

Sent by email

[REDACTED]
Hon. Treasurer
Tackle Prostate Cancer
Prostate Cancer Support Federation

4 June 2014

Dear [REDACTED]

Final Appraisal Determination: Degarelix for treating advanced hormone dependent prostate cancer

Thank you for your letter in reply to my letter of 12 May. I note that you did intend your earlier letter to stand as an appeal letter, and that you have now set out your concerns under the Institute's grounds of appeal.

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:

- 1(a) NICE has failed to act fairly,¹ or
- 1(b) NICE has exceeded its powers;²
- (2) the recommendation is unreasonable in the light of the evidence submitted to NICE

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

¹ formerly ground 1

² Formerly ground 3

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.

1 Ground 1a: the wording of the proposed guidance has changed significantly between ACD and FAD without re-consultation.

A valid ground 1(a) appeal point.

2 Ground 1a: No additional evidence is presented to explain the change in wording from ACD to FAD which lacks transparency.

A valid ground 1(a) appeal point.

3 ground 1a: The recommendation may lead to unintended consequences. The new recommendation is restrictive and many patients who might benefit from Degarelix will not receive it.

Ground 1a is concerned with alleged procedural unfairness. An example is your first point that there should have been more consultation but there was not. Your complaint here is not to do with the process by which the guidance was produced, but its likely effect. Although I understand that patient groups and others may strongly feel that it is "unfair" not to recommend a treatment as widely as may be, that is not of itself a ground of appeal. Therefore I will not be referring this point to the appeal panel.

4 Ground 2: The recommendation in the FAD does not take full account of the evidence in support of the drug

As you will know, the appeal process is not a repeat of the appraisal, and unfortunately simply disagreeing with aspects of the analysis or the conclusions reached is not a valid ground of appeal. I have no doubt that the papers you refer to describe benefits of the drug. However an appraisal committee must take account of the evidence that is put before it. In a single technology appraisal process, an evidence review is undertaken by the manufacturer and validated and commented on by an independent evidence review group. That process seems to have taken place in the usual way here. I can see no ground to conclude that the appraisal committee may have ignored relevant evidence, and what weight they give to the various strands of evidence is a matter for them. I am afraid I will not be referring this point to an appeal panel.

Your valid appeal points are points 1 and 2, which will be considered at an oral hearing alongside the appeal points of the other appellants.

Yours sincerely

Dr Maggie Helliwell
Vice Chair of NICE
National Institute for Health and Care Excellence