European Medicines Agency
Press office

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Press release
European Medicines Agency adopts first positive opinion for a similar biological medicinal product

The European Medicines Agency has adopted the first positive opinion for a similar biological medicinal product. The product, Omnitrope, is manufactured by Sandoz GmbH and contains somatropin, a recombinant-DNA growth hormone. It is intended for the treatment of growth disturbance and growth hormone deficiency in children and adults.

The Agency's scientific committee, the Committee for Medicinal Products for Human Use (CHMP) adopted the opinion at its meeting of 23-26 January 2006. The Committee considered that, in accordance with European Union requirements, Omnitrope has been shown by studies demonstrating comparable quality, safety and efficacy to be similar to a reference medicinal product already authorised in the EU, namely Genotropin.

The European Commission and European Medicines Agency have worked actively over a number of years to put in place a legal and regulatory framework for similar biological medicinal products. The first guidelines on quality, non-clinical and clinical issues were adopted by the CHMP in December 2003. A general regulatory guideline on similar biological medicinal products was adopted in September 2005.

Further guidelines, including guidance on specific classes of products, are planned for adoption during the first quarter of 2006. A conference was held in Paris in December 2005 as part of the public consultation process.

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NOTES:

1. A summary of opinion for Omnitrope has been published and can be found here.
2. Similar biological medicinal products may be authorised on the basis of appropriate non-clinical and clinical data requirements. This is based on the experience gained with the reference medicinal product, against which appropriate studies and comparisons are made. However, compared with generics, in the case of similar biological medicinal products, substantial additional data, in particular the toxicological and clinical profile, have to be provided.
3. The adopted EMEA guidelines are available here and the draft guidelines available here. A further set of draft concept papers relating to specific classes of products is also available here.
4. This press release, together with other information on the work of the European Medicines Agency, can be found on the EMEA website: http://www.emea.eu.int

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