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) 27 – 30 October 2025

PRAC agrees on a communication to healthcare professionals on injectable tranexamic acid medicines

New safety information for healthcare professionals

Injectable tranexamic acid: serious adverse reactions when inadvertently given intrathecally

PRAC agreed on a direct healthcare professional communication (DHPC) to remind healthcare professionals that extreme caution should be taken when handling and giving injectable tranexamic acid to ensure it is only given intravenously (into a vein). It must not be given intrathecally (into the fluid-filled space between the thin layers that cover the brain and spinal cord), epidurally (into the space between the wall of the spinal canal and the covering of the spinal cord), intraventricularly (into a fluid-filled cavity in the brain) or intracerebrally (into the brain).

Tranexamic acid, which blocks the breakdown of blood clots, is used in adults and children from 1 year of age to prevent and treat bleeding.

PRAC reviewed cases of medication errors, including reports from across the EU, where injectable tranexamic acid was mistakenly given either intrathecally or epidurally due to mix-ups with other medicines, mostly local anaesthetics. Intrathecal use resulted in serious side effects, including severe pain in the back, buttock and legs, seizures and cardiac arrhythmias (abnormal or irregular heartbeat), and in some cases death.

Healthcare professionals should take measures to prevent potential mix-ups between injectable tranexamic acid and other injectable medicines, especially those given intrathecally, that may be used during the same procedure, such as local anaesthetics.

To reduce the risk of medication errors, syringes containing tranexamic acid should be clearly labelled for intravenous use only. It is also advised to store injectable tranexamic acid separately from local anaesthetics.

The product information of injectable tranexamic acid medicines, including the outer packaging, will be updated to strengthen the warnings that these medicines must only be given intravenously.

The DHPC for injectable tranexamic acid will be forwarded to the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh). When adopted, the DHPC will be disseminated to healthcare professionals by the marketing authorisation holder, according to an agreed communication plan, and published on the Direct healthcare professional communications page and in national registers in EU Member States.

PRAC statistics: November 2025

[infographic]

Ongoing referrals

Procedure
Levamisole-containing medicinal products

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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