

Recommendations of the SEC (Endocrinology & Metabolism) made in its 07th/25 meeting held on 08.04.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
7.	SND/CT/25/000002 Semaglutide Solution for injection in pre-filled pen 2 mg/1.5 ml, Semaglutide Solution for injection in pre-filled pen 4 mg/3 ml & Semaglutide Solution for injection in pre-filled pen 8 mg/3ml	M/s Biocon Pharma Limited	<p>Firm presented the subacute toxicity study data for Semaglutide Injection 2mg/3mL (0.68mg/mL) in New Zealand White Rabbits & Sprague Dawley rats and BE study report vide no. SYNCD-025-24, dated 18-Feb-2025 (Final, Version1.0) before the committee.</p> <p>The Committee opined that firm should submit detailed anatomic pathology reports including histopathological reports & autopsy reports of survived and dead animals along with detailed causality assessment of animals died during subacute toxicity study.</p> <p>Further, Committee also opined that firm should submit detailed causality assessment report for reported SAEs in BE study.</p>