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First biosimilar epoetin secures EU recommendation

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Retacrit is to become the first biosimilar of epoetin to achieve a subcutaneous licence in renal patients.
The biosimilar, manufactured by Hospira, received a positive opinion from the CHMP for subcutaneous (SC) use in renal anaemia.

Once approved by the European Commission (EC), Retacrit will be the first biosimilar epoetin (EPO) for SC and intravenous (IV) administration in the nephrology setting.

This new recommendation supplements the existing licence of Retacrit IV administration in renal anaemia, plus SC administration in anaemia associated with cancer chemotherapy.

“As part of Hospira’s continued commitment to expand biosimilar options for patients, we are pleased that Retacrit is the first biosimilar epoetin to get a recommendation from the CHMP for subcutaneous administration in the nephrology setting,” said Michael Kotsanis, Hospira’s President of Europe, Middle East and Africa.

“Once approved by the European Commission, Retacrit will be suitable for subcutaneous as well as intravenous administration in the nephrology setting. This will give clinicians greater flexibility in managing symptomatic anaemia in their renal patients and provide healthcare professionals with a cost-effective alternative to originator epoetins.”

Biosimilars can provide a more cost-effective option than originator brands and so help to reduce healthcare costs. The European Generic Medicines Association estimates that biosimilar competition resulting in a 20% price reduction in five off-patent biopharmaceuticals could save the EU over €1.6 billion per year.
Kees Groenhout, Vice President of Global Clinical R&D, Hospira, added: “The approval will be a significant step forward, because patients who aren’t yet on haemodialysis can be treated with Retacrit at home. Many will also be able to self-inject Retacrit for the first time. For several reasons, subcutaneous administration can conserve hospital resources and save valuable time for patients, too.”

The recommendation of Retacrit is based on data from a rigorous Phase III clinical trial demonstrating comparable efficacy and safety between epoetin zeta and the reference product, epoetin alfa, when administered subcutaneously in patients with end-stage renal failure on chronic haemodialysis.