Celgene Ltd.
Morgan House, Madeira Walk
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United Kingdom

3 May 2010

Dear [redacted]

Final Scrutiny Scrutiny Letter Dated 23 April 2010 ("Final Letter")

Thank you for your Final Scrutiny Letter. We are pleased that you have decided to allow the majority of our grounds for appeal, and we have restructured our appeal letter to take account of your suggestions. In particular, we have inserted the arguments under our original ultra-orphan, procedural ground 1.2 into section 2.3 of our letter, which discusses ultra-orphan issues under the perversity heading. Ground 2.3 had previously only cross-referred to the ultra-orphan arguments in ground 1.2.

I hope that you will forgive my coming back to you again on our ultra-orphan arguments under grounds 1 and 3 but these do raise important issues for us. In your initial scrutiny letter dated 31 March 2010 and re-stated in the Final Letter, you said:

> *I am afraid I cannot quite understand how it is that you say the SVJ document makes it clear that ultra-orphan drugs must be appraised in a different way or to different thresholds?* ***It seems to say that it is not expected they will be appraised at all, and is silent on what if anything should be done differently if they are?*** **(Emphasis added.)**

The SVJ is binding on the Institute. Given that you yourself suggest that its silence results in a lack of clarity, we believe that we have an arguable ground. At a minimum, the Appeal Panel should surely decide whether the SVJ obliges the Institute to treat ultra-orphan drugs differently.

By rejecting this ground, you have concluded that the SVJ does not, as a matter of fact, require the Institute to approach ultra-orphan drugs differently or to apply different thresholds. By doing so, we would argue that you have decided on the merits of our appeal, rather than merely considering whether the ground is arguable. We urge you to reconsider your position on this issue.

We make clear that should our appeal be rejected, we reserve our right to seek judicial review on all grounds raised in our appeal letter, including the procedural unfairness of failing to appraise ultra-orphan drugs on a different basis from orphan/non-orphan drugs.

We note that in relation to our human rights arguments, you propose to obtain a written note of provisional advice for the appeal panel from its legal advisor. We would ask

that this note should be provided to us by Wednesday 19 May at the latest, so as to allow adequate time for us to prepare a written response for the panel. It will obviously assist the panel if they receive written notes from both their legal advisor and the appellants in good time before the hearing.

Yours sincerely,

[redacted]

General Manager, Celgene UK