EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Media and Public Relations

News announcement

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 13-16 January 2025

Medicines containing semaglutide: PRAC investigating risk of rare eye condition
PRAC will assess risk of non-arteritic anterior ischemic optic neuropathy (NAION)

EMA's safety committee, the PRAC, has started a review of medicines containing semaglutide following concerns regarding an increased risk of developing NAION, a rare eye condition, as suggested in two recent observational studies, while two other recent observational studies do not suggest an increased risk.

Semaglutide, a GLP-1 receptor agonist, is the active substance in certain medicines used in the treatment of diabetes and obesity (namely Ozempic, Rybelsus and Wegovy).

The PRAC is assessing whether patients treated with semaglutide may have an elevated risk of developing NAION. This is a disorder caused by reduced blood flow to the optic nerve in the eye with potential damage to the nerve, which can lead to loss of vision in the affected eye. Patients with type 2 diabetes might already have an inherently higher risk of developing this condition.

The PRAC will now review all available data on NAION with semaglutide including data from clinical trials, post-marketing surveillance, studies on the mechanism of action and the medical literature (including the results of the observational studies).

EMA will communicate further when appropriate.

Related content:

- Chou CC, Pan SY, Sheen YJ, Lin JF, Lin CH, Lin HJ, Wang IJ, Weng CH. Association between Semaglutide and Non-Arteritic Anterior Ischemic Optic Neuropathy: A Multinational Population-Based Real-World Study. Ophthalmology. 2024 Nov 2: S0161-6420(24)00685-7. doi: 10.1016/j.ophtha.2024.10.030. Epub ahead of print. PMID: 39491755.;
- Klonoff DC, Hui G, Gombar S. Real-World Evidence Assessment of the Risk of Nonarteritic Anterior Ischemic Optic Neuropathy in Patients Prescribed Semaglutide. J Diabetes Sci Technol 2024: 19322968241268050.
- Grauslund, J., Abou Taha, A., Dehghani Molander, L., Kawasaki, R., Möller, S., Højlund, K., & Stokholm, L., Once-weekly semaglutide doubles the five-year risk of nonarteritic anterior ischemic optic neuropathy in a Danish cohort of 424,152 persons with type 2 diabetes, *International Journal of Retina and Vitreous*, accepted for publication.
- Emma Simonsen, Lars Christian Lund, Martin Thomsen Ernst, Vidar Hjellvik, Laszlo Hegedüs, Steffen Hamann, Øystein Kalsnes Jørstad, Hanne Løvdal Gulseth, Øystein Karlstad, Anton

Pottegård Use of semaglutide and risk of non-arteritic anterior ischemic optic neuropathy: A Danish–Norwegian cohort study (pre-print)

PRAC statistics: January 2025

[infographic]

Glossary:

Safety signal assessments. A safety signal is information which suggests a new potentially causal association, or a new aspect of a known association between a medicine and an adverse event that warrants further investigation. Safety signals are generated from several sources such as spontaneous reports, clinical studies and the scientific literature. More information can be found under 'Signal management'.

Periodic safety update reports, abbreviated as PSURs, are reports prepared by the marketing authorisation holder to describe the worldwide safety experience with a medicine in a defined period after its authorisation. PSURs for medicinal products that contain the same active substance or the same combination of active substances but have different marketing authorisations and are authorised in different EU Member States, are jointly assessed in a single assessment procedure. More information can be found under 'Periodic safety update reports: questions and answers'.

Risk management plans, abbreviated as RMPs, are detailed descriptions of the activities and interventions designed to identify, characterise, prevent or minimise risks relating to medicines. Companies are required to submit an RMP to EMA when applying for a marketing authorisation. RMPs are continually updated throughout the lifetime of the medicine as new information becomes available. More information is available under 'Risk-management plans'.

Post-authorisation safety studies, abbreviated as PASSs, are studies carried out after a medicine has been authorised to obtain further information on its safety, or to measure the effectiveness of risk-management measures. The PRAC assesses the protocols (aspects related to the organisation of a study) and the results of PASSs. More information can be found under 'Post-authorisation safety studies'.

Referrals are procedures used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral related to safety of medicines, the PRAC is requested by a Member State or the European Commission to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the EU. More information can be found under referral procedures.

Ongoing referrals

Procedure	Status	Update
Finasteride- and dutasteride-containing medicinal products - referral	Under evaluation	PRAC continued its assessment.

Notes

1. This press release, together with all related documents, is available on the Agency's website at: <LINK>
2. <Note>.
3. <Note>.

4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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