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Sent: 11 January 2010 15:03

To: TA Comm B

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Subject:Growth failure (in children) - human growth hormone (HGH) (review) -

ACD:

Dear NICE

Thank you for the opportunity to comment on the Appraisal Consultation Document and Evaluation Report for the above health technology appraisal.

I have received comments from my colleagues in the Department of Health, as follows:

"We are not certain as to which children, born small for gestational age, should be offered somatropin as a treatment option:

In 1.1, the committee recommends somatropin (GH) as a treatment option in children with the following condition - being born small for gestational age (SGA) - but that term does not appear to be specifically defined.

In 2.6, various thresholds for SGA are mentioned.

In 4.1.21, we are unable to identify RCTs that met the criteria for the use of GH, as prescribed in the licence for GH in children born SGA. We would be

grateful for clarification.

In 4.2.17, the cost per cm in the SGA group is substantially higher than other conditions, accepting that there are other cost calculations. In our view, there is a need to be very precise about which children should be offered such a treatment option. If this is within the licensed indications, we feel that this should be clearly stated from the outset.

We are aware that a huge proportion of paediatric medicines are prescribed by paediatricians off licence. We are also aware of the variability of access to medicines around the country. We believe that the recommendations to the NHS should be more precise and clear, in order to prevent both inequity in access and inappropriate treatment of children".

Many thanks and best wishes

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Department of Health