Australia: Medicines containing GLP-1 and dual GIP/GLP-1 receptor agonists

The Therapeutic Goods Administration (TGA) announces new warnings added of risks during anaesthesia or deep sedation.

Summary
Glucagon-like peptide-1 (GLP-1) receptor agonists (RAs) and dual glucose-dependent insulinotropic polypeptide (GIP)/GLP-1 RAs are relatively new and high-profile classes of medicines that are used to treat type 2 diabetes mellitus (T2DM) and/or obesity.

The GLP-1 RAs currently marketed in Australia include:
- **Ozempic** (semaglutide), **Trulicity** (dulaglutide) and **Victoza** (liraglutide), which are approved for the management of adults with T2DM.
- **Saxenda** (liraglutide) and **Wegovy** (semaglutide), which are approved for chronic weight management in patients who are obese or overweight.

The dual GIP/GLP-1 RA currently marketed in Australia:
- **Mounjaro** (tirzepatide) is approved for both T2DM and chronic weight management.

There is a known potential for all medicines in these classes to delay passage of food through the stomach (gastric emptying).

This poses a potential risk for patients during general anaesthesia or deep sedation as the usual fasting period beforehand may not be sufficient to empty the stomach.

We have required updates to Product Information (PI) and Consumer Medicine Information (CMI) documents for all these medicines with a warning about the risk of accidentally inhaling stomach contents during general anaesthesia or deep sedation.

Trulicity and Ozempic are available on the PBS (authority streamlined).

What health professionals should do
Be alert to the class-wide warning being added to the PIs for these medicines about the risk of pulmonary aspiration during general anaesthesia or deep sedation.

Advise patients of the risk and to alert health professionals, including anaesthetists, that they are taking one of these medicines before a surgical procedure to ensure appropriate management.

Anaesthetists should:
- be particularly alert that residual gastric contents may remain despite preoperative fasting in patients taking these medicines
- ask patients whether they are taking one of these medicines
- consider the risk of aspiration in patients taking these medicines within the preoperative risk

assessment, so it can be managed appropriately.

Information for consumers

Patients are advised to tell health professionals, including anaesthetists, that they are taking one of these medicines before a surgery or other procedures.

Background

In 2023, the TGA conducted an independent assessment following sponsor notification of a safety signal from the US Food and Drug Administration (FDA) regarding aspiration during general anaesthesia (GA) and deep sedation for these medicines.

We approved updates to the PIs of all 3 GLP-1 receptor agonists on the ARTG (dulaglutide, liraglutide and semaglutide; under 5 tradenames) and one dual GIP/GLP-1 receptor agonist (tirzepatide) to include a precaution in section 4.4 for aspiration during GA and deep sedation.

Delayed gastric emptying, which is a risk factor for aspiration, was already a recognised effect described in the PI of all these medicines.

Adverse events reported to us

A search of our publicly available Database of Adverse Event Notification (DAEN) on 14 May 2025 for the GLP-1 and dual GIP/GLP-1 receptor agonists identified 7 cases for aspiration and 1 case of pneumonia aspiration for semaglutide, 1 case of aspiration and 1 case of pneumonia aspiration for liraglutide and 1 case of pneumonia aspiration for dulaglutide. All cases were reported with a single suspected medicine.

Changes to the PI

The following warning has been added to the PIs for Trulicity (dulaglutide), Victoza (liraglutide), Saxenda (liraglutide), Ozempic (semaglutide), Wegovy (semaglutide), and Mounjaro (tirzepatide):

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

Aspiration in association with general anaesthesia or deep sedation

Cases of pulmonary aspiration have been reported in patients receiving GLP-1 RAs undergoing general anaesthesia (GA) or deep sedation despite reported adherence to preoperative fasting recommendations. Therefore, the increased risk of residual gastric content because of delayed gastric emptying should be considered prior to performing procedures with GA or deep sedation.

Please refer to the following website in TGA for details:
http://www.tga.gov.au/news/safety-updates/medicines-containing-glp-1-and-dual-gipglp-1-

receptor-agonists

In Hong Kong, there are registered pharmaceutical products containing GLP-1 and dual GIP/GLP-1 receptor agonists 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 10 cases of adverse drug reactions with regard to semaglutide, of which 4 were related to pulmonary aspiration. The DH has also received adverse drug reactions with regard to dulaglutide (5 cases), exenatide (2 cases), liraglutide (1 case) and lixisenatide (1 case), but these cases were not related to aspiration or pulmonary aspiration. The DH has not received any case of adverse drug reaction related to tirzepatide. Related news was previously issued by the European Medicines Agency and the United Kingdom Medicines and Healthcare products Regulatory Agency, and was posted on the Drug Office website on 13 Jul 2024 and 1 February 2025. Letters to inform local healthcare professionals were issued on 15 Jul 2024. As previously reported, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

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