Recommendations of the SEC (Endocrinology & Metabolism) made in its 12th/24 meeting held on 19.06.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/03/24 Online Submission (41209) Cagrilintide + Semaglutide	M/s. Novo Nordisk India Pvt. Ltd.	In light of earlier SEC recommendation dated 24.01.24, the firm presented Phase II clinical study protocol No. NN9388-7700 version No. 1.0 dated 25 September 2023 After detailed deliberation, the committee recommended for grant of permission to conduct the trial with condition that the firm should include the Nephrologists as PI/Co-PI from the same site /institute.
Biological Division			
2.	BIO/CT18/FF/2023/39333 Insulin Icodec 700U/ 1 mL, 1050 U/1.5 mL & 2100 U/3 mL	M/s. Novo Nordisk	In light of the SEC recommendations dated 11.01.2024 and 10.04.2024, the firm presented the product approval from NRA of country of origin i.e EMA for grant of permission to import and market Insulin Icodec 700 U/ml, 1050 U/1.5 ml, 2100 U/3ml. After detailed deliberation, the committee recommended for grant of permission for import and market the Insulin Icodec 700 U/ml, 1050 U/1.5 ml, 2100 U/3ml for the indication of treatment of diabetes mellitus in adults with following condition: 1) The firm should conduct active PMS study. 2) The drug shall be prescribed only by the Registered Endocrinologist or Physician having Post Graduate qualification in Medicine. Accordingly, the firm shall submit active PMS study protocol within three months of grant of marketing authorization permission and revised PI of the product to CDSCO for approval.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
3.	SND/IMP/24/000032 Tirzepatide 2.5mg/0.5 ml, 5mg/0.5ml,7.5mg/0.5 ml, 10mg/0.5ml,12.5mg/0.5ml & 15mg/0.5 ml solution for injection in a single dose pre-filled pen	M/s. Eli Lily & Company (India) Private Limited	The firm presented the proposal for grant of permission to Import and marketing of Tirzepatide 2.5mg/0.5ml, 5mg/0.5ml, 7.5mg/0.5ml, 10mg/0.5ml, 12.5mg/0.5ml and 15mg/0.5ml solution for injection in a single dose prefilled pen and in a single-dose vial (additional Indication) along with justification including India specific clinical study reports from two global clinical studies in which India is also one of the participating country before the committee. The firm informed that the Tirzepatide single dose pre-filled pens is approved in United states (Country of origin), European Union, United-kingdom, United Arab Emirates, Hong Kong, Kuwait and Qatar and Tirzepatide single dose vials is approved in United states (Country of origin), European Union and Egypt for Chronic Weight Management. The firm has submitted two separate applications for both the dosage form (single dose pre-filled pens & single dose vials) for proposed indication to this division vide application no. SND/CT18/FF/2024/42512 and SND/CT18/FF/2024/42517. After detailed deliberation, the committee recommended for grant of permission for import and marketing of Tirzepatide 2.5mg/0.5ml, 5mg/0.5ml, 7.5mg/0.5ml, 10mg/0.5ml, 12.5mg/0.5ml and 15mg/0.5ml solution for injection in a single dose prefilled pen and in a single-dose vial for chronic weight management subject to condition that firm should conduct Phase-IV clinical trial. In addition to the above, the firm should fulfil the requirement of CMC data. Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within 03 months from the date

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			of approval of the drug for further review by the committee.
4.	SND/CT/24/000036 Liraglutide Injection 18mg/3ml	M/s. Enzene Biosciences Limited	The firm present the proposal for grant of permission to conduct Phase-III clinical trial of synthetic Liraglutide solution for injection 18mg/3ml along with Phase-III clinical trial protocol before the committee. The firm has informed that synthetic Liraglutide solution for injection 18mg/3ml not yet approved in anywhere in the world. After detailed deliberation, the committee recommended to conduct Phase-III clinical trial of synthetic Liraglutide solution for injection 18mg/3ml as per protocol presented by the firm subject to following conditions: 1. 1. The firm should increase the study duration from 16 weeks to 06 months. 2. 2. The firm should include younger population in pharmacokinetic study arm i.e. age between 18 to 60 years. 3. 3. The firm should take detailed informed consent form for pharmacokinetic (PK) arm. 4. 4. History of drug abuse patients shall be included in exclusion criteria. Accordingly, the firm should submit revised Phase-III clinical trial protocol to CDSCO for further consideration.