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Dear [REDACTED]

FAD Ranibizumab and Pegaptinib for age related macular degeneration

Thank you for your letter dated 20 May. This letter represents my final determination on the admissibility of your appeal points.

Aspect 1.1

I have considered your additional points. I have also reminded myself that the issue here is arguable unfairness, ie were Pfizer able to contribute meaningfully to the consultation on the guidance, and not whether or not the figure of 50% is the only reasonable figure.

It remains my view that the SHTAC analysis gives very considerable analysis on additional costs, and the FAD discusses in reasonable detail the impacts on cost effectiveness. I would accept that it appears that the 50% figure derives from the judgement of the committee informed by the cost analysis, rather than from specific modelling, but I do not consider that it is arguable that this has caused procedural unfairness. (I note in that regard that the figure was included in the ACD rather than emerging only in the FAD).

Therefore I conclude this point should not proceed.

Aspect 1.2

As you have not commented further on my preliminary conclusion under this aspect, I confirm that it should not proceed.

Aspect 1.3

Already accepted as valid.

Aspect 1.4

As you have not commented further on my preliminary conclusion under this aspect, I confirm that it should not proceed.

Aspect 1.5: Subgroups

I accept your argument that the clinical and cost effectiveness evidence for pegaptinib should be reviewed independently of the evidence for ranibizumab. My point was rather that the Committee seem to have decided not to explore subgroups in any detail, and that approach did not seem to be procedurally unfair. I note there is some discussion of subgroup analysis for pegaptinib at FAD 4.3.24. No doubt the conclusions of that paragraph could be debated but I still cannot see that the committee's approach to subgroup analysis can be said to have caused unfairness.

Aspect 1.5: sensitivity analysis

I am not sure I had appreciated from your earlier letter that your concern was around sensitivity analysis of the 50% uplift rather than the "headline" cost per QALY figures. But as the uplift is applied to the end product of the economic modelling, rather than introduced as a new term in the model, it seems to me that all of the sensitivity analyses carried out "pre uplift" would apply equally to the cost effectiveness figures once uplifted. I am not sure this is an issue of sensitivity analyses as such, as it seems the consequence of an uplift of any given size must have been clear to the committee and to consultees, and any modelling of different uplifts would have been trivial. Rather, the issue seem to be why the figure of 50% was selected when as your letter notes, lower uplifts might have the effect that some use of pegaptinib was within the range which might be considered cost effective (the same percentage improvement in cost effectiveness would also be seen for ranibizumab, of course, but that may not be relevant). As I noted under aspect 1.1 above, whatever else may be said about this, I cannot see this is an issue of procedural unfairness.

Aspect 1.5: Equalities

As regards your first comment, I do not believe that patients with an allergy or with an adverse reaction can be described as disabled for that reason, and therefore I would not be minded to allow that argument to go forward.

As regards your second comment (that patients are partially sighted, disabled, and therefore "more favourable" treatment should be considered), it seems to me that there may be difficulties in praying in aid the very disability which a treatment is designed to address. However this is a novel point, and I agree that it should be argued before an appeal panel.

Aspect 2.1

I have considered your additional comments. It seems to me there is sufficient material here that it would be right for this point to go before an appeal panel.

Aspect 2.2

Already accepted as valid.

Therefore your appeal will go forward to be considered under aspects 1.3, 1.5 (in part) 2.1 and 2.2.

Yours sincerely

Mark Taylor
Chair of the Appeal Committee