

Recommendations of the SEC (Endocrinology & Metabolism) made in its 1/24 meeting held on 11.01.2024 at CDSCO (HQ), New Delhi:

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|----------------------------|---|--------------------------------|--|
| GCT Division | | | |
| 1. | CT/133/23 Online Submission (40143) Dated 20/10/2023 Semaglutide C 25 mg tablets, Semaglutide C 50 mg tablets | M/s Novo Nordisk India Pvt Ltd | The applicant had withdrawn the application. |
| 2. | CT/162/23 Online Submission (41014) Dated 19/12/2023 Insulin icodec 700 U/mL | M/s Novo Nordisk | The firm presented Phase 3b clinical study protocol no. NN1436-7724. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that addendum, clearly defining rescue and withdrawal criteria shall be submitted to CDSCO. |
| Biological Division | | | |
| 3. | BIO/CT21/FF/2023/3 6217 Insulin Glargine injection IP 100IU/mL | M/s. M.J. Biopharm Pvt Ltd. | The firm presented their proposal for grant of permission to manufacture and market Insulin Glargine 100 units/mL solution for injection based on the Phase III clinical trial results conducted in India. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Insulin Glargine 100 units/mL solution for injection subject to the condition that the firm shall conduct Phase IV study in the country. Accordingly, protocol to conduct the Phase IV study shall be submitted within three months of grant of marketing authorization. |
| 4. | BIO/IMP/22/000015 Semaglutide | M/s Novo Nordisk | As per the request of the firm the proposal was deferred to next meeting. |
| 5. | BIO/IMP/21/000050 Semaglutide | M/s Novo Nordisk | As per the request of the firm the proposal was deferred to next meeting. |
| 6. | BIO/CT18/FF/2023/3 9333 Insulin Icodec 700U/1 mL, 1050 U/1.5 mL | M/s Novo Nordisk | The firm presented the proposal to import and market Insulin Icodec 700 U/ml, 1050 U/1.5 ml, 2100 U/3ml solution for injection in prefilled pen indicated for the treatment of diabetes mellitus in adults |

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| | & 2100 U/3 mL | | <p>based on the global clinical trials ONWARDS 1 to 6 where 102 Indian patients for the test product were part of the ONWARDS trial 1, 4 and 6.</p> <p>The committee noted that the drug is not yet approved anywhere including the country of origin and indication proposed by the firm is not specific.</p> <p>After detailed deliberation, the committee recommended that firm should present specific indication based on the data generated from global clinical studies along with the approval status of the proposed product in country of origin for further review by the committee.</p> <p>(Dr. Rajesh Khadgawat & Dr. Rajesh Rajput didn't participate in the deliberation.)</p> |
| FDC Division | | | |
| 7. | <p>FDC/MA/23/000085</p> <p>Lobeglitazone sulfate 0.25mg/0.25mg + Sitagliptin Phosphate Monohydrate IP Eq. to Sitagliptin 50mg/100mg film coated tablet</p> | Ltd. M/s Akums Drugs & Pharmaceuticals | The Firm did not turn up for presentation. |
| 8. | <p>FDC/MA/23/000089</p> <p>Dapagliflozin Propanediol monohydrate eq to Dapagliflozin 5mg/5mg/10mg/10mg + Linagliptin 5mg/5mg/5mg/5mg + Metformin HCl eq to Metformin (as extended release) 500mg/1000mg/500mg/ 1000mg tablets</p> | M/s Exemed Pharmaceuticals | The Firm did not turn up for presentation. |