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News announcement

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 31 August – 3 September 2026

PRAC starts safety review of injectable iron-containing medicines

Review will assess risk of low blood phosphate levels and related bone problems with injectable iron medicines

EMA's safety committee, PRAC, has started a review of injectable iron-containing medicines following concerns about the risk of hypophosphataemia (low blood phosphate levels) and related bone problems, including osteomalacia (softening of the bones). Phosphate is important for keeping bones healthy. When phosphate levels become too low, osteomalacia can occur causing symptoms such as bone pain. In some cases, it can result in fractures.

Injectable iron-containing medicines are used to treat iron deficiency and iron deficiency anaemia (low red blood cell levels) when iron taken by mouth does not work well enough, cannot be used, or when iron levels need to be restored quickly.

Hypophosphataemia and hypophosphataemic osteomalacia (softening of the bones caused by low blood phosphate levels) are known side effects of injectable iron medicines containing the active substance ferric carboxymaltose. Hypophosphataemia is listed as a common side effect in the product information, meaning it affects up to 1 in 10 people taking the medicine. However, the frequency of hypophosphataemic osteomalacia is unknown because the available data do not allow an estimate of how often it occurs. The product information also includes measures to reduce the risk of hypophosphataemic osteomalacia including recommendations to monitor blood phosphate levels in people receiving high doses or long-term treatment and those with known risk factors.

The review was triggered following reports that raised concerns about the effectiveness of the current measures to reduce this risk for medicines containing ferric carboxymaltose. These included serious cases of hypophosphataemia, some of which resulted in osteomalacia, including in people who had received only one or two doses of ferric carboxymaltose and who did not have recognised risk factors. Furthermore, in some cases there were delays in diagnosing hypophosphataemia. This could be because symptoms of hypophosphataemia such as tiredness, muscle pain and bone pain may overlap with those of iron deficiency. In addition, the bone problems reported in these cases, such as osteomalacia, may not always be visible on X-rays.

As similar cases have also been reported with other injectable iron-containing medicines, the scope of the review covers all of these medicines rather than only those containing ferric carboxymaltose.

Iron-containing medicines taken by mouth are not included in the review because they provide considerably lower amounts of iron over time than injectable medicines and are therefore less likely to cause hypophosphataemia. PRAC will now review the risk of hypophosphataemia and related bone

disorders associated with injectable iron-containing medicines, as well as the effectiveness of existing measures to reduce these risks. The Committee will assess whether these risks affect the overall benefit-risk balance of the medicines and determine whether any changes to their marketing authorisations are needed.

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

Information on all topics discussed by the PRAC is available in the agenda.

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.