European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 23 July 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
RATIOEPO

International Nonproprietary Name (INN): ***epoetin theta***

On 23 July 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Ratioepo, 1000 IU/0.5 ml, 2000 IU/0.5 ml, 3000 IU/0.5 ml, 4000 IU/0.5 ml, 5000 IU/0.5 ml,10000 IU/1.0 ml, 20000 IU/1.0 ml, 30000 IU/1.0 ml, solution for injection intended for the treatment of symptomatic anaemia associated with chronic renal failure in adult patients and in adult cancer patients with non-myeloid malignancies receiving chemotherapy. The applicant for this medicinal product is Ratiopharm GmbH.

The active substance of Ratioepo is epoetin theta, a recombinant human erythropoetin. Ratioepo is an antianaemic medicinal product that stimulates the proliferation and differentiation of red blood cell progenitors, leading to more red blood cells and increased oxygen-carrying capacity.

The benefit with Ratioepo is its correction of anaemia in adult patients with chronic renal failure and in adult cancer patients with non myeloid malignancies receiving chemotherapy. The most common side effects are hypertension, influenza-like illness and headache.

A pharmacovigilance plan for Ratioepo, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: Treatment of symptomatic anaemia associated with chronic renal failure in adult patients and treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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