



London, 26 June 2007



## **PRESS RELEASE**

### **EMA recommends a new warning for epoetins for their use in cancer patients**

The European Medicines Agency (EMA) has recommended updating the product information for epoetin-containing medicines with a new warning for their use in cancer patients stating that blood transfusion should be the preferred method of correcting anaemia in patients suffering cancer. Epoetin-containing medicines are indicated in patients with chronic renal failure and for the treatment of anaemia in symptomatic patients with non-myeloid tumours receiving chemotherapy.

The Agency's Committee for Medicinal Products for Human Use (CHMP) had reviewed new data from studies that showed an increased risk of tumour progression, venous thromboembolism and shorter overall survival in cancer patients who received epoetins compared to patients who did not receive them. Following this review, the CHMP concluded, at its June 2008 meeting, that the benefits of epoetins continue to outweigh their risks in the approved indications. However, in cancer patients with a reasonably long life-expectancy, the benefit of using epoetins does not outweigh the risk of tumour progression and shorter overall survival and therefore the Committee concluded that in these patients anaemia should be corrected with blood transfusions.

Doctors and patients are advised that the decision to administer epoetin-containing medicines should be based on an informed assessment of the benefits against the risks on individual basis, taking into account the type and stage of tumour, the degree of anaemia, the patient's life-expectancy, the environment in which the patient is being treated and patient preference.

The Committee agreed that there is no consequence of the new information on the use of epoetin-containing medicines for the treatment of anaemia in patients with chronic renal failure.

The Agency is closely monitoring the safety of epoetin-containing medicines. In September 2007 a full safety review of all epoetins was finalised. As a consequence, the product information was updated and the indication for all the epoetin-containing medicines was changed to state that epoetins should be used in the treatment of anaemia only if associated with symptoms such as weakness and lack of energy.

The CHMP will continue to review the safety profile of the epoetins within the terms of their currently authorised indications in the EU as additional data become available.

The CHMP also requested that the marketing authorisation holders for epoetin-containing medicines should carry out, as a priority, additional studies to clarify the risks and benefits of epoetins in the treatment of patients with cancer under the new treatment recommendations.

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Notes:

1. More information is available in a question-and-answer document.
2. Epoetin-containing medicines are approved at the level of Member States. Epoetin-containing medicines available in the European Union contain epoetin alfa (Abseamed, Binocrit, Epoetin Alfa Hexal, Eprex, Erypo), darbepoetin alfa (Aranesp, Nespo), epoetin beta (NeoRecormon), methoxy polyethylene glycol-epoetin beta (Mircera), epoetin delta (Dynepo) and epoetin zeta (Retacrit, Silapo). All of these medicines, except Mircera and Dynepo, are approved for the treatment of anaemia in cancer patients and patients with chronic renal failure.
3. Further information on the outcome of the review of epoetins finalised in September 2007 can be found [here](#).
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: [www.emea.europa.eu](http://www.emea.europa.eu)

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