mg + Lobeglitazone sulfate 0.5mg/0.5mg uncoated bilayer tablets | M/s. Glenmark Pharmaceuticals Ltd. | In light of earlier recommendation dated 19.09.2023, the firm presented their BE waiver and CT waiver justification before the committee.<br>After detailed deliberation, the committee reiterated its earlier recommendation dated 19.09.2023. |
| **GCT Division** | | | |
| 8. | CT/133/23<br>Online Submission (40143)<br>Semaglutide C 25 mg tablets, Semaglutide C 50 mg tablets | M/s. Novo Nordisk India Pvt. Ltd | The firm didn't turn up for presentations. |
| 9. | CT/152/23<br>Online Submission (40672)<br>ALXN1850 100mg/mL (50mg/ vial) or Placebo Solution for injection | M/s. AstraZeneca | The firm has presented Phase III Clinical trial Protocol no. D8590C00002.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. |
| 10. | CT/147/23<br>Online Submission (40531)<br>Cagrilintide + Semaglutide | M/s. Novo Nordisk | The firm has presented Phase 3a Clinical trial Protocol no. NN9388-4894.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. |
| 11. | CT/68/23<br>Online Submission(29833) | M/s. Eli Lilly | The firm has presented Protocol Amendment J2A-MC-GZGQ (d) dated 31 Oct 2023. Protocol no. J2A-MC-GZGQ<br><br>After detailed deliberation, the committee recommended for approval of the Protocol amendment as presented by the firm. |