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Press Office

Press release

Reliance GeneMedix Plc. withdraws its marketing authorisation application for Epostim (erythropoietin)

The European Medicines Agency has been formally notified by Reliance GeneMedix Plc. of its decision to withdraw its application for a centralised marketing authorisation for the medicine Epostim (erythropoietin), 2000IU/0.5 ml, 4000IU/0.4 ml, and 10 000IU/ml solution for injection in pre-filled syringes.

This medicine was intended to be used for the following indications:

- treatment of anaemia associated with chronic renal failure in paediatric and adult patients on haemodialysis and adult patients on peritoneal dialysis,
- treatment of severe anaemia of renal origin accompanied by clinical symptoms in adult patients with renal insufficiency not yet undergoing dialysis,
- treatment of anaemia and reduction of transfusion requirements in adult patients receiving chemotherapy for solid tumours, malignant lymphoma or multiple myeloma,
- to increase the yield of autologous blood from patients in a predonation programme,
- to reduce exposure to allogenic blood transfusions in adult non-iron deficient patients prior to major elective orthopaedic surgery.

The application for the marketing authorisation for Epostim was submitted to the Agency on 29 October 2010. At the time of the withdrawal it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that its decision to withdraw the application was based on its inability to address the CHMP's request to provide additional data within the timeframe allowed in the centralised procedure.

More information about Epostim and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the

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withdrawal letter from the company, will be published on the Agency's website after the next CHMP meeting on 11 – 14 April 2011.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. The withdrawal of the application has no impact on the ongoing clinical trials with Epostim.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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