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(來函請敘明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

23 Jul 2026

Dear Healthcare Professionals,

GLP-1 RAs and Rare Vision Disorder

Your attention is drawn to the following Australia Therapeutic Goods Administration's (TGA) announcement that safety information updated across class.

Summary

Product warnings across the glucagon-like-peptide-1 receptor agonist (GLP-1 RA) class of medicines have been updated due to the potential for these products to cause a rare, but severe, form of eye disorder.

The GLP-1 RA class of prescription medicines are used primarily to manage type 2 diabetes mellitus and obesity.

The eye disorder, non-arteritic anterior ischaemic optic neuropathy (NAION), is a rare but serious condition that may result in permanent visual impairment, including blindness, and no treatment has been shown to improve visual acuity outcomes.

The GLP-1 RA class of medicines currently marketed in Australia are:

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

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

What health professionals should do

Be alert to the new class-wide warnings in the Product Information (PI) documents for GLP-1 RAs (see 'Updates to the Product Information' below).

Advise patients to seek urgent medical attention if they experience sudden vision loss, including partial loss of vision.

The Consumer Medicine Information (CMI) leaflets for each product will be aligned with the updated PI documents and these should be provided to patients, if deemed clinically appropriate, as part of the counselling process.

Background

We first identified the potential association of GLP-1 RAs and NAION in July 2024 following a study published in JAMA Ophthalmology. Since then, the association has been closely monitored including through analysis of Australian cases reported to us, and investigations and regulatory actions by overseas regulators.

We conducted an independent assessment of the potential association between GLP-1 RAs and NAION. As the available evidence was conflicting, we sought expert advice from the Advisory Committee on Medicines (ACM) on whether the evidence supported additional risk mitigation measures.

Following discussion at its October 2025 meeting, the ACM concluded that the current evidence may support the signal for semaglutide, but not dulaglutide or tirzepatide and recommended a range of risk mitigation strategies, including:

- updates to the PI and CMI documents
- communication to relevant health professionals, including general practitioners, optometrists and ophthalmologists.

After considering all available evidence, including the ACM advice, we made a final decision on regulatory actions including PI and CMI document updates, and publication of safety communications.

Adverse events reported to us

A search of our Database of Adverse Event Notifications (DAEN) found 36 cases of optic ischaemic neuropathy with GLP-1 RAs, 23 for semaglutide and 3 for liraglutide, 10 for tirzepatide. No cases were found for dulaglutide, though one semaglutide case had a history of prior dulaglutide use.

Updates to Product Information

Australian PI documents have been updated with the following wording:

Semaglutide

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

Non-arteritic anterior ischaemic optic neuropathy (NAION)

It is known that individuals with an anatomical predisposition ('disc at risk'), whether or not they are taking a GLP-1 agonist, are at highest risk of developing non-arteritic anterior ischaemic optic neuropathy (NAION). This pre-existing risk can be assessed by an optometrist or ophthalmologist. Some epidemiological studies indicate an increased risk of NAION during treatment with semaglutide. There is no identified time interval for when NAION may develop following treatment start. Patients reporting a sudden loss of vision (including partial loss) should be urgently referred for ophthalmological examination and treatment with semaglutide should be discontinued if NAION is confirmed (see section 4.8 ADVERSE EFFECTS).

4.8 ADVERSE EFFECTS

Post-Market Adverse Effects

- Eye disorders: Non-arteritic anterior ischaemic optic neuropathy (NAION)

Cases of NAION have been reported with GLP-1 RAs, including semaglutide. A sudden loss of vision should lead to ophthalmological examination.

Dulaglutide and Tirzepatide

4.8 ADVERSE EFFECTS

Postmarketing data

Eye disorders - Events of non-arteritic anterior ischaemic optic neuropathy (NAION), a rare condition associated with the potential for decreased vision including permanent loss of vision, have been reported in patients treated with products with GLP-1 receptor agonist activity. A sudden loss of vision should lead to ophthalmological examination.

Liraglutide

4.8 ADVERSE EFFECTS

Post-marketing adverse effects:

Non-arteritic anterior ischaemic optic neuropathy (NAION): Cases of NAION have been reported with GLP-1 RAs, including liraglutide. A sudden loss of vision should lead to ophthalmological examination.

Please refer to the following website in TGA for details:

<https://www.tga.gov.au/news/safety-updates/glp-1-ras-and-rare-vision-disorder>

In Hong Kong, there are registered pharmaceutical products containing GLP-1 receptor agonists including dulaglutide (4 products), semaglutide (11 products), liraglutide (5 products), lixisenatide (2 products), exenatide (1 product) and tirzepatide (6 products). All products are prescription-only medicines. So far, the Department of Health (DH) has received 2 cases of adverse drug reaction with regard to tirzepatide, of which one case was reported as blurred vision. DH has also received adverse drug reaction cases with regard to dulaglutide (5 cases), semaglutide (11 cases), liraglutide (1 case), lixisenatide (1 case) and exenatide (2 cases), but these cases were not related to NAION or eye disorder.

Related news on the risk of NAION associated with semaglutide 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 18 Jan 2025, 7 Jun 2025 and 6 Feb 2026. Letters to inform local healthcare professionals were issued by DH on 9 Jun 2025. In light of the above TGA's announcement on update of product information across the GLP-1 RA drug class and as previously reported, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Clinical Trials and Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": <http://www.drugoffice.gov.hk/adr.html>. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,



(Clive CHAN)

for Assistant Director (Drug)