CLOSER LOOK

MEMORANDUM

Wegovy pill becomes first oral GLP-1 RA approved in the EU for obesity and overweight – July 15, 2026

Wegovy HD (7.2 mg) also receives approval; approval follows positive opinion issued by the CHMP in May 2026 for Wegovy's oral and pen formulations

Novo Nordisk announced today that the European Commission (EC) has approved the Wegovy pill (once-daily oral semaglutide 25 mg) and Wegovy HD (injectable 7.2 mg) for the treatment of adults with obesity or overweight with at least one weight-related comorbidity. The Wegovy pill's approval is based on the OASIS program – including phase 3 OASIS-4 trial (n=307), which found that oral semaglutide 25 mg conferred up to 14% weight loss compared with 2% with placebo at Week 64. Wegovy HD's approval supported by the STEP-UP program, which investigated semaglutide 7.2 mg in adults with obesity, with and without T2D.

Table of Contents

1. EU approval of Wegovy pill follows four others, with launch expected in 2H26
2. Wegovy pill experienced favorable uptake in the US thus far
3. Oral Wegovy requires higher manufacturing throughput compared to Rybelsus, but still offers advantages compared to injectable therapies
4. International review for the Wegovy pill continues, including a planned submission in China
5. Close Concerns' Questions

EU approval of Wegovy pill follows four others, with launch expected in 2H26

The Wegovy pill's EU approval marks its fifth regulatory approval, beginning with the FDA's in December 2025. Approval in Bahrain followed in January 2026, while the UAE became the first OUS market to approve and gain access to the Wegovy pill in June 2026. Weeks later, Novo Nordisk announced that the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) approved the Wegovy pill. In each of its regulatory approval announcements Novo Nordisk has committed to launching oral Wegovy in additional markets during 2H26. Given the early impact that has been very positive for oral Wegovy, we see no slowdown in sight. The main complexity continues to be around the GI side effects.

Wegovy pill experienced favorable uptake in the US thus far

The US launch has been highly successful so far, with uptake of the Wegovy pill quite rapid. The FDA made injected and oral Wegovy interchangeable, which likely helped create a market ready for the pill. In 1Q26 commentary, management characterized the Wegovy pill's launch as "record-breaking," reporting $353 million in sales during its first three months on the US market. In June 2026, the number of oral Wegovy prescriptions surpassed 3 million, with over 80% of patient being GLP-1 RA treatment-naïve.

Oral Wegovy requires higher manufacturing throughput compared to Rybelsus, but still offers advantages compared to injectable therapies

Of note, oral semaglutide is already available in Europe for T2D. Novo Nordisk's Rybelsus received EC approval in April 2020 and has been widely prescribed in PWD since. The Wegovy pill requires substantially more semaglutide and absorption enhancer per patient compared to Rybelsus, placing a greater demand on manufacturing capacity – but still

offering practical advantages compared to injectable therapies.

Novo Nordisk's continues to invest in expanding and retooling its manufacturing capacity to support the Wegovy pill's production prior to OUS launches. In June 2026, the company introduced an updated Rybelsus formulation in Canada that delivers a similar clinical profile at lower dose strengths (1.5 mg, 4 mg, and 9 mg) compared to Rybelsus' original tablet formulations (3 mg, 7 mg, and 14 mg). Both of its oral semaglutide products (Rybelsus and the Wegovy pill) use sodium N-(8-[2-hydroxybenzoyl] amino) caprylate (SNAC) technology to protect the semaglutide from gastric enzymatic breakdown and enhance absorption. Consequently, Rybelsus is likely the more economical oral semaglutide to manufacture per tablet, as its 9 mg dose requires substantially less semaglutide and SNAC (100 mg vs. 300 mg) than the 25 mg Wegovy pill.

At the same time, compared with injectable biologics, oral, solid-dose formats are generally cheaper and more scalable to manufacture. Oral tablets also do not require cold-chain logistics, which may be particularly advantageous as recent heat waves in Europe strain refrigeration-dependent supply chains.

International review for the Wegovy pill continues, including a planned submission in China

The Wegovy pill continues to be evaluated for regulatory approval around the globe, including a planned submission in China. If approved, the Wegovy pill would enter a market where injectable semaglutide has already been added to China's National Essential Medicines List (NEML) – a government-mandated list representing medications required to be prioritized by public medical institutions. However, generic semaglutide entry is delayed until April 2027.

Close Concerns' Questions

1. How does Novo Nordisk predict its EU expansion to affect its manufacturing constraints?
2. Does Novo Nordisk have plans to optimize the Wegovy's pills formulation, similar to Rybelsus?
3. When does Novo Nordisk plan to officially submit for Wegovy's regulatory approval in China?

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