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Questions and answers on Genotropin and associated names (somatropin injection)

Outcome of a procedure under Article 6(12) of Regulation (EC) 1084/2003 as amended

The European Medicines Agency has completed an arbitration procedure for Genotropin and associated names. The Agency's Committee for Medicinal Products for Human Use (CHMP) had been asked to arbitrate on a change to the marketing authorisation for Genotropin to include a new indication for the treatment of stunted growth caused by the long-term use of steroids in children with juvenile idiopathic arthritis. The Committee concluded that the change to the marketing authorisation cannot be granted.

What is Genotropin?

Genotropin is a medicine that contains somatropin, which is a copy of natural growth hormone. Growth hormone promotes growth during childhood and adolescence, and also acts on the way the body handles proteins, fat and carbohydrates. Genotropin is used as replacement therapy in children and adults who have a growth hormone deficiency. It is also used to correct short height in children who have the genetic diseases Turner syndrome and Prader Willi syndrome, and in children who have long-standing kidney problems. Somatropin is produced by a method known as 'recombinant DNA technology': it is made by an organism that has received a gene (DNA), which makes it able to produce growth hormone.

Genotropin, also marketed under the trade name Genotonorm, is available throughout the European Union (EU). The company that makes the medicine is Pfizer.

Why was Genotropin reviewed?

In 15 Member States of the EU, Genotropin is authorised under a mutual recognition procedure on the basis of the initial authorisation granted by Denmark on 7 May 1987¹. In July 2008, Pfizer applied for a change (variation) to the marketing authorisation to add a new indication in Denmark (the 'reference Member State'). This variation was to be recognised in Austria, Belgium, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden and the United Kingdom

¹ In all other Member States of the EU, the medicine has received a marketing authorisation at national level. These national marketing authorisations are not affected by this referral.



(the 'concerned Member States'). The new indication was the use of Genotropin in children on long-term treatment with steroids for juvenile idiopathic arthritis (JIA), a rare childhood disease causing inflammation of many joints. Genotropin was to be used to improve growth and body composition in children with severe JIA in whom the prolonged use of steroids to help control inflammation had led to a slowing down of growth. Because the Member States were not able to reach an agreement, the Netherlands referred the matter to the CHMP for arbitration on 28 October 2009.

The grounds for the referral were that fewer patients currently need to use steroids than in the past, because other medicines that do not affect growth have become available to control JIA. Another point was the fact that the company had presented too few data on the final height reached by the patients in the studies.

What are the conclusions of the CHMP?

The Committee looked at the studies presented by the company to support the new indication. It also looked at published information on the use of growth hormone in patients with JIA, and convened a meeting of experts, which included experts both in the treatment of hormonal disorders (endocrinologists) and in the treatment of joint diseases (rheumatologists).

Based on the evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that the variation to the marketing authorisation for Genotropin cannot be approved in Denmark as well as in all concerned Member States.

The European Commission issued a decision on 02 September 2010.

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