

**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**  
**Health Technology Appraisal**

**Appeal Hearing**

**Advice on ranibizumab and pegaptinib for the treatment of age-related macular degeneration**

**Decision of the Panel**

**Introduction**

1. An Appeal Panel was convened on 30<sup>th</sup> June 2008 to consider an appeal against the Institute's Final Appraisal Determination, to the NHS, on the use of ranibizumab and pegaptinib for the treatment of age-related macular degeneration
2. The Appeal Panel consisted of Mark Taylor (chair of the Panel), Ms Mercy Jeyasingham (non-executive director of the Institute), Mrs Jean Gaffin (lay representative), Dr Robert Donnelly (industry representative), and Professor Robin Ferner (NHS representative). Dr Frank McKenna was present as an observer.
3. The Panel considered appeals submitted by:
  - Pfizer Limited
  - Derbyshire County Primary Care Trust
4. In addition, the following individuals involved in the appraisal were present and available to answer questions from the Appeal Panel: Professor Andrew Stevens (chair of the Appraisal Committee), Dr Carole Longson (Director, Centre for Health Technology Evaluation), Dr Helen Chung, Ms Elizabeth George, and Dr Peter Jackson.

5. The Institute's legal advisor (Stephen Hocking, Beachcroft LLP) was also present.
6. Under the Institute's appeal procedures members of the public are admitted to appeal hearings and a number of members of the public were present at this appeal.
7. There are three grounds on which an appeal can be lodged:
  - 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;
  - The Institute has prepared guidance that is perverse in light of the evidence submitted;
  - The Institute has exceeded its legal powers.
8. The chair of the Appeals Committee (Mr Mark Taylor), in preliminary correspondence, had confirmed that the appellants had potentially valid grounds of appeal as follows:
  1. Pfizer Limited: grounds 1 and 2
  2. Derbyshire County Primary Care Trust: grounds 1, 2, and 3.
9. The Appeal Panel heard Pfizer's appeal first, and then Derbyshire County Primary Care Trust's appeal.

### **Appeal by Pfizer Limited**

#### **Appeal Ground 1: The Institute has failed to act fairly and in accordance with its procedures**

##### **Pfizer Aspect 1.3 There is inconsistent decision-making by the Institute regarding the impact of treating the first eye in this Technology Appraisal**

**compared to the previous Technology Appraisal in 2003 for photodynamic therapy**

10. Mr Steven Kelly, for Pfizer Limited, explained that a previous Technology Assessment, assessing photodynamic therapy for age-related macular degeneration, had considered the cost-effectiveness of treating only the better-seeing eye when two eyes were affected, and then went on to recommend treatment for the first-affected eye, without adjusting the calculations of cost-effectiveness. By contrast, the Appraisal Committee had on this occasion, and for the same condition, considered the cost-effectiveness of treating the better-seeing eye when two eyes were affected, and then speculated that to recommend treatment of the first affected eye would be 50% less cost effective. This approach was inconsistent, and therefore unfair.
  
11. Mr Kelly did not accept that the quality of life differed greatly between a state where the patient could see well with one eye, and a state where a patient was blind in both eyes. He pointed to the utilities found in a study by Williams (1998).
  
12. Professor Andrew Stevens, for the Appraisal Committee, stated that the utility loss from being blind in both eyes, which was about 0.5 units, was substantially greater than the utility loss due to blindness in one eye, which was about 0.1 unit.
  
13. Professor Stevens explained that he had been a member of the Appraisal Committee considering photodynamic therapy. That Appraisal Committee had determined the cost per quality-adjusted life-year of photodynamic therapy for treatment in the better-seeing eye. This was sufficiently low that the treatment would remain within the Institute's acceptable bounds for cost-effectiveness under any reasonable assumption for the additional cost of treating the first-affected eye. This was not true for treatment with ranibizumab and pegaptinib, and so the current Appraisal Committee needed to perform some calculation of the additional cost per quality-adjusted life-year of treating the better-seeing

eye. The figure of 50% was an overall estimate arrived at by the Appraisal Committee. He felt it was at the lower end of the reasonable range of values.

- 14.** The Appeal Panel noted the discussion of utilities at paragraphs 4.2.2.4, 4.2.2.8, and 4.2.3.4 of the Final Appraisal Determination; and in section 4.1.3 of the Assessment Report. The Appeal Panel understood that some overall measures of quality of life showed rather small decrements between blindness in one eye and blindness in both. However the Appeal Panel accepted the Appraisal Committee's contention that utilities that were more strongly related to visual loss were appropriate, and considered that the estimates used by the Appraisal Committee were reasonable in view of the range of utility analyses available to it.
- 15.** The Appeal Panel considered several points established. Costs of treatment were high. There were two strategies: to treat the better-seeing eye or the first-affected eye. The gains in utility differed significantly between the two strategies. Therefore the difference in cost per quality-adjusted life-year between the two treatment strategies was likely to be substantial. In view of the calculated costs per quality adjusted life year for a better eye strategy, the cost of the first eye strategy could lie beyond the upper bound of usual acceptability. It was therefore right that the Appraisal Committee should estimate the difference in costs between the two strategies. Since the circumstances differed from those in the Technology Assessment of photodynamic therapy, the Appraisal Committee acted fairly when it used a different (and more precise) method to reach its decision.
- 16.** The Appeal Panel also felt that it was reasonable for the Appraisal Committee to have departed from the approach taken in the assessment of photodynamic therapy in light of the considerable time since that appraisal was carried out, and the development of the Institute's working methods in that time.
- 17.** The Appeal Panel therefore dismissed the appeal on this point.

**Pfizer Aspect 1.5 The exclusion of pegaptanib for the sub-group of patients with visual acuity between 6/12 and 6/24 does not comply with the Institute's obligations under the equalities legislation as, despite ranibizumab being available, there will be patients that would benefit from pegaptanib should they be unsuitable for treatment with ranibizumab**

18. Mr Kelly suggested to the Appeal Panel that there were some patients for whom treatment with pegaptanib would be cost-effective within the values accepted by the Institute, and who were unable to have treatment with ranibizumab. He had in mind patients with visual acuities between 6/12 and 6/24 in whom one drug was contra-indicated while the other drug was not. Other relevant patients might be those who were at high cardiovascular risk, or who were unable to attend for monthly treatments. Since they were or could become partially sighted, it was important not to discriminate against them.
19. Mr Stephen Hocking, legal advisor to the Appeal Panel, explained that all the patients for whom the Final Appraisal Determination was relevant were or could become sight-disabled, and disability equality provisions applied equally to all of them. His advice was that the relevant group for the purposes of the Disability Discrimination Act (DDA) 1995 was all patients with wet age-related macular degeneration, and that the guidance appeared to treat all of that group equally. The Final Appraisal Determination could not, therefore, be said to discriminate between them on the grounds of disability, distinct from wet age-related macular degeneration, at least where the reason for non-treatment with the recommended drug was not itself a disability. In so far as it was necessary to have due regard to the needs of disabled people including the possibility of "more favourable" treatment, the panel would have to ask whether or not the appraisal amounted to "due regard" and whether the Appraisal Committee had been aware of the possibility of more favourable treatment, for example by recommending a drug at a lower than usual level of cost effectiveness.

20. Professor Stevens stated that the Appraisal Committee was aware of the possibility of recommending a poorly cost-effective treatment, but very wary of doing so. Pegaptinib was such a treatment.
21. Contra-indications were described in essentially identical terms in the Summaries of Product Characteristics for ranibizumab and pegaptinib.
22. Mr Kelly drew the attention of the Appeal Panel to the Technology Assessment for treatments of osteoporosis, in which poorly cost-effective treatments were recommended as alternatives in patients with disabilities that prevented them from taking the first recommended treatment.
23. Professor Stevens explained that the circumstances of the osteoporosis assessment were different, because there were manifestly patients in whom the first choice drug was contra-indicated, and where the contra-indication was itself a disability, but who would be able to take an alternative.
24. Dr Carole Longson, for the Appraisal Committee, stated that the Appraisal Committee had to consider on balance whether there was a group for whom one treatment rather than another was appropriate. She accepted that there could be some patients who might be able to benefit from pegaptinib but not ranibizumab .
25. Dr Peter Jackson, for the Appraisal Committee, stated that there was no evidence to demonstrate that patients who developed a reaction to ranibizumab could be safely or effectively treated with pegaptinib.
26. Dr Longson explained that an Appraisal Committee's process was first to assess whether a treatment was cost-effective, and then to consider special groups. The Appraisal Committee had considered the question of disability in making this appraisal..

27. The Appeal Panel determined that the Final Appraisal Determination could not be said to discriminate against those disabled with wet age-related macular degeneration, because it dealt specifically with treatments for those patients. It was not legitimate to subdivide that group except on the basis of some other unrelated disability. There did not seem to be a material group of patients in whom treatment with ranibizumab was contra-indicated by virtue of some disability, but who could be treated with pegaptinib. Certainly neither the Appraisal Committee nor Pfizer had in practice identified such a group. The Appeal Panel was satisfied that the Appraisal Committee had considered whether there were any disabled groups requiring more favourable treatment.

28. The Appeal Panel therefore dismissed the appeal on this point.

**Appeal Ground 2 – The Institute has prepared a Final Appraisal Determination that is perverse in the light of the evidence submitted**

**Pfizer Aspect 2.1. The Institute has made an error in its calculation for the cost effectiveness of pegaptinib when the first eye is treated**

29. Mr Kelly stated that the decision by the Appraisal Committee to apply a 50% uplift to the cost-effectiveness calculation to account for treatment in the first eye had significantly influenced the Committee's recommendations. The uplift was based on the false assumption that 30% of patients present with age-related macular degeneration affecting only one eye. In a study of 360 patients whose visual acuity lay between 6/12 and 6/24, only 17% presented with age-related macular degeneration in just one eye. It was for these patients that Pfizer was advocating the use of pegaptinib. The Appraisal Committee's decision was therefore, in Pfizer's view, perverse.

30. Professor Stevens stated that the Appraisal Committee had considered three factors: the proportion of patients presenting with disease in one eye only; the utility of preventing blindness in one eye against the utility of preventing total blindness; and the additional cost of support needed for those who were blind in both eyes as opposed to one eye. The Appraisal Committee had considered

that preventing complete blindness brought four to five times the benefit of preventing blindness in one eye. Overall, the Appraisal Committee had considered the extra cost of a strategy of treating the first-affected eye could be reasonably estimated as 50% greater than the cost of treating the better-seeing eye.

31. The Appeal Panel accepted that there were substantial extra costs in treating the first-affected eye rather than the better-seeing eye when both eyes were affected. It noted that the Appraisal Committee's calculations were estimates only, but did not regard that as an unreasonable approach. Even had the Appraisal Committee adopted Pfizer's figure for the proportion of patients presenting with disease in one eye only there would still have been a decisive extra cost in treating the first affected eye. The Appraisal Committee had taken a reasonable view of the difference in costs. The decision was not perverse.

32. The Appeal Panel therefore dismissed the appeal on this point.

**Pfizer Aspect 2.2. The Institute has failed to take into account consultee feedback that significantly more than 25% of anti-VEGF treatments are currently administered in Outpatients facilities and this will rise in the future**

33. Dr Longson explained that the Appraisal Committee generally prefers to use NHS tariff costs to represent costs of treatment. However, if the true cost differs substantially from the tariff cost, then the Appraisal Committee can use the true cost.

34. Professor Stevens stated that in this case, the outpatient costs were much higher than tariff cost, because provision had to be made for sterile conditions and sterile equipment to inject the drug into the eyeball. The Royal College of Ophthalmologists had estimated the cost of outpatient treatment of an appropriate standard as £450 per treatment. This was higher than the day-case costs. The Appraisal Committee had therefore made a reasonable estimate.



35. Professor Stevens stated that the average cost used by the Appraisal Committee was equivalent to the cost based on an assumption that 75% of the procedures were day cases and 25% outpatient visits, costed at tariff. He accepted that paragraph 4.3.17 of the Final Appraisal Determination could have been worded more clearly to reflect this.
36. The Appeal Panel accepted the argument that tariff costs were not always appropriate. They also accepted that the estimate of non-drug treatment costs used by the Appraisal Committee for intra-vitreous injection was appropriate. Neither the conclusion nor the reasoning process leading to it was perverse.
37. The Appeal Panel therefore dismissed the appeal on this point.
38. However, the wording of paragraph 4.3.17 of the Final Appraisal Determination was misleading and unhelpful and failed to reflect the process by which the Appraisal Committee had actually arrived at its estimate of non-drug treatment costs.
39. The Panel held the clear view that paragraph 4.3.17 of the Final Appraisal Determination should be revised to reflect the deliberations of the Appraisal Committee. This matter should be considered by the Institute's Guidance Executive.

**Appeal Ground 3: The Institute has exceeded its legal powers**

40. No appeal point from Pfizer was considered under this ground.

**Appeal by Derbyshire County Primary Care Trust**

**Appeal Ground 1: The Institute has failed to act fairly and in accordance with its procedures**

**Derbyshire County Primary Care Trust appeal point 1. The Primary Care Trust did not have the opportunity to contribute fully to the appraisal. NICE**

**named High Peak and Dales Primary Care Trust as a consultee, but at the time the appraisal was begun this Primary Care Trust had ceased to exist**

41. Mr David Lock, representing the Derbyshire County Primary Care Trust, stated that the Institute had invited High Peak and Dales Primary Care Trust to comment on the various stages of the appraisal process, but that at the time the appraisal was begun, the relevant functions of the High Peak and Dales Primary Care Trust had been transferred to the Derbyshire County Primary Care Trust. It was widely known within the NHS that major changes to the organisation of Primary Care Trusts were to take place on 1<sup>st</sup> October 2006. By addressing the invitation to a non-existent body, the Institute had unfairly deprived the successor body of the opportunity to comment.

42. Dr Longson stated that the Institute had first written to a named individual at High Peak and Dales Primary Care Trust on 21<sup>st</sup> April 2006 inviting that Primary Care Trust to become a consultee. The Institute received no response. A further communication was sent on 22<sup>nd</sup> August 2006, but there was still no response.

43. Dr Richard Richards, for Derbyshire County Primary Care Trust, explained that the process of merging six Primary Care Trusts into one was very disruptive, and many managers left before 1<sup>st</sup> October 2006.

44. Dr Longson told the Appeal Panel that Derbyshire County Primary Care Trust had in fact, contacted the Institute on 2<sup>nd</sup> October 2007, and they were then invited to become consultees. The Institute received a response to the first Appraisal Consultation Document written by Dr Richards on behalf of the Primary Care Trust and dated 24<sup>th</sup> October 2007.

45. The comments in this response were taken into account in drafting the second Appraisal Consultation Document, as was acknowledged by Dr Richards in the Primary Care Trust's response of 10<sup>th</sup> January 2008 to the second Appraisal Consultation Document. Paragraph 1 of this response read: 'It is noted that many of the points raised in the initial response from Derbyshire

County Primary Care Trust have been specifically addressed in the December 2007 Appraisal Consultation Document. That is gratifying to see.'

46. The Appeal Panel decided that the Institute had made reasonable attempts to engage High Peak and Dales Primary Care Trust in the process as consultees while that Primary Care Trust was still in existence. It was unfortunate that responsibility for responding to the appraisal had not been properly handed over from that Trust to the successor Primary Care Trust. When Derbyshire County Primary Care Trust realised that a response was desirable, the Trust contacted the Institute, and the Institute took their comments into account. There had been sufficient opportunity for a proper response to be formulated. Perhaps fortunately, as there was a second Appraisal Consultation Document in this case, these comments were available for consideration before the final decision was taken. The panel considered whether there might nevertheless have been unfairness caused by the failure or inability to comment on the first Appraisal Consultation Document, but, as the first Appraisal Consultation Document had been overtaken by the second, it concluded there had not been.

47. It was possible to be critical of both the Appraisal Committee and the Primary Care Trust in their mutual failure to resolve this problem until relatively late in the process; however there had been no unfairness.

48. The Appeal Panel therefore dismissed the appeal on this point.

**Appeal Ground 2 – The Institute has prepared a Final Appraisal Determination that is perverse in the light of the evidence submitted**

**Derbyshire County Primary Care Trust appeal point 2. The inclusion of a subgroup of patients whose visual acuity at presentation was between 6/60 and 6/96 in the Final Appraisal Determination as suitable for treatment with ranibizumab was perverse, since such patients with poor initial visual acuity were very unlikely to benefit from treatment**

49. Mr Lock argued that the clinical benefits of treating those with poor visual acuity must necessarily be less than those of treating patients with preserved vision; that the gain in well-being measured by utilities must be less, since the difference in utility between very poor sight and blindness was small; and that insofar as the Final Appraisal Determination referred to treatment of the better-seeing eye, the maximum gain if the other eye had full vision must necessarily be low, because the disutility of poor vision in one eye was small.
50. Professor Stevens explained that, while the difference in utility between very poor sight and blindness was small, ranibizumab improved vision. Therefore contrary to the Primary Care Trust's argument those with very poor sight could be made substantially better by treatment, as they had greater opportunities to gain utility.
51. Dr Jackson explained that the data from the MARINA trial of ranibizumab presented in the New England Journal of Medicine did not analyse the effect of treatment according to the visual acuity at baseline. They did show that over the course of a year vision deteriorated significantly in only 5% of patients treated with ranibizumab, and it improved in about one third of patients.
52. It was true that in one study (by Brown and colleagues) utility did not alter greatly with changes in visual acuity at the lower end of the range, but this was not true in another study (by Brazier and colleagues).
53. Mr Lock contended that the Appraisal Committee had failed to follow the Guide to Methods of Technology Assessment, paragraph 5.9.5.1 of which, he submitted, requires that the Appraisal Committee should examine separate estimates of clinical and cost effectiveness for each relevant subgroup of patients.
54. Professor Stevens explained that the group of patients whose visual acuity was between 6/60 and 6/96 had inadvertently been omitted from the second Appraisal Consultation Document. The clinical trials of ranibizumab had

included these patients, and there was no separate published analysis of the data for those with more severe visual impairment. Several consultees had pointed out that the clinical trial evidence referred to the whole group, and the Appraisal Committee had accepted that the evidence did not distinguish between patients by visual acuity.

55. Mr Lock asked the Appeal Panel to consider whether the statements in the Final Appraisal Determination or in the minutes of meetings of the Appraisal Committee reflected these deliberations, and drew attention to what he said was the Appraisal Committee's obligation to maintain adequate records of their deliberations in such appraisals.
56. Dr Longson was of the view that the Final Appraisal Determination captured deliberations of importance, and that in this instance the Appraisal Consultation Document, taken with the published comments and the Institute's response to them, and with the Final Appraisal Determination, made matters clear.
57. The Appeal Panel's view was that it was entitled to consider Professor Steven's explanations for why the recommendations had been "extended" between the second Appraisal Consultation Document and the Final Appraisal Determination, provided those were reasons genuinely in mind at the time. In so far as the reasons were not to be found in any contemporaneous document, the Panel would be more cautious before accepting them, but it acknowledged that the processes adopted by the Appraisal Committee generally were not designed to capture all reasons for changes between documents. This was not a case where otherwise detailed contemporaneous minutes failed to mention a reason advanced at a later stage.
58. The Appeal Panel did find the history of the inclusion of patients below 6/60 in the first Appraisal Consultation Document, their "removal" in the second Appraisal Consultation Document, and their eventual reinstatement in the Final Appraisal Determination troubling. Quite apart from the reasons behind

these changes, it observed that if an Appraisal Consultation Document does not accurately reflect the Committee's decision in a material respect, this may jeopardise the consultation process. The Panel decided that was not the case here, partly because the issue of where to set the limit of visual acuity below which treatment would not be given was in play during the consultation exercise.

59. The Appeal Panel decided that there was no evidence to indicate that the Appraisal Committee had ever considered that a subgroup of patients existed whose visual acuity was below 6/60. The Appeal Panel reached this conclusion primarily because the trial data regarding ranibizumab does indeed cover the whole range of visual acuity, so that it was intrinsically implausible that the Committee intended to create subgroups for whom no evidence-based recommendations could easily be made. There was no evidence of lesser efficacy or cost-effectiveness in those with poor baseline visual acuity. The Appeal Panel regarded Professor Steven's evidence as corroborative of this conclusion. The Appeal Panel observes that had this been a case where, on the basis of the trial data, subgroups could plausibly have been in consideration, it may have reached a different conclusion.
60. The Appraisal Committee had therefore acted reasonably in including patients with visual acuities between 6/60 and 6/96 in the recommendations of the Final Appraisal Determination.
61. The Appeal Panel therefore dismissed the appeal on this point.
62. Although it has not allowed the appeal on this point, the Appeal Panel was concerned at the lack of transparency in the process by which the visual acuity at or above which treatment was deemed worthwhile had changed from 6/96 to 6/60 and back to 6/96 in successive draft documents and recommendations. In particular the Panel regards it as extremely unfortunate that an important part of a recommendation can be misdescribed in a consultation document, and it warns that it is quite possible that this could lead to a successful appeal

on the right facts. The Panel wishes the Institute to consider whether more rigorous requirements can, or should, be placed on the Appraisal Committee with regard both to quality-assuring consultation documents and to the way in which critical aspects of its deliberations are recorded for subsequent scrutiny by interested parties.

### **Ground 3: The Institute has exceeded its legal powers**

#### **Derbyshire County Primary Care Trust appeal point 3. The recommendation in the Final Appraisal Determination that the cost of treatment with ranibizumab beyond 14 injections in the treated eye is met by the manufacturer is unclear**

63. Mr Lock argued that the condition that the manufacturer should meet costs beyond 14 injections was potentially illegal. The Final Appraisal Determination failed to make the arrangements clear, and other documentary evidence had not been advanced. The Final Appraisal Determination could not in any case be final, because the details of the arrangement had not been agreed at the time that the Final Appraisal Determination was issued.
64. It was common ground that it would not be correct for the Institute to advance an arrangement that was necessarily illegal if implemented.
65. Professor Stevens accepted that the costs referred to in Final Appraisal Determination paragraphs 1.1 and 4.3.22 were the costs of drug, and not the total costs of treatment. The costs of treatment were approximately 40% greater than the costs of drug alone. The Appraisal Committee felt it was unlikely that many patients would require more than 14 injections, but that in any case the scheme of reimbursement would act as an insurance policy against the potentially substantial cost of this happening.
66. Dr Longson explained that the initiative for the scheme had come from Novartis Limited in their response to the first Appraisal Consultation Document, and the arrangements had been made between that company and

the Department of Health. The arrangements had been described to the Institute by the Department of Health in an e-mail dated 5<sup>th</sup> February 2008, so that the Appraisal Committee knew that the Department had approved of the arrangements when it met on 13<sup>th</sup> February 2008. The arrangement was confirmed in a letter from the Department dated 12<sup>th</sup> March 2008,.

67. Mr Lock pointed out other uncertainties; for example, it was not clear whether the arrangements referred to 14 injections per eye or per patient.
68. Professor Stevens stated that the Appraisal Committee had heard that it was extremely unusual to treat two eyes simultaneously; the better-seeing eye was treated. However, if during a separate episode the second eye required treatment, then the NHS would pay for 14 injections during that episode also.
69. Dr Longson told the Appeal Panel that the scheme was final in every material respect, and that the remaining uncertainties concerned the precise nature of the administrative arrangements for recording the number of injections and reclaiming the cost when the number of injections exceeded 14. The scheme was part of the recommendation of the Appraisal Committee. There was no question of a Primary Care Trust being obliged by the Guidance to fund the cost of the drug beyond 14 injections: that was not what was recommended.
70. The Appeal Panel accepted that the scheme by which the manufacturer paid for drug costs when the number of injections in one eye exceeded 14 was authorised by the Department of Health. The Appraisal Committee had known the material components of the scheme when it adopted the Final Appraisal Determination. However, the Final Appraisal Determination was incorrect in describing the costs as 'treatment' costs when they were in fact drug costs. The NHS would still have to pay for non-drug costs, which amounted to 40% of the total cost of treatment. The Appeal Panel concluded that the Appraisal Committee was aware of this, and that it was the wording of the Final Appraisal Determination that was in error on this point.



71. The point that the Institute had exceeded its powers or that the scheme was too uncertain to amount to final guidance therefore fell away. Under the circumstances the Appeal Panel did not find it necessary to reach a view as to whether the scheme might be unlawful for any of the other reasons Mr Lock had advanced, as this would be a matter for the Department of Health.
72. The Appeal Panel therefore dismissed the appeal on this point.
73. The Appeal Panel requires the Guidance Executive to correct paragraphs 1.1 and 4.3.22 of the Final Appraisal Determination to reflect the true nature of the scheme.

#### **Conclusion and effect of the Appeal Panel's decision**

74. The Appeal Panel considered the appeals by Pfizer Limited and by Derbyshire County Primary Care Trust. None of the grounds for appeal was upheld.
75. However, it identified misleading or incorrect statements in the Final Appraisal Determination. These are at paragraphs 1.1, 4.3.17, and 4.3.22. These statements should be corrected. It also noted the failure of the Final Appraisal Determination to explain the process by which the visual acuity at or above which treatment was deemed worthwhile had changed from 6/96 to 6/60 and back to 6/96 in successive draft documents and recommendations, and requested the Institute to consider whether more informative records of the Appraisal Committee's deliberations could, and should, be kept.
76. There is no possibility of further appeal within the Institute against this decision of the Appeal Panel. However, the decision of the Appeal Panel and the Institute's decision to issue the Guidance may be challenged by an interested party through an application to the High Court for permission to apply for judicial review. Any such application must be made promptly and in any event within three months of this Decision.

