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Media and Public Relations

News announcement

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 2 – 5 June 2025

PRAC concludes eye condition NAION is a very rare side effect of semaglutide medicines

Treatment with semaglutide should be stopped if NAION occurs

EMA's safety committee (PRAC) has concluded its review of medicines containing semaglutide following concerns regarding a possible increased risk of developing non-arteritic anterior ischemic optic neuropathy (NAION), an eye condition that may cause loss of vision. 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).

After reviewing all available data on NAION with semaglutide, PRAC has recommended that the product information for semaglutide medicines is updated to include NAION as a side effect with a frequency of 'very rare' (it may affect up to 1 in 10,000 people). If patients experience a sudden loss of vision or rapidly worsening eyesight during treatment with semaglutide, they should contact their doctor without delay. If NAION is confirmed, treatment with semaglutide should be stopped.

More information is available in EMA's public health communication.

PRAC reviewing risk of encephalitis with varicella vaccines

EMA's safety committee (PRAC) is reviewing the known risk of encephalitis (inflammation of the brain) with two varicella (chickenpox) vaccines, Varilrix and Varivax, following a report of a fatal outcome after vaccination with Varilrix.

Varilrix and Varivax are authorised for vaccination of adults and children from 12 months of age, and in certain populations from 9 months of age, against chickenpox. They contain live attenuated (weakened) varicella virus.

Varicella is caused by the varicella-zoster virus, which also causes shingles (herpes zoster). Varicella mainly affects children aged 2-8 years where it is usually a mild disease and children recover quickly. In some cases, varicella can cause complications including bacterial infection of the skin or blood, pneumonia (infection and inflammation of the lungs) and encephalitis. Encephalitis can also be caused by other viral or bacterial infections. While most people with encephalitis recover, the condition can be life-threatening.

This review was initiated by the PRAC following a case report in Poland of a child who developed encephalitis a few days after receiving the Varilrix vaccine. The patient died of the consequences of encephalitis several days later. As a precaution, the Polish medicines agency has suspended the distribution of vaccines from the batch in question.

These vaccines are widely used across the EU, and encephalitis is listed as a side effect in their product information based on rare reports during post-marketing surveillance.

The committee will now assess all available evidence to better understand the risk of encephalitis and to determine if any regulatory action is necessary.

While EMA is investigating the issue, the vaccines can continue to be used in line with the approved product information.

PRAC statistics: June 2025

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.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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