

Australia: GLP-1 RAs: warnings aligned over potential risk of suicidal thoughts or behaviours

Summary

Product warnings across the GLP-1 RA class of medicines have been aligned to ensure consistent information regarding the potential risk of suicidal thoughts or behaviours.

The glucagon-like-peptide-1 receptor agonist (GLP-1 RA) prescription medicines are used primarily to manage type 2 diabetes mellitus and obesity.

The updates follow investigations by Therapeutic Goods Administration (TGA) and other international regulators.

We sought advice from the Advisory Committee on Medicines (ACM) who found that the evidence available was not sufficient to support an association between GLP-1 RAs and suicidal or self-harming behaviours. However, the ACM noted that the Product Information (PI) and Consumer Medicines Information (CMI) documents across the class were inconsistent and should be harmonised.

The ACM stressed that updates should not imply a causal association, but reflect a class level awareness.

The GLP-1 RAs currently marketed in Australia are:

- Ozempic (semaglutide)
- Wegovy (semaglutide)
- Saxenda (liraglutide)
- Trulicity (dulaglutide)
- Mounjaro (tirzepatide)*

* Tirzepatide is a dual glucose-dependent insulinotropic polypeptide (GIP)/GLP-1 RA.

Ozempic and Trulicity are both PBS subsidised in certain circumstances.

What health professionals should do

Health professionals should monitor for the emergence or worsening of depression, suicidal thoughts or behaviours, or any unusual changes in mood or behaviour.

Consider the benefits and risks for individual patients before initiating or continuing therapy in patients with suicidal thoughts or behaviours.

Advise patients to tell their health professional if they experience new or worsening depression, suicidal thoughts or any unusual changes in mood or behaviour.

Background

We conducted a comprehensive investigation following notification of a potential international signal for GLP-1 RAs and suicidal or self-injurious ideation.

As part of this investigation we sought independent expert advice from the ACM at their June 2025 meeting.

While finding insufficient evidence for causality, the ACM noted there was a complex interplay between mental illness and chronic endocrine disorders for which GLP-1 RAs may be used for treatment, and the potential relationship between weight loss and suicidal/self-injurious ideation.

Updates to Product Information

The following wording has been added to the PIs for all GLP-1 RAs (except Saxenda as it already included suitable wording):

Psychiatric disorders

Suicidal behaviour and ideation have been reported with GLP-1 receptor agonists. Monitor patients for the emergence or worsening of depression, suicidal thoughts or behaviours, and/or any unusual changes in mood or behaviour. Consider the benefits and risks for individual patients prior to initiating or continuing therapy in patients with suicidal thoughts or behaviours or have a history of suicidal attempts.

Adverse events reported to us

A search of the TGA's Database of Adverse Event Notifications (DAEN) on 23 September 2025 for the GLP-1 RA class (semaglutide, liraglutide, dulaglutide and tirzepatide) retrieved:

- 72 reports for suicidal ideation
- 6 reports for depression suicide
- 4 reports of suicide attempt
- 2 reports of completed suicide
- 1 report of self-injurious ideation.

Please refer to the following website in TGA for details:

<http://www.tga.gov.au/news/safety-updates/ghp-1-ras-warnings-aligned-over-potential-risk-suicidal-thoughts-or-behaviours>

In Hong Kong, there are registered pharmaceutical products containing GLP-1 RAs and dual GIP/GLP1 RAs including dulaglutide (4 products), exenatide (1 product), liraglutide (5 products), lixisenatide (2 products), semaglutide (11 products) and tirzepatide (6 products). All products are prescription-only medicines. So far, the Department of Health (DH) has received adverse drug

reaction reports with regard to dulaglutide (5 cases), exenatide (2 cases), liraglutide (1 case), lixisenatide (1 case) and semaglutide (10 cases), but these cases were not related to suicidal thoughts or behaviours, while no adverse drug reaction report with regard to tirzepatide was received. Related news was previously issued by various overseas drug regulatory authorities, and was posted on the Drug Office website since 12 Jul 2023, with the latest update posted on 28 Mar 2025. In light of the above TGA's announcement on the aligned class warnings for medicines containing GLP-1 RAs, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

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