**Recommendations of the SEC (Endocrinology & Metabolism) made in its 11th/24 meeting held on 11.06.2024 at CDSCO (HQ), New Delhi:**

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| **Biological Division** | | | |
| 1. | E-17636<br>Denosumab<br>(60mg/mL in PFS) | M/s. Reliance Life Sciences | The firm presented the proposal for approval of revised Package insert for the product- Denusumab (60mg/ml in PFS) in-line with Innovator PI.<br><br>After detailed deliberation, the committee recommended for approval for revised package insert of the drug version 01 dated Feb, 2024. |
| 2. | E-11350<br><br>Velaglucerase Alfa 400 units/vial powder for solution for infusion | M/s. Takeda | The firm presented the Post Marketing Surveillance study titled: "A PMS study for VIPRIV® Velaglucerase alfa 400 units/vial powder for solution for infusion in India" vide protocol No. SHP669-406 version 1.0 dated 15.11.2023.<br><br>After detailed deliberation, the committee recommended the following:<br>1. The firm has to present data separately for retrospective and prospective study of the subjects who participated in the study.<br>2. To submit patient wise data regarding size reduction of organ- liver and spleen.<br>Further, the proposal will be deliberated in the presence of expert of Pediatrics Neurology/ Pediatrics genetics.<br><br>Accordingly, the firm should submit PMS study data for further review by the committee. |
| 3. | r-DNA-11016(13)/10/ 2024-eoffice<br><br>Fiasp (Insulin Aspart100 units/mL) | M/s. Novo Nordisk | The firm presented the clinical study report for the Post Marketing Surveillance study titled "An Indian multi-centre, prospective, open-label, single-arm, non-interventional, Post Marketing surveillance study of Fiasp® (Insulin Aspart 100 units/ml) to evaluate the safety and effectiveness in patients with Diabetes mellitus in routine clinical practice" vide Study ID: NN1218-4489 version 4.0 dated 13.10.2020.<br><br>After detailed deliberation, the committee noted the results of the study. |

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| 4. | BIO/CT04/FF/2024/42592<br><br>Insulin Glargine Injection | M/s. Biogenomics | The firm presented the proposal to conduct Phase III clinical trial study titled "A Phase III, multi-center open-label, randomized, parallel group study To compare the efficacy, safety And immunogenicity of biosimilar Recombinant Insulin Glargine (Manufactured By Biogenomics Limited) with Lantus@(Manufactured By Sanofi) in Diabetes Mellitus patients" vide protocol No. BGL-IG-CTP301-V1, version 01 dated 15-Jan-2024 for Insulin Glargine injection I.P. 100 IU/ml (r-DNA origin).<br><br>After detailed deliberation, the committee recommended the firm to conduct the Phase III study as per the protocol presented. |
| **FDC Division** | | | |
| 5. | FDC/CT/24/000001<br><br>Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Glimepiride + Extended Release Metformin Hydrochloride Tablets (10 mg + 1 mg + 1000 mg) & (10 mg + 2 mg + 1000 mg) Tablets | M/s. Sun Pharma Laboratories Limited | In light of the condition mentioned in permission in Form CT-23 dated 10.10.2023, the firm presented the Phase IV clinical trial protocol before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct of the Phase IV clinical trial.<br><br>The firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee. |