

Appendix 4

Sandoz receives European Commission approval for biosimilar filgrastim^{1,*}

Novartis Media releases

Sandoz has received final approval for its third biosimilar, filgrastim, paving the way for this important oncology medicine to be made available to patients across the European Union.

Filgrastim is indicated for the treatment of neutropenia, a condition characterized by a lack of neutrophils – one of the most common types of white blood cells – whose role is to fight infection in the body. Neutropenia is often associated with chemotherapy or bone marrow transplants, as well as advanced HIV infections. Filgrastim is a natural protein produced commercially by recombinant DNA technology, which stimulates production of white blood cells. The Sandoz product is approved for the same range of indications as the reference product, Neupogen[®] and offers patients comparable quality, safety and efficacy combined with greater cost-effectiveness. The novel Sandoz filgrastim needlestick protection device decreases the risks of injury and exposure to blood-borne infection, thus contributing significantly to protecting health professionals.

Sandoz CEO Jeff George says: “As the pioneer of biosimilars and a company with a global reputation for offering high-quality medicines at affordable prices to patients and payors worldwide, Sandoz is looking forward to providing this important new cost-effective option for oncology patients. Filgrastim particularly helps patients receiving chemotherapy to increase their neutrophil counts, meaning they can better avoid the risk of the serious life threatening infections that so often force clinicians to change their optimal therapeutic chemotherapy regimen, dose or schedule”.

Sandoz is the only company with marketing authorization for more than one biosimilar medicine. In a precedent-setting decision in April 2006, Sandoz received the first-ever EU approval for a biosimilar medicine, human growth hormone Omnitrope[®]. Binocrit[®]/Epoetin alfa Hexal[®], the first follow-on erythropoetin and the first complex (glycoprotein) biosimilar, was approved in the EU in August 2007 and launched the same year. Sandoz has a comprehensive biopharmaceuticals pipeline, with numerous projects at various stages of development.

The European Commission approval followed a positive opinion issued in November by the European Medicines Agency’s Committee on Medicinal Products for Human Use (CHMP), which provides scientific reviews of medicines for the Commission.

¹ Available at: <http://www.novartis.com/newsroom/media-releases/en/2009/1290168.shtml>. Last accessed 15 February 2009. Republished with permission.

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