

Astellas Pharma Ltd
2000 Hillswood Drive
Chertsey, KT16 0RS

By email to: [REDACTED]

27 January 2016

Dear [REDACTED]

Final Appraisal Determination: immunosuppressive therapy for kidney transplantation in adults

Thank you for lodging Astellas' appeal against the above Final Appraisal Determination. I am replying in place of Dr Helliwell as I am the new Vice Chair of NICE.

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:

- 1(a) NICE has failed to act fairly, or
- 1(b) NICE has exceeded powers;
- (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 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 (a)

1a.1 Inconsistent selection of study populations during systematic review biases the results of the AG model unfairly against prolonged release tacrolimus contrary to section 3.5.3 of NICE Process Guide

A valid appeal point

1a.2 Inconsistent calculation of price of tacrolimus formulations in the AG model that does not represent the true cost of tacrolimus to the NHS (NICE Process Guide 3.5.3)

A valid appeal point

Ground 2

2.1 Failure by the AC to appropriately handle the available data leading to a manifestly wrong conclusion being drawn that prolonged-release tacrolimus is inferior to immediate release tacrolimus.

As you will appreciate, an appeal hearing is not an appropriate venue and is not well equipped to re-evaluate evidence in detail that has already been considered during an appraisal. An appeal panel's approach to the question of whether a recommendation is unreasonable is likely to be that points that demonstrate unreasonableness, as opposed to a disagreement between experts, tend to be, if not obvious on the face of the document, then at least capable of fairly short explanation.

Your point concerning the safety profile of prolonged release tacrolimus is a good example: although some explanation is needed, once given the point is easy to grasp (and whether or not it is a good point will be for an appeal panel to decide).

Your other points are either less easy to grasp or seem to be disputes on fairly narrow points of modelling and analysis. I am also not sure that you have adequately addressed what seems to be the fundamental driver of the committee's decision on prolonged release tacrolimus, namely that it appears broadly clinically equivalent to but more expensive than immediate release tacrolimus.

I should also point out that it is the appraisal committee's treatment of the evidence that the appeal panel will be most concerned with.

I would be minded to refer your concern about the possible difference of opinion with the CHMP to an appeal panel, but not the remainder of this point.

2.2 The AC and AG dismissed other relevant evidence, resulting in unreasonably restrictive recommendations

A valid appeal point

As I agree your appeal points are valid they will be passed to an appeal panel for consideration. There will be an oral hearing. It is not necessary to respond to this letter, save that if after considering my comments under point 2.1 you wish to narrow (not add to) the subpoints made in your original letter, it would be helpful if you could let me know by no later than **Wednesday 10 February**, so that the appeal panel can use its preparation time most effectively.

Yours sincerely

Andy McKeon
Vice Chair
National Institute for Health and Care Excellence