

Summary Safety Review - Glucagon-like Peptide 1 Receptor Agonists (GLP-1 RAs) (dulaglutide, exenatide, liraglutide, lixisenatide and semaglutide) - Assessing the Potential Risks of Suicide, Self-harm and Suicidal/Self-harm Ideation

Product: Glucagon-like peptide 1 receptor agonists (GLP-1 RAs) (dulaglutide-, exenatide-, liraglutide-, lixisenatide- and semaglutide-containing products)

Potential Safety Issue: Suicide, self-harm and suicidal/self-harm ideation (thoughts of suicide/self-harm)

Key Messages

- Health Canada's safety review did not find evidence to support a link between GLP-1 RAs and the risks of suicide, self-harm and suicidal/self-harm ideation in patients with type 2 diabetes. There was not enough information to determine if there is a link in patients with obesity.
- Health Canada published a Health Product InfoWatch communication in [December 2024](#) to share information about the review with healthcare professionals.
- Health Canada will continue to monitor the safety of GLP-1 RAs.

Overview

Health Canada reviewed the potential risks of suicide, self-harm and suicidal/self-harm ideation with the use of GLP-1 RAs. The safety review was triggered by case reports of suicidal thoughts and self-harm submitted to the European Medicines Agency (EMA).

Use in Canada

- Glucagon-like peptide 1 receptor agonists are a class of prescription drugs authorized for sale in Canada
 - for adults with type 2 diabetes [Ozempic/Rybelsus (semaglutide), Victoza (liraglutide), Trulicity (dulaglutide), Xultophy (insulin degludec and liraglutide) and Soliqua (insulin glargine and lixisenatide)], or
 - for chronic weight management in adults and adolescents who are obese or overweight [Wegovy (semaglutide) and Saxenda (liraglutide)].
- Glucagon-like peptide 1 receptor agonists have been marketed in Canada since 2010. All GLP-1 RA products are available as subcutaneous (under the skin) injections. Semaglutide is also available as an oral tablet.
- Approximately 7.1 million prescriptions for GLP-1 RAs were dispensed by Canadian retail pharmacies in 2023.

Safety Review Findings

- Health Canada reviewed the available information provided by manufacturers, and from searches of the Canada Vigilance database^a, the World Health Organization's adverse drug reaction database^b and the scientific literature.
- Health Canada reviewed 15 cases (3 Canadian and 12 international) of suicide, self-harm and suicidal/self-harm ideation in patients using GLP-1 RAs, including 2 from the published

^a Canadian reports can be accessed through the [Canada Vigilance Online Database](#).

^b [World Health Organization's adverse drug reaction database](#)

literature^{1,2}. Of the 15 cases, 12 (3 Canadian) were found to be possibly linked to the use of GLP-1 RAs and 3 could not be assessed due to missing clinical information.

- A definitive link could not be confirmed due to insufficient information about possible confounders (other factors that may have contributed to the occurrence of suicide, self-harm and suicidal/self-harm ideation), such as pre-existing mental health problems, family history, life stressors, social and environmental factors, and use of other medications that has labelling related to suicidality.
- Health Canada also reviewed clinical trial data from the manufacturers, and real-world data from published^{3,4} and unpublished sources. Overall, the evidence from these studies does not support a link between GLP-1 RAs and the risks of suicide, self-harm and suicide/self-harm ideation in patients with type 2 diabetes. However, in the subgroup of patients with obesity (with or without type 2 diabetes), the evidence was not as clear. Additional information is needed to determine if there is a link between GLP-1 RAs and suicide, self-harm, and suicide/self-harm ideation in patients with obesity (with or without type 2 diabetes).

Conclusions and Actions

- Health Canada's review did not find evidence to support a link between GLP-1 RAs and the risks of suicide, self-harm and suicidal/self-harm ideation in patients with type 2 diabetes. There was not enough information to determine if there is a link in patients with obesity.
- Health Canada has published a [Health Product InfoWatch communication](#) to share information about the findings of its review with healthcare professionals.
- Health Canada encourages consumers and healthcare professionals to [report](#) any side effects related to the use of GLP-1 RAs, and other health products, to the [Canada Vigilance Program](#).
- Health Canada will continue to monitor safety information involving GLP-1 RAs, as it does for all health products on the Canadian market, to identify and assess potential harms. Health Canada will take appropriate and timely action should new health risks be identified.

Additional Information

The analysis that contributed to this safety review included scientific and medical literature, Canadian and international information and what is known about the use of GLP-1 RAs both in Canada and internationally.

For additional information, [contact the Marketed Health Products Directorate](#).

References

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