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11<sup>th</sup> January 2010

Jeremy Powell  
Technology Appraisal Project Manager  
National Institute for Health and Clinical Excellence  
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Dear Jeremy

**Human Growth Hormone (somatropin) for the treatment of growth failure in children.**

Thank you for sending us the Appraisal Consultation Document (ACD) on Humatrope (somatropin) for the treatment of growth failure in children and for the opportunity to comment on it.

We are pleased with the recommendations made by the Committee as set out in the ACD and look forward to a positive final recommendation from NICE after the second Appraisal Committee meeting.

We are also happy that the Committee concluded that there is sufficient evidence to demonstrate the efficacy of somatropin in promoting growth in children. RCTs are generally not appropriate to capture long term outcomes. This is particularly the case in growth failure where longer term outcomes such as final height need extensive follow up. The recommendation from NICE that further research is needed to collect long term evidence should take a more pragmatic approach allowing for observational studies such as the KIGS database to be considered.

The Committee acknowledged a purely 'utility' based approach is likely to underestimate the true impact of treatment on the health and wellbeing of individuals with growth failure. Lilly welcomes this approach as somatropin provides broader health benefits that could improve patient QoL and wellbeing that are difficult to quantify but make all the difference to patients with this condition including self-esteem, improved lean body mass, bone mass and muscle strength to name a few.

Section 4.2.5 states the manufacturers model is an extension of model from 2002. The model developed by Pfizer as part of the Collaboration of 5 of the manufacturers was a de novo Markov economic model. This needs correcting.

Please do not hesitate to contact me if you have any queries.

Yours sincerely

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Lilly UK