9 November 2007

National Institute for Health and Clinical Excellence

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Sent by email

Dear Consultee/Commentator

Health Technology Appraisal

Drugs for the treatment of pulmonary arterial hypertension

I write with reference to the letter of my colleague Ms Natalie Bemrose (dated 17 October 2007) that informed you of the extension to the timeline of this appraisal.

At the first Committee meeting it was highlighted that to aid the Committee's decision making process further data on the survival benefit provided by the above drugs in a clinical setting is required.

In order to inform the additional analyses to be undertaken by the West Midlands Health Technology Assessment Collaboration, the Institute is therefore urgently seeking additional observational or registry data on the survival benefit provided by the drugs that are subject to this appraisal; epoprostenol, iloprost, bosentan, sitaxentan and sildefanil.

Ideally, these data would be most useful if they were provided in the following format:

1. Survival data by drug, stratified by functional class at the initiation of treatment and by subcategories of PAH (if mixed populations, i.e. idiopathic PAH, PAH associated with connective tissue disease).
2. In addition, if possible, please provide information with regard to when the data were collected, the selection criteria for the patients, baseline characteristics of the patients (e.g. time since diagnosis, 6 minute walking distance (6MWD), haemodynamics), whether changes in other treatments were allowed during follow-up and if allowed, whether there were pre-defined criteria under which such a change could occur.
3. Please provide data for the licensed dose only.

We understand that this request my raise specific technical queries and we are more than happy to assist you in your response. Please contact Emma Pugh, Health Technology Analyst, on 0161 209 3449 or emma.pugh@nice.org.uk, who will be happy to help.

The West Midlands Health Technology Assessment Collaboration must complete its investigation by mid January 2008 in order for the Institute to present the results to the Appraisal Committee at its next meeting in early February. This will limit the extent of the investigation. **We would therefore be most grateful to receive this data by Friday 7 December 2007.**

To speed the delivery of any material, we would prefer to receive any data or analyses by email attachment, to be sent to natalie.bremrose@nice.org.uk.

If you are not able to submit your material electronically, please send by post to the address in letterhead above.

Please indicate whether or not any data supplied are academic-in-confidence.

This email and an additional hard copy of this request are being sent to formal consultees and commentators in this appraisal.

Yours sincerely,

Meindert Boysen, Associate Director

Centre for Health Technology Evaluation