Ten years of biosimilar recombinant human growth hormone in Europe

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Abstract: Recombinant human growth hormone (rhGH) has been in clinical use for more than 30 years. With the expiration of patent exclusivity for the first wave of rhGH products and other biopharmaceuticals, the opportunity emerged for the development of biosimilar medicines. A biosimilar is defined by the European Medicines Agency (EMA) as a biological medicine that is similar to another biological medicine that has already been authorized for use. The EMA led the way (well ahead of the Food and Drug Administration in the US) in developing the biosimilar concept, and the type of science-based regulatory framework required to ensure high-quality, safe, and effective biosimilar medicines; the provisions for approval of biosimilars have been in place in Europe since 2005. Under these provisions, Omnitrope® was approved by the EMA in 2006 as the world’s first biosimilar medicine; 2016 therefore marks the 10th anniversary of its approval in Europe. A substantial data set, based on clinical development studies and 10 years of postapproval use, has now accumulated for biosimilar rhGH; this data set shows that the product is an effective treatment option for children who require rhGH treatment, and has a safety profile that is consistent with the rhGH class. The decade since the EMA approved biosimilar rhGH has seen the successful approval and clinical use of 20 biosimilar medicines, confirming the integrity of the scientific basis for the biosimilar concept, as well as the quality of regulatory decision-making.

Keywords: recombinant human growth hormone, Omnitrope®, biosimilar

Introduction
Recombinant human growth hormone (rhGH) has been in clinical use for more than 30 years since the approval of the first product in the mid-1980s in the US.1,2 Before the development of recombinant DNA technology, GH for replacement therapy could be obtained only by extraction and purification from cadaveric human pituitary glands (Figure 1). Supply was therefore scarce, and GH replacement therapy was reserved for only the most severe cases of growth hormone deficiency (GHD).1 The advent of a plentiful supply of rhGH was an important milestone, enabling treatment of more children (and subsequently adults) with GHD and expansion of use to other indications.

With the expiration of patent exclusivity for the first wave of rhGH products and other biopharmaceuticals, the opportunity emerged for the development of biosimilar medicines.3,4 A biosimilar is defined by the European Medicines Agency (EMA) as a biological medicine that is similar to another biological medicine that has already been authorized for use. The EMA led the way in developing the biosimilar concept, and the type of science-based regulatory framework required to ensure high-quality, safe, and effective biosimilar medicines; the provisions for approval of biosimilars have...
Summary

Data from clinical development studies and a decade of postapproval experience affirm that biosimilar rhGH is an effective treatment option for children who require rhGH treatment, and has a safety profile that is consistent with the rhGH class. The decade since the EMA approved biosimilar rhGH has seen the successful approval and clinical use of 20 biosimilar medicines, confirming the integrity of the scientific basis for the biosimilar concept, as well as the quality of regulatory decision-making.

Acknowledgment

Medical writing assistance was provided by Tony Reardon of Spirit Medical Communications Ltd, funded by Sandoz GmbH.

Disclosure

PS has acted as an advisor for, and received lecture fees from, Sandoz. The author reports no other conflicts of interest in this work.
References