CLOSER LOOK

MEMORANDUM

EU'S CHMP issues a positive opinion for Wegovy 7.2 mg single-dose pen, easing administration of high-dose Wegovy – May 22, 2026

Follows February 2026 EU approval of Wegovy 7.2 mg administered as three 2.4 mg injections

In addition to the news regarding oral Wegovy in the EU, Novo Nordisk also announced today that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending Wegovy 7.2 mg (once-weekly injectable semaglutide) delivered via a single-dose pen for adults with obesity. This new formulation follows the February 2026 EU approval of the same 7.2 mg dose administered as three 2.4 mg injections in one sitting. The positive opinion and prior approval were supported by the STEP-UP program, which investigated semaglutide 7.2 mg in adults with obesity, with and without T2D. Novo Nordisk anticipates launching the single-dose pen in the EU in 3Q26.

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Single-dose pen will simplify administration of high dose Wegovy

The single-dose pen is expected to meaningfully improve convenience and adherence for people using Wegovy 7.2 mg. The high-dose pen received FDA approval in the US in March 2026 under the name Wegovy HD, while the UK's MRA has still only approved the three 2.4 mg injections as of January 2026. The new EU approval would align the region with the US market and replace the current regimen of administering three separate 2.4 mg injections in one sitting. By consolidating the full 7.2 mg dose into a single injection, the pen offers a convenient, easy-to-use alternative to the current three-injection regimen. While the single-dose pen is less environmental than the injections, we imagine that it is considerably more motivating to use the pen as well as also easier to prescribe.

The STEP-UP trial demonstrated 21% mean weight loss with semaglutide 7.2 mg

In the STEP-UP trial (n=1,407), participants with obesity taking semaglutide achieved 21% mean body weight loss under the efficacy estimand and 30% achieved ≥25% weight loss. Under the treatment-regimen estimand, mean weight loss was 19%.

The STEP UP T2D trial (n=512) evaluated semaglutide 7.2 mg in adults with obesity and T2D, demonstrating 14% mean weight loss under the efficacy estimand and 13% under the treatment-regimen estimand.

Across both trials, the most common adverse events were GI-related, with the majority of these being mild to moderate events that diminished over time.

High-dose Wegovy has been positioned as a global growth priority for Novo Nordisk

At JPM 2026, Novo Nordisk EVP Emil Kongshøj Larsen emphasized that high-dose Wegovy is a major strategic priority for the company's growth outside the US in 2026. Today's press release follows through on his comments that Novo Nordisk expects to be "particularly busy" with high-dose Wegovy launches outside the US, underscoring the importance of the 7.2 mg single-dose pen for the company's global obesity strategy.

CEO Maziar Mike Doustdar also noted that the company initially launched semaglutide cautiously at the 2.4 mg dose

after demonstrating 15-16% weight loss versus liraglutide but now views the 7.2 mg dose as an opportunity to reposition semaglutide among "next-generation" incretin therapies, including Lilly's Mounjaro and Zepbound. Others with incretins in the pipeline include Innovent Biologics (dual GLP-1/glucagon RA mazdutide), BI/Zealand (dual glucagon/GLP-1 RA survodutide), AstraZeneca (oral GLP-1 RA elecoglipron), and more.

Close Concerns' Questions

1. How has the early uptake of the three-injection 7.2 mg regimen progressed since its February EU approval?
2. How is the 7.2 mg single-dose pen likely to compare with next-generation high-potency incretin therapies such as retatrutide?
3. When might Novo Nordisk pursue a T2D indication for the 7.2 mg dose in the EU compared to this obesity management indication?

-- by Kayla Mathieu, Nour Khachemoune, Monica Oxenreiter, and Kelly Close