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8 October 2010

Dear [redacted]

Final Appraisal Determination: Imatinib for the treatment of unresectable and/or metastatic gastrointestinal stromal tumours

Thank you for lodging your appeal against the above Final Appraisal Determination.

Introduction

The Institute's appeal procedures provide for an initial scrutiny of points that an appellant wishes to raise, to confirm that they are at least arguably within the permitted grounds of appeal ("valid"). The permitted grounds of appeal are:

- Ground 1: The Institute has failed to act fairly
- Ground 2: The Institute has formulated guidance which cannot reasonably be justified in the light of the evidence submitted.
- Ground 3: The Institute has exceeded its powers.

This letter sets out my initial view of the points of appeal you have raised: principally whether they fall within any of the grounds of appeal, or whether further clarification is required of any point. Only if I am

satisfied that your points contain the necessary information and arguably fall within any one of the grounds will your appeal be referred to the Appeal Panel.

You have the opportunity to comment on this letter in order to elaborate on or clarify any of the points raised before I make my final decision as to whether each appeal point should be referred on to the Appeal Panel.

Initial View

Establishing a Scope for the Appraisal

I will take each of your four complaints in turn. Your first compliant is that an explicit promise (of a "full review") was given and not honoured. I am afraid I cannot see from the material you have quoted where that promise was given. I think you are referring to the review date in TA86. However, these review dates indicate the date on which the Institute will consider whether the evidence base for a technology has evolved sufficiently that a review is indicated. Whether a review will take place, and if so the scope of the review, depends on the degree to which new evidence is available. It is clear that the Institute did conclude a review was indicated and so I cannot see there is any arguable failure to honour any express promise.

Your next complaint is a failure to keep an implied promise, by which I think you mean of a "full review". The Institute considered whether a review was indicated, and in January 2008 concluded that it was "appropriate to proceed with the review of guidance TA 86". I am afraid I cannot see that that statement contained any implied promise as to the scope of the review, which, in accordance with NICE's procedures, would be set out in a subsequent document, expressly called the scope. The draft scope then indicated the scope of the review, to appraise within licensed indications. That may or may not amount to a "full review" as you use the term, but I cannot see how it is inconsistent with any express promise given earlier.

Your third complaint is that there was a failure to communicate the limited nature of the proposed review. Yet both the draft and final scopes explicitly state that the appraisal will be within the licensed indications/marketing authorisation. This seems very clear. Further, NICE only ever issues recommendations for use within the terms of a marketing authorisation. You are or should have been aware of the terms of the marketing authorisation and should have been under no misunderstanding as to the scope of the review.

Your final complaint is that NICE passed off a disallowable item of evidence as acceptable in order to placate responders. I am afraid I do not understand this allegation at all.

I am therefore minded not to allow these points to go forward to an appeal hearing.

Choice of comparator technology

Your complaint is that it was unreasonable when formulating the scope not to agree with advice from RCP that there was no valid comparator data.

This question has to be considered as at the time the scope was being formulated. It is reasoning with hindsight to look at what data was subsequently uncovered. Further, it is at best questionable to allow the scope to be overly shaped by what may be expected to be found.

First, the Institute does not appear to have been advised by the RCP that there was no valid comparator data. What the RCP said was there was a lack of direct comparative data, and that a trial was under way to address this. Even taking that statement in isolation, it does not seem to me arguable to assert that the only possible conclusion would be not to include sunitinib as a comparator at all. NICE not infrequently has to make use of indirect comparisons, and that could have been the case here. Alternatively data may have been available from the trial to which you refer. And finally sunitinib is an alternative treatment in use, and furthermore is recommended for such use by NICE. I can see no grounds on which it can be argued that it was unreasonable to include it within the scope as a comparator.

I am therefore minded not to allow these points to go forward to an appeal hearing.

Fairness to consultees and expert witnesses

Your complaint appears to be that the manufacturer of Imatinib stated that there was no new evidence on the effectiveness of increased doses after disease progression. In your view there is a large amount of such evidence.

I do not agree that recording that statement by the manufacturer can amount to unfairness. The FAD contains an extended discussion of the evidence available and the Committee's view on it. I assume that your experts disagree with that discussion, but that is not of itself a valid ground of appeal.

I am therefore minded not to allow this point to go forward to an appeal hearing.

Conclusion

As I am currently not minded to rule that any of your appeal points are valid, I will not pass your appeal to the Appeal Panel for consideration at this time.

If you wish to make any further comment on the points that I have indicated that I do not, at this

preliminary stage, view as valid please provide to me this within 10 working days from the date of this letter, **no later than 5pm on Friday 22 October**. I will then reach a final decision on the validity of those points, and whether the appeal should be passed to an appeal panel.

Yours sincerely

Maggie Helliwell
Appeals Committee Chair
National Institute for Health and Clinical Excellence