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Date 11th January 2010
Division/Dept. Health and Clinical Excellence
Care of
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Your letter
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Dear Jeremy,

Comments on the Appraisal Consultation Document (ACD) – Human Growth Hormone for the treatment of growth failure in children (review)

Merck Serono appreciates the opportunity to comment on the ACD. We feel that it is a thorough consideration of the evidence on clinical and cost effectiveness of Human Growth Hormone (HGH) in this setting and welcome the positive recommendations. We would like to provide minor comments on a few areas: the description of biosimilars; long term studies on the effectiveness of growth hormone; the manufacturer's model; the utilities used in the model; the review date for the guidance.

Description of biosimilars

In sections 4.3.5 and 4.36 the Institute gives a description around biosimilars, and states that 'making specific recommendations around the safety of a drug was outside the remit of NICE.' Although Merck Serono agree with this statement, we feel that it may be helpful to record the official description of biosimilars as per the BNF for scientific accuracy.

In the BNF no. 58 it states that 'a biosimilar medicine is a new biological product that is similar to a medicine that has already been authorised to be marketed (the biological reference product) in the European Union. The active substance of a biological medicine is similar, but not identical, to the reference medicine. Biological products are different from standard chemical products in terms of their complexity and although theoretically there should be no meaningful differences between the biosimilar and the biological reference medicine in terms of safety or efficacy, when prescribing biological products, it is good practice to use the brand name. This will ensure that automatic substitution of a biological medicine does not occur when the medicine is dispensed.'

Long term effectiveness studies

Although there is a lack of studies published examining the long-term effectiveness of HGH in these indications as noted in the ACD, there are a few long-term observational databases available. These include KIGS (Kabi International Growth) database, which has been used in the manufacturer model and mentioned by the Institute in the ACD.

The manufacturers' model

There are two points of accuracy we want to bring to the Institute's attention. Firstly under 4.2.5 it states that the model was based upon the one for NICE Technology Appraisal Guidance 42. In fact the model submitted in the review was constructed de novo to incorporate analysis of QALYs gained as requested in the NICE reference case. Secondly Merck Serono did not produce their own version of the model. The only aspect that differed from the core model was the costs were adjusted in the main analysis presented to take into account the potential waste elimination benefit of the Easypod™ delivery device

The utilities and costs in the model

Merck Serono appreciate that the Institute has acknowledged the difficulties in finding utilities relevant for the analysis of the cost-effectiveness of HGH, and particularly that our conservative approach could not account for the additional benefits such as those on self-esteem and body composition. Therefore it was appropriate for social value judgements to be applied.

The review date for this appraisal

Merck Serono feel that a review date of May 2013 will likely be too early for this appraisal. We would suggest that 2014 may be more appropriate.

If you require any further information regarding the points outlined in this letter, please don't hesitate to contact me.

Best wishes,

[redacted]
[redacted], Merck Serono Ltd.

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