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Questions and answers

Withdrawal of the marketing authorisation application for Epostim (epoetin alfa)

On 15 March 2011, Reliance GeneMedix Plc officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Epostim to be used to treat anaemia and stimulate red blood cell production.

What is Epostim?

Epostim is a solution for injection that contains the active substance epoetin alfa.

Epostim was developed as a 'biosimilar' medicine. This means that Epostim was intended to be similar to a biological medicine that is already authorised in the European Union (also known as the 'reference medicine') and contains the same active substance. The reference medicine for Epostim is Eprex. For more information on biosimilar medicines, see the question-and-answer document here.

What was Epostim expected to be used for?

Epostim was expected to be used in the following situations:

- to treat anaemia (low red blood cell counts) that is causing symptoms in adults and children with 'chronic renal failure' (long-term, progressive decrease in the ability of the kidneys to work properly);
- to treat anaemia in adults receiving chemotherapy for certain types of cancer and to reduce their need for blood transfusions;
- to increase the amount of blood that can be taken from patients who are going to need the blood after surgery (autologous blood transfusion);

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- to reduce the need for blood transfusions in non-iron deficient patients who are about to undergo major orthopaedic (bone) surgery.

How is Epostim expected to work?

A hormone called erythropoietin stimulates the production of red blood cells from the bone marrow. Erythropoietin is produced by the kidneys. In patients receiving chemotherapy or with kidney problems, anaemia can be caused by a lack of erythropoietin, or by the body not responding enough to the erythropoietin. In these cases, erythropoietin is used to replace the missing hormone or to increase red blood cell counts. Erythropoietin is also used before surgery to increase the number of red blood cells and help minimise the consequences of blood loss.

The active substance in Epostim, epoetin alfa, is a copy of human erythropoietin and was expected to work in exactly the same way as the natural hormone to stimulate red blood cell production. The epoetin alfa in Epostim is produced by a method known as 'recombinant DNA technology': it is made by a cell that has received a gene (DNA), which makes it able to produce it.

What did the company present to support its application?

The effects of Epostim were first tested in experimental models before being studied in humans. In a main study in 75 adults with anaemia caused by kidney problems, patients were treated with Epostim and their blood levels of haemoglobin (a protein in red blood cells) measured to see how much their anaemia improved. This was then compared with results reported in the scientific literature.

A second main study in 188 kidney patients compared Epostim with the reference medicine Eprex. This study is still ongoing and aims to show that Epostim has the same effect on maintaining haemoglobin levels as Eprex.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn before 'day 120'. This means that the CHMP was still evaluating the initial documentation provided by the company.

What was the recommendation of the CHMP at that time?

As the CHMP was evaluating the initial documentation provided by the company, it had not yet made any recommendations.

What were the reasons given by the company for withdrawing the application?

The letter from the company notifying the Agency of the withdrawal of the application is available under the tab 'All documents'.

What consequences does this withdrawal have for patients in clinical trials or compassionate use programmes?

The company informed the CHMP that here are no consequences for patients currently in clinical trials using Epostim. If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.