



11th January 2010

Jeremy Powell
National Institute for Health and Clinical Excellence
MidCity Place
71 High Holborn
London
WC1V 6NA

Dear Mr Powell,

Re: Human Growth Hormone for the treatment of growth failure in children

Thank you for allowing Novo Nordisk to comment on the Appraisal Consultation Document (ACD) for the above review. We have the following comments regarding the ACD under the appropriate headings.

I. Do you consider that all of the relevant evidence has been taken into account?

Novo Nordisk believes that the committee has fairly concluded that sufficient evidence was available to demonstrate the efficacy of somatropin. Nevertheless, more long-term evidence (including final height data) would have been available for consideration had the Assessment group expanded the inclusion criteria of its systematic review to include dose-ranging studies. This would have been appropriate in this instance as long-term RCTs comparing somatropin with a placebo/untreated group are considered unethical.

II. Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence and that the preliminary views on the resource impact and implications for the NHS are appropriate?

Novo Nordisk is pleased that the committee has acknowledged the difficulties associated with the calculation of utility scores to reflect the impact of short stature and the benefits of somatropin other than height gains. We therefore believe that it is appropriate that the committee has concluded that the true cost-effectiveness of somatropin is likely to fall within the range normally considered acceptable.

In section 4.2.17, the cost per cm gained for small for gestational age is stated to be £9697. However, as pointed out in our comments on the Assessment report, this calculation is based on 1 year of height gains and 6 years of treatment costs. The cost per cm gained using comparable time horizons for costs and benefits should be presented.

Please note that as of 1st January 2010 the price of Norditropin SimpleXx reduced from £21.39/mg to £21.27/mg.

Novo Nordisk Ltd.

Broadfield Park
Brighton Road
Crawley
West Sussex RH11 9RT
United Kingdom

Telephone:

██████████

Direct dial:

██████████

Telefax:

██████████

E-mail:

██████████@novonordisk.com

Internet:

www.novonordisk.co.uk

CVR Number:

1118740

III. Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?

Yes, Novo Nordisk believes that the committee has come to a fair conclusion based on the evidence. We would also like to suggest that 2013 is too soon to consider the review of this guidance, given that the evidence base is unlikely to change significantly by such time.

IV. Are there any equality related issues that may need special consideration?

No

We are pleased that NICE has recognised the important benefits of human growth hormone for the treatment of growth failure in children and welcome the recommendations set out in the ACD. If you have any further questions regarding our response, or any other matters please do not hesitate to contact me.

Yours sincerely


@novonordisk.com