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The CML Support Group  
PO Box 56213  
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By email

12 September 2011

Dear [REDACTED]

**Appeal Against Final Appraisal Determination: 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 lodging CML's 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.

I can confirm that there will be an oral hearing of the appeal.

## **Initial View**

### **Ground 1**

**The Appraisal Committee have failed to follow the NICE procedures set out in the 2008 NICE “Guide to the methods of technology appraisals” in the selection of a comparator, in this case hydroxycarbamide (HU). (Your paragraphs 1.1-1.5)**

A valid ground one appeal point

### **Ground 2**

**FAD Section 4.3.3. The Committee’s conclusion is flawed (Your paragraphs 2.1-2.1.1)**

A valid ground two appeal point.

**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.

Yours sincerely



**Appeals Committee Chair  
National Institute for Health and Clinical Excellence**