Communication of the President of the Office of 12 July 2023 regarding the European Medicines Agency's PRAC Committee's review of data on the risk of suicidal thoughts during GLP-1 receptor agonist therapy.

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EMA’s safety committee, the PRAC, is reviewing data on the risk of suicidal thoughts and thoughts of self-harm with medicines known as GLP-1 receptor agonists (dulaglutide, exenatide, liraglutide, lixisenatide and semaglutide), including Ozempic (semaglutide), Saxenda (liraglutide) and Wegovy (semaglutide). These medicines are used for weight loss and for treating type 2 diabetes.

The review was triggered by the Icelandic medicines agency following reports of suicidal thoughts and self-injury in people using liraglutide and semaglutide medicines. So far authorities have retrieved and are analysing about 150 reports of possible cases of self-injury and suicidal thoughts.

Liraglutide and semaglutide medicines are widely used, with an exposure of over 20 million patient-years (one patient-year is the equivalent of one patient taking a medicine for one year) to date. It is not yet clear whether the reported cases are linked to the medicines themselves or to the patients’ underlying conditions or other factors.

The review is being carried out in the context of a signal procedure. A signal is information on a new adverse event that is potentially caused by a medicine or a new aspect of a known adverse event that warrants further investigation. The presence of a signal does not necessarily mean that a medicine caused the adverse event in question.

Saxenda and Wegovy are authorised for weight management, together with diet and physical activity in people who are obese or overweight in the presence of at least one weight-related health problem. Ozempic is authorised for the treatment of adults with insufficiently controlled type 2 diabetes as an adjunct to diet and exercise but has been used off-label for weight loss. Suicidal behaviour is not currently listed as a side effect in the EU product information for any GLP-1 receptor agonists.

The review of Ozempic, Saxenda and Wegovy started on 3 July 2023 and has now been extended to include other GLP-1 receptor agonists. This review is expected to conclude in November 2023.

Information about the start of reviews of safety signals is available in the published agendas of the PRAC’s monthly plenary meetings, and the outcomes of the reviews are published on a dedicated webpage. The outcomes of certain reviews of signals will also be included in the monthly PRAC highlights. In certain cases, e.g. when there is high public interest, EMA may issue a news announcement during a signal review.

As with all medicines, patients and healthcare professionals are advised to use GLP-1 receptor agonists in accordance with the approved product information. Patients and healthcare professionals should also report suspected side effects to authorities. Information on how to report suspected side effects is available in the package leaflets and on the websites of national medicines authorities.

More information available on the website: https://www.ema.europa.eu/en/news/ema-statement-ongoing-review-glp-1-receptor-agonists [1]

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President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Links
[1] https://www.ema.europa.eu/en/news/ema-statement-ongoing-review-glp-1-receptor-agonists