

Recommendations of the SEC (Endocrinology & Metabolism) made in its 15th/24 meeting held on 11.09.2024 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2024/43161 Semaglutide tablets (1.5mg,4mg & 9mg)	M/s. Novo Nordisk India Pvt. Ltd.	<p>The firm presented the proposal to import and market Semaglutide tablets 1.5 mg, 4 mg & 9 mg along with result of bio-equivalence study data generated in US and Canada.</p> <p>The firm has claimed that Semaglutide tablets 1.5 mg, 4 mg, 9 mg are equivalent to the approved doses of Semaglutide tablets 3 mg, 7 mg & 14 mg respectively due to new formulation.</p> <p>The committee has noted that the drug is not yet approved anywhere including the NRA of country of origin.</p> <p>After detailed deliberation, the committee recommended that the firm should present the specific difference/improvement between the manufacturing process of approved formulation and proposed formulation along with approval status of the proposed product in the NRA of country of origin for further review by the committee.</p>
New Drugs Division			
2.	ND/CT/24/000059 Tirzepatide 2.5 mg/0.5 mL, 5 mg/0.5 mL, 7.5 mg/0.5 mL, 10mg/0.5 mL, 12.5 mg/0.5 mL and 15 mg/0.5 mL solution for injection in a single dose prefilled pen	M/s. Eli Lilly and Company (India) Pvt. Ltd.	The firm did not turn up for presentation.