

Addendum to chapter 7

(Anaemia in patients with chronic renal failure)

IMPORTANT INFORMATION CONCERNING EPOIETIN ALFA

In Chapter 7, paragraph 11, we state:

"A proportion of patients (15-20% of all those treated) fail to respond adequately with the expected rise in haemoglobin concentration within six months, and require higher doses than anticipated. An evidence-based definition of hypo-responsiveness ("resistance") to epoetin is > 300 IU/Kg/week (95th centile). Such patients require investigation and (if possible treatment) for haemoglobinopathies, iron deficiency, malignancies, inflammatory diseases, hyperparathyroidism, aluminum intoxication and a number of rarer conditions, as well as effects of drugs such as ACE inhibitors. A European directive noted that resistance leading on to pure red cell aplasia has been reported in about 1:10,000 of patients treated with epoetin alpha. In such patients epoetin should be stopped and anti-erythropoietin antibodies sought. Further advice on usage of epoetin alpha is awaited."

Further information is now to hand regarding Epoetin alpha and pure red cell aplasia. Full information appears on the Medicines Control Agency website: <http://www.mca.gov.uk> under the heading "our work" and the subheadings "monitoring the safety and quality of medicines" and "important safety messages".

The current (12 December 2002) summary advice to subscribers is as follows:

“Advice to prescribers:

- Patients who are currently receiving Eprex subcutaneously for anaemia associated with chronic renal disease should have their treatment changed at the next convenient opportunity. Subcutaneous administration of Eprex should then cease. Eprex may still be administered intravenously to these patients.
- If intravenous administration of Eprex is not feasible, appropriate alternative treatment should be given.
- In other approved indications there is no evidence to date of an increased risk of PRCA, and Eprex may continue to be administered subcutaneously.”