EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 October 2026

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 26 – 29 October 2026

PRAC starts review of depression and anxiety medicine Deanxit and a safety signal related to human normal immunoglobulin medicines

PRAC starts review of depression and anxiety medicine Deanxit (flupentixol/melitracen)

PRAC has started a review of Deanxit, a fixed-dose combination medicine for treating depression and anxiety, following reports of serious neurological and psychiatric side effects in patients taking the medicine.

The reports concern cases involving movement disorders, such as tremors, stiffness, restlessness and involuntary movements, and memory and thinking problems. In some cases, symptoms persisted after treatment was stopped.

More information is available in EMA's start of referral communication.

PRAC reviews increased reporting of allergic reactions with specific batches of human normal immunoglobulin medicines

PRAC has started a review of a safety signal concerning increased reporting of hypersensitivity (allergic) reactions associated with specific batches of human normal immunoglobulin medicines.

Human normal immunoglobulins are used to help prevent infections in people who do not have enough antibodies, including those with certain immune disorders or blood cancers. They are also used to treat some conditions in which the immune system attacks the body's own tissues.

Hypersensitivity reactions are a known side effect of these medicines. Their product information includes warnings that serious hypersensitivity reactions can occur, even in patients who have previously tolerated treatment. However, reports indicate that hypersensitivity reactions may be occurring more frequently than expected with specific batches of some human normal immunoglobulin medicines.

The reported cases include hypersensitivity reactions of varying severity, from rash and itching to serious and potentially life-threatening hypersensitivity reactions. These include anaphylaxis (a

sudden, severe allergic reaction) and angioedema (rapid swelling under the skin that can affect areas such as the face and throat). Clusters of these cases have led to recalls of specific batches of some of these medicines in recent months, including Flebogamma DIF, Yimmugo and Gamunex, in certain EU Member States. These batches have already been withdrawn from the market as a precautionary measure following increased reporting of hypersensitivity reactions.

Despite investigations to date, the cause of these clusters of hypersensitivity reactions has not yet been established. It is also not yet clear whether other human normal immunoglobulin medicines could be affected. The review undertaken by PRAC will therefore cover all human normal immunoglobulin medicines, regardless of how they are given, including those given into a vein (intravenously), under the skin (subcutaneously) or into a muscle (intramuscularly).

PRAC will request all relevant data from the companies marketing these medicines and assess it alongside the available evidence to investigate possible causes and evaluate whether further measures are needed to reduce the risk

Healthcare professionals are reminded to follow the existing warnings and precautions in the product information, including recommendations to monitor patients during treatment. Patients should seek medical attention without delay if they experience signs of a hypersensitivity reaction, such as rash, dizziness, palpitations, wheezing or difficulty breathing, even if they have not experienced such reactions during previous treatment. EMA will communicate further on the outcome of PRAC's review.