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**From:**  
**Sent:** 04 September 2008 10:27  
**To:**  
**Cc:**  
**Subject:** Final Appraisal Determination: Febuxostat for the management of hyperuricaemia in patients with gout  
**Importance:** High

4 September 2008

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Dear

**Final Appraisal Determination: Febuxostat for the management of hyperuricaemia in patients with gout**

Thank you for lodging Ipsen Limited'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 and in accordance with its published procedures as set out in the Institute's Guide to the Technology Appraisal Process.
- Ground 2: The Institute has prepared guidance which is perverse 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

Ground one

Point one: a valid ground one appeal point.

Point two: a valid ground one appeal point in so far as it alleges there is no evidence to support the decision.

Point three: Please could you elaborate, by reference to the FAD or other documents, on why it is argued that the Institute has focused on gout flares to the extent of, in effect, redefining the scope? I see that gout flares are discussed in the FAD but I am not convinced as yet that it is arguable that this can be said to be to the exclusion of other considerations? I should explain that my view is that the committee is required to consider all relevant material within the scope, but is not necessarily required to discuss all of that material within an FAD. At present I am not persuaded this is a valid appeal point.

Point four. The social values judgement document does not form part of the Institute's published procedures, and I cannot at present see that there is any procedural unfairness in any failure to discuss the principle of non-maleficence in the FAD. At present I am not persuaded this is a valid appeal point.

## Ground Two

Points five to seven: all valid ground two points.

As I am minded to rule that at least some of your appeal points are valid, I will pass your appeal to the Appeal Panel for consideration.

If you wish to make any further comment on the points I have queried above (three and four) , I would be grateful to receive this within fourteen days from the date of this letter. I will then reach a final decision on the validity of those points.

Yours sincerely

**Mark Taylor**

**Appeals Committee Chair**

**National Institute for Health and Clinical Excellence**