registered charity: 1114037

[redacted]
Chair, Appeal Committee
National Institute for Health and Clinical Excellence
MidCity Place
71 High Holborn
London WC1V 6NA

21st September, 2011

Dear [redacted],

Re: Appeal against the Final Appraisal Determination (FAD): *Dasatinib, high dose imatinib and nilotinib for the treatment of imatinib-resistant chronic myeloid leukaemia (CML) (part review of NICE technology appraisal guidance 70), and dasatinib and nilotinib for people with CML for whom treatment with imatinib has failed because of intolerance.*

Thank you for your initial scrutiny letter outlining your views on the validity of the grounds of our appeal.

As the representative of the CML Support Group I am writing to clarify the point of appeal in Ground 2 as you requested in your letter:

> **"Claims made of "poor quality of the evidence base" (4.3.8) and "the limited evidence base" (4.3.9.) are rebutted** (your paragraph 2.2)
>
> This appears to be a disagreement on the quality or weight of the evidence. The appeal panel cannot re-evaluate the evidence itself, it can only consider whether guidance cannot be justified at all. The fact that an expert disagrees with the Committee's assessment would not, without more, support a finding that guidance could not be justified. It is not uncommon in appraisals for

> experts to have different, sometimes very substantially different, views on the evidence.
> Of course, you would be free to draw attention to Professor Apperley as part of your overall argument, but if this was intended to be a stand alone argument, I would not have been minded to allow it to proceed.
>
> Conclusion
> As I am minded to agree some of your appeal points are valid I will pass them to an appeal panel for consideration.
> If you wish to make any further comment on the point I believe is not valid, together with the clarification requested above, please provide to me by Monday 26 September 2011."

I am aware that the appeal panel cannot, as you point out "re-evaluate the evidence itself" and understand the logic of the limitation as to the grounds on which a submission to appeal can be made.

However my point 2.2. rests on the following.

The guidance is:
"*obviously and unarguably wrong, illogical or so absurd that a reasonable Appraisal Committee could not have reached such conclusions*"
(3.4.6. Guide to the technology appraisal appeal process)

That is, it is not just one "expert", or even a handful of experts, who disagree with the findings, but rather it is the entire global community of expert CML clinicians.

Obviously we have to assume the veracity of Professor Apperley's assertion, but not to do so would be to question her integrity.

There is certainly little reason to doubt that her assertion was evidence based because of her centre's global preeminence in CML research and clinical practice.

We support evidence based medicine and agree that technology appraisals have an essential role to play in establishing the clinical and cost effectiveness of novel technologies, but we are also mindful that on occasion, for one or more of the reasons detailed in italics above, conclusions are reached that should not have been.

This is one such occasion.

Yours faithfully,

XXXXXXXXXX

Director and on behalf of

The CML Support Group