資料1

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Press Office

Press release

European Medicines Agency to review the safety of somatropin-containing medicines

The European Medicines Agency is starting a review of the safety of somatropin-containing medicines authorised centrally or by national procedures in the European Union. The review will look into all available data on somatropin to reassess the benefit-risk balance of these medicines.

This review is being initiated further to information received from the French medicines agency on a long-term epidemiological study in patients treated during childhood with somatropin-containing medicines. The study results suggest an increased risk of mortality with somatropin therapy compared to the general population. The risk appears to be particularly increased when high doses are used (beyond doses as recommended in the Summary of Product Characteristics). The study looked at patients treated during childhood for growth hormone deficiency or short stature of unknown cause. Based on this observational study alone, the risk cannot be associated with certainty to the growth hormone treatment. The results need to be confirmed and complemented with further analyses.

Somatropin is a human growth hormone, manufactured using recombinant DNA technology. It promotes growth during childhood and adolescence, and also affects the way the body handles proteins, fat and carbohydrates.

Somatropin is used to treat a number of conditions associated with a lack of growth hormone and short stature. This includes children who fail to grow due to a lack of growth hormone, Turner syndrome or chronic renal insufficiency.

The Agency will provide further information on this review after the CHMP plenary meeting of 13-16 December 2010. In the meantime, the Agency is reminding prescribers to strictly follow the indications and the approved doses.

Notes

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1. This press release, together with all related documents, is available on the Agency's website at: http://www.ema.europa.eu/ema/index.jsp?curl=/pages/news_and_events/news/2010/12/news_detail_001160.jsp&murl=menus/news_and_events/news_and_events.jsp&mid=WC0b01ac058004d5c1
2. There are three centrally authorised somatropin medicines in the EU: NutropinAq, Omnitrope and Valtropin. More information on these medicines can be found in the European public assessment report available on the Agency's website.
3. Several other somatropin medicines have been authorised through national procedures throughout the EU.
4. The French safety study, “Santé Adulte GH Enfant” (SAGhE), had been initiated in October 2007 and aims at improving the knowledge on recombinant growth hormone and evaluating the health of young adults who have been treated during childhood with recombinant growth hormone. Using the national compulsory France-Hypophyse register, investigators of the SAGhE study identified more than 10,000 young adults who started a recombinant growth hormone treatment between 1985 and 1996. The available analysis covers approximately 7,000 of these patients.
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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