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Human Medicines Development and Evaluation

Public statement on

Valtropin (somatropin)

Withdrawal of the marketing authorisation in the European Union

On 24 April 2006 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Valtropin (somatropin), which had been approved for the treatment of children in the following situations:

- children from two years of age and adolescents who fail to grow because they lack growth hormone (replacement therapy);
- children who are short because of Turner syndrome (a rare genetic disorder affecting girls), confirmed by chromosome analysis (DNA testing);
- children before puberty, who fail to grow because of longstanding kidney disease (chronic renal insufficiency).

Valtropin was also approved for the treatment of adults with pronounced growth hormone deficiency, which has started in adulthood or childhood and needs to be confirmed by testing before treatment (replacement therapy).

The marketing authorisation holder (MAH) responsible for Valtropin was BioPartners GmbH. The European Commission was notified by a letter dated 31 October 2011 of the MAH's decision to voluntarily withdraw the marketing authorisation for commercial reasons. Valtropin was not marketed in any EU country.

On 10 May 2012 the European Commission issued a decision to withdraw the marketing authorisation for Valtropin.

Pursuant to this decision the European Public Assessment Report for Valtropin will be updated to reflect that the marketing authorisation is no longer valid.

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