

Risk of suicidal thoughts with popular weightloss drugs being investigated by European regulators

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The European Medicines Agency is investigating concerns that popular weight-loss drugs like Ozempic and Saxenda may be linked to suicidal thoughts and thoughts of self-harm.

Three case reports from Iceland spurred the agency's safety committee to conduct a medication review, *CNN* reported Monday. The EMA is Europe's equivalent of the U.S. Food and Drug Administration.

The Icelandic Medicines Agency reported two cases of suicidal thoughts. One happened after use of Ozempic (semaglutide) and the other after taking Saxenda (liraglutide). The third report was about Saxenda and thoughts of self-injury.

Both drugs are made by Novo Nordisk. The company said, "patient safety is a top priority," adding it takes "all reports about adverse events from use of our medicines very seriously," *CNN* reported.

Prescribing information in the United States for Saxenda includes a recommendation to monitor patients for depression or suicidal thoughts, but Ozempic does not carry a similar warning. The weight-loss drug Wegovy (semaglutide, the same <u>active ingredient</u> as in Ozempic) includes in its prescribing information that reports of suicidal behavior and ideation have occurred in clinical trials with other weight-management medications, the news report said.

Clinical trials in adults for Saxenda found that nine people among 3,300 reported suicidal ideation, while two in 1,900 reported suicidal ideation while on a placebo in those drug trials, *CNN* reported.

One adult taking Saxenda attempted suicide, the prescribing information says.

In pediatric clinical trials, one person died of suicide among 125 trial



participants. However, "there was insufficient information to establish a <u>causal relationship</u> to Saxenda," according to the prescribing information.

The Wegovy prescribing information says that patients should be monitored for depression, <u>suicidal thoughts</u> or behavior, and unusual changes in mood or behavior.

These medications are in a class of drugs known as GLP-1 receptor agonists. Ozempic was approved by the FDA in 2017 for diabetes. Saxenda and Wegovy were approved for weight loss in 2014 and 2021, respectively.

GLP-1 medications stimulate the release of insulin, lowering blood sugar and slowing food as it passes through the gut.

The FDA told *CNN* said it "routinely evaluates individual adverse event reports and adverse event reports from the published literature for all approved drugs."

However, it doesn't comment on third-party research "as a general matter."

The agency is continuing to monitor the medications and evaluate them through its risk-assessment programs, *CNN* reported.

The EMA's safety committee will consider whether its review should extend beyond the drugs in question to other medicines in the class of GLP-1 receptor agonists. This could include Wegovy and drug company Eli Lilly's Mounjaro.

More information: The U.S. Food and Drug Administration has more on <u>semaglutide</u>.



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