EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 April 2012
EMA/CHMP/262205/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rienso

Ferumoxytol

On 19 April 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rienso, 30 mg/ml, solution for injection intended for the intravenous treatment of iron deficiency anaemia in adult patients with chronic kidney disease (CKD). The diagnosis of iron deficiency must be based on appropriate laboratory tests. The applicant for this medicinal product is Takeda Global Research and Development Centre (Europe) Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Rienso is Ferumoxytol, a colloidal iron-carbohydrate complex. Upon release from the complex, the iron either enters the intracellular storage iron pool (e.g., ferritin) or is transferred to plasma transferrin for transport to erythroid precursor cells for incorporation into haemoglobin.

The benefits with Rienso are its ability to increase haemoglobin levels. The most common side effects are diarrhoea, nausea, constipation, headache, dizziness and hypotension.

A pharmacovigilance plan for Rienso will be implemented as part of the marketing authorisation.

The approved indication is: "Rienso is indicated for the intravenous treatment of iron deficiency anaemia in adult patients with chronic kidney disease (CKD). The diagnosis of iron deficiency must be based on appropriate laboratory tests (see section 4.2)".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Rienso and therefore recommends the granting of the marketing authorisation.