

Recommendations of the SEC (Cardiovascular) made in its 24th meeting held on 17.12.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2024/4 4686 Semaglutide Injection 0.25mg / 0.5mg /1mg /1.7mg /2.4mg (Single dose and multi-dose Pen injector)	M/s. Novo Nordisk India Pvt. Ltd.	<p>Firm presented the proposal for approval of additional indication i.e. “Semaglutide Injection is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight” for the already approved drug Semaglutide injection. The firm presented global clinical trial data along with safety updates for drug-drug interaction with acenocoumarol & intestinal obstruction. The firm also presented Indian subset analysis data in 492 patients.</p> <p>The committee noted that proposed indication is approved by USFDA, EMA, UK and Switzerland. The committee also noted that drug product is not yet marketed in India.</p> <p>After detailed deliberation, the committee recommended for the approval of proposed indication with condition to conduct PMS (Post marketing surveillance) study in India. Accordingly, firm shall submit protocol to conduct PMS study within 03 months of approval of additional indication.</p> <p>The committee further recommended that drug shall be prescribed by Cardiologist along with already permitted prescribers i.e. Endocrinologist and Internal medicine.</p>