

**Recommendations of the SEC (Endocrinology & Metabolism) made in its 20<sup>th</sup> meeting held on 11.12.2024 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/53/23 Online Submission 36064 LY3437943	M/s Eli Lilly	The firm presented protocol amendment (d) dated 27 August 2024 and protocol addendum 2 dated 01 October 2024 protocol no. J1I-MC-GZBJ.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm
<b>SND Division</b>			
2.	SND/MA/22/000262 Vildagliptin SR Tablets 100mg	M/s Eris Life Sciences Limited	The firm did not turn up for the presentation.
3.	SND/IMP/24/000041 Tirzepatide Multiple Dose Pen (additional of new presentation – KwkPen) 2.5mg/0.6ml, 5mg/0.6ml, 7.5mg/0.6ml, 10.0mg/0.6ml, 12.5mg/0.6ml, 15.0mg/0.6ml, in India)	M/s. Eli Lilly and Company (India) Pvt.Ltd.	In light of the earlier SEC recommendation dated 13.08.2024, firm presented the justification for Cmax values at 90% confidence interval based on clinical data and intended use. Firm has informed that Tirzepatide Multiple Dose Pen (KwkPen) is already approved in UK, Europe, Canada etc. After detailed deliberation, committee recommended for the grant of permission for import and marketing of Tirzepatide Multiple Dose Pen (additional of new presentation –KwkPen) 2.5mg/0.6ml, 5mg/0.6ml, 7.5mg/0.6ml, 10.0mg/0.6ml, 12.5mg/0.6ml, 15.0mg/0.6ml in India with subject to condition that firm should conduct Phase-IV clinical trial. Accordingly, firm should submit Phase-IV clinical trial protocol within 03 months from the date of approval of drug to CDSCO for further review by the committee.
4.	SND/MA/22/000288 Semaglutide Solution for Injection, Multi-dose Prefilled Pens 2mg/1.5ml (1.34mg/ml) & 4mg/3ml (1.34mg/ml) (Synthetic Origin)	M/s. Natco Pharma Limited	<b><i>“Under Discussion”</i></b>