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Questions and answers on Norditropin and associated names (somatropin, 5 mg, 10 mg and 15 mg/1.5 ml solution for injection)

Outcome of a procedure under Article 13 of Regulation (EC) 1234/2008

The European Medicines Agency has completed an arbitration procedure for Norditropin and associated names. The Agency's Committee for Medicinal Products for Human Use (CHMP) had been asked to arbitrate on a requested change to the marketing authorisation for these medicines to include a new indication for use in children with Prader-Willi syndrome. The Committee concluded that the change to the marketing authorisation cannot be granted.

What is Norditropin?

Norditropin is a medicine that contains somatropin, which is a copy of naturally occurring human growth hormone. Growth hormone promotes growth during childhood and adolescence, and also affects the way the body handles proteins, fat and carbohydrates.

Norditropin is used as replacement therapy in children and adults who have a growth hormone deficiency. It is also used to correct short height in girls who have the genetic disease called Turner syndrome, in children who have long-standing kidney problems, and in children born small for their gestational age and who have not caught up by the age of four.

The somatropin in Norditropin is produced by a method known as 'recombinant DNA technology': it is made by an organism that has received a gene (DNA), which makes the organism able to produce it.

Norditropin is marketed in the EU Member States under the names Norditropin FlexPro, Norditropin NordiFlex, Norditropin SimpleXx and associated names. The company that makes the medicine is NovoNordisk.

Why was Norditropin reviewed?

Norditropin is authorised under a mutual recognition procedure based on an initial authorisation granted by Denmark. In May 2010, the company applied for an additional indication in Denmark and in the following Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the

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Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom[1]. The new indication was for the use of Norditropin in children with Prader-Willi syndrome, a rare genetic disease that affects children's growth and development. Although somatropin medicines are already approved in EU Member States for use in Prader-Willi syndrome, the Member States were unable to reach agreement on whether to accept this indication for Norditropin. On 20 April 2011, Denmark referred the matter to the CHMP for arbitration.

The grounds for the referral were the concerns of some Member States that the data on Norditropin submitted in the application were not sufficient to demonstrate its effectiveness in Prader-Willi syndrome. The Member States cited methodological weaknesses in the study presented, the wide range of doses used and insufficient data (e.g. missing data on body composition measurements).

What are the conclusions of the CHMP?

The Committee looked at the study presented by the company to support the new indication.

Based on the evaluation of the currently available data and the scientific discussion within the Committee, the CHMP agreed that the data were insufficient and that the study presented, which was an observational study, did not meet required methodological standards. The CHMP therefore recommended that the new indication for Norditropin and associated names should not be granted in Denmark or in the concerned Member States.

The European Commission issued a decision on 06 March 2012.

[1] In May 2011 the marketing authorisations of the concerned products were withdrawn in Estonia, and in June 2011 the marketing authorisations of the concerned products were withdrawn in Latvia.