

FDA recommends lower doses of anemia drugs

June 24 2011, By MATTHEW PERRONE , AP Health Writer

(AP) -- Food and Drug Administration officials say doctors should use lower doses of anemia drugs when treating patients with failing kidneys due to the increased risk of stroke, blood clots and death.

The new warnings announced Friday are the latest to hit the widely used medications since 2007, when the [Food and Drug Administration](#) first linked them to fatal side effects.

The medicines - Procrit, Aranesp and Epogen - are multibillion-dollar sellers because of their ability to boost oxygen-carrying [red blood cells](#), reducing the need for painful blood transfusions. But a study published in 2009 suggested they could double the risk of stroke. Doctors had previously assumed that higher doses would help prevent [heart attack](#), stroke and other [cardiovascular problems](#).

All three of the drugs are manufactured by biotech giant Amgen Inc., while Procrit is sold by Johnson & Johnson

Doctors must adjust each patient's dosing to maintain healthy levels of hemoglobin, a component of blood that carries oxygen and helps keep [anemia](#) patients active. Anemia causes weakness and shortness of breath and is a side effect of chemotherapy and kidney failure. FDA's announcement specifically deals with patients who are not yet on dialysis, the treatment for late-stage kidney failure.

The old labeling for the drugs recommended keeping patients'

hemoglobin levels between 10 grams and 12 grams per deciliter.

The new label does away with that specific target range, stating only that doctors should begin using the drugs if patients' hemoglobins fall below 10 grams per liter.

"The goal is to individualize therapy and use the lowest dose possible to reduce the need for red blood cell transfusions," said Dr. Robert Kane, of FDA's division of hematology products. Kane said there is no way to make an all-purpose dosing recommendation that covers all patients.

More than 20 million people in the U.S. have chronic kidney disease, according to the Centers for Disease Control and Prevention.

Deutsche Bank analyst Robyn Karnauskas said most investors have already priced the labeling changes into sales expectations. Wall Street analysts generally expect sales of the drugs to decline by 8 percent in 2012, Karnauskas said in an email.

Amgen, based in Thousand Oaks Calif., licenses Procrit to Johnson & Johnson's Centocor Ortho Biotech division, under a long-standing agreement between the companies.

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