

**Recommendations of the SEC (Endocrinology & Metabolism) made in its 15<sup>th</sup>/26 meeting held on 24.06.2026 at CDSCO HQ New Delhi:**

| S. No.                     | File Name & Drug Name, Strength                                                                                                     | Firm Name                                      | Recommendations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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| <b>Biological Division</b> |                                                                                                                                     |                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 1.                         | BIO/CT21/FF/2026/54977<br><br>Semaglutide tablets 3mg, 7 mg, and 14 mg                                                              | M/s Sun Pharma Laboratories Limited            | <p>The firm presented the proposal for grant of permission to manufacture and market Semaglutide Tablets 3 mg, 7 mg and 14 mg based upon the results of comparative phase 3 clinical trial conducted in India to evaluate efficacy, safety and immunogenicity of the drug products in Type 2 Diabetes Mellitus.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market Semaglutide Tablets 3 mg, 7 mg and 14 mg for use as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 Diabetes Mellitus subject to condition that firm shall conduct the Phase-IV clinical trial in India.</p> <p>Limitations of Use:</p> <ul style="list-style-type: none"> <li>• Has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.</li> <li>• Not indicated for use in patients with type 1 diabetes mellitus.</li> </ul> <p>Accordingly, the protocol to conduct the Phase IV study shall be submitted within three months of grant of marketing authorization permission.</p> |
| <b>New Drugs Division</b>  |                                                                                                                                     |                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 2.                         | ND/CT/26/000011<br><br>Inosine+ Nicotinamide+ Riboflavin+ Succinic Acid enteric coated tablet and intravenous solution for infusion | M/s Invitro Research Solutions Private Limited | <p>The firm has presented Phase III Clinical Trial Protocol (Protocol ID: iVRS-CD-25-029, Version no.: 01, Date: 21 Aug 2025) of drug Inosine + Nicotinamide + Riboflavin + Succinic Acid enteric coated tablet and intravenous solution for infusion before the committee.</p> <p>After detailed deliberation, committee recommended that the firm should revise the protocol with the following points:</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

| S. No.              | File Name & Drug Name, Strength                                                                                               | Firm Name                                   | Recommendations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
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|                     |                                                                                                                               |                                             | <ol style="list-style-type: none"> <li>1. Vitamin B12 levels, glycemic parameters (HbA1C) every month and at least 7- point SMPG twice a week should be monitored throughout the study for both groups.</li> <li>2. Dose of metformin should be comparable in both the groups.</li> <li>3. Firm should provide pre-clinical data and data on drug-drug interaction.</li> <li>4. Firm should clarify the withdrawal criteria w.r.t. exacerbations of diabetic polyneuropathy.</li> <li>5. Standard of care in case of exacerbation of the condition should be clearly mentioned in the protocol.</li> <li>6. Firm should monitor the baseline retinopathy.</li> </ol> <p>Accordingly, firm should submit the revised Phase-III CT protocol to CDSCO for further review by the committee.</p>                                                                                                                           |
| <b>SND Division</b> |                                                                                                                               |                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 3.                  | <p>SND-11011/44/2025-e-office<br/>SND-11011/62/2025-eoffice</p> <p>Tirzepatide single dose &amp; multiple-dose injection.</p> | M/s Eli Lilly and Company (India) Pvt. Ltd. | <p>Firm has presented the proposal to harmonise the Prescribing information of Tirzepatide injection single dose vial and multidose vial/prefilled Pen.</p> <p>Experts opined that Tirzepatide injection is still not considered as first line of therapy in diabetes mellitus without comorbidities, as per the guidelines and practices followed in Indian context, therefore the following is more specific to the approved indication of type 2 diabetes mellitus. i.e.</p> <ul style="list-style-type: none"> <li>• as monotherapy when metformin is considered inappropriate due to intolerance or contraindication</li> <li>• in addition to other medicinal products for the treatment of diabetes.</li> </ul> <p>For weight management indication, the definition of obesity and overweight is different in case of US and Asian population, hence removing BMI cut off value from the indication is not</p> |

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|                     |                                                                                                                                                                                                                             |                                | appropriate.<br>Hence, the committee did not consider the update of PI as proposed by the firm.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>FDC Division</b> |                                                                                                                                                                                                                             |                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 4.                  | FDC/MA/25/000214<br><br>Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg + Gliclazide IP 30 mg (as sustained release) + Metformin Hydrochloride IP 500 mg (as sustained release) film coated bilayered tablet | M/s Eris Lifesciences Limited. | <p>The firm presented the proposal along with BE study protocol (under fasting and fed condition)and justification for Phase III CT waiver before the committee.</p> <p>The committee noted that:</p> <ul style="list-style-type: none"> <li>Firm has conducted Phase III Clinical Trial study on FDC of Sitagliptin 100 mg + Gliclazide XR 60 mg Tablets kept Metformin as background therapy.</li> <li>FDC of Gliclazide IP (SR) + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin (30 mg + 100 mg &amp; 60 mg + 100 mg) film coated bilayered tablets is already approved by CDSCO on 07.12.2023.</li> <li>The higher strength i.e. Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg + Gliclazide IP (as Sustained release) 60 mg + Metformin Hydrochloride IP (as Sustained release) 500 mg film coated bilayered tablet is already approved by CDSCO on 19-09-2025.</li> </ul> <p>After detailed deliberation, the committee considered the request for Phase III CT waiver and recommended to conduct BE study(under fasting and fed condition).</p> <p>Accordingly, the firm should submit BE study report to CDSCO for further review by the committee.</p> |