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April 25, 2007

Dear Reetan.

**Health Technology Appraisal
Bortezomib for relapsed multiple myeloma**

Thank you for your letter of 4 April in relation to the 'responder scheme' arrangements proposed by Janssen-Cilag for the provision of bortezomib (Velcade), within its licensed indication, for relapsed multiple myeloma, in the NHS in England and Wales.

I understand that you have received details of the proposed scheme direct from Janssen-Cilag, but for reference we attach a summary of the scheme as we understand it along with the detailed documentation that has been supplied to DH by the manufacturer. We have studied Janssen-Cilag's proposals in detail discussed this proposal with representatives from the manufacturer, with officials from the Welsh Assembly Government, the National Cancer Director and some of his clinical advisors. WAG colleagues will respond to you direct with their views.

It is important from the Department's perspective that any such scheme is transparent, that it is based on clinically appropriate criteria (including monitoring arrangements) and that it does not impose an unreasonable administrative load on the NHS, in particular on treating clinicians. We believe that the scheme is reasonable in terms of its clinical basis, are satisfied that its proposed operation is transparent and believe that it will not impose a disproportionate organisational burden on relevant NHS organisations in England. We note that Janssen Cilag's proposal involves supplying credit notes or replacement stock in the event of patients not responding to Velcade because their understanding is that this is easier for provider units to administer. We are content with this approach but are equally happy with a cash payment as long as the process remains easy for the NHS to manage locally.

We agree that the scheme should apply to patients who have suffered first relapse but do not hold a strong view on whether the number of cycles at which the response should be determined should be at 3 or 4. We understand that the great majority of patients who respond to Velcade will have done so after 3 cycles, but that extending the response assessment point to 4 cycles would probably result in a small increase in the number of

patients responding to treatment. In the Department's view, from a clinical perspective either 3 or 4 treatment cycles would be a reasonable point at which to assess response. The issue is whether the additional costs of treatment to 4 cycles are justified by additional benefits, and we would wish NICE to consider that question on its own merits.

Our understanding is that if it were established such a scheme would be expected to remain in place until the conclusion of any future NICE review of its appraisal of Velcade, and that the NICE review would provide an opportunity for interested parties to review their stance on the scheme.

Please let me know if you need any further information from the Department at this stage.

Simon Reeve
Head of Clinical and Cost Effectiveness

CC. Andrew Dillon, Meindert Boysen, Wendy Chatham, Carole Longson