Department of
Health, Social Services and Public Safety

An Roinn
Sláinte, Seirbhísí Sóisialta agus Sábháilteachta Poiblí

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From: DHSSPS NI
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DHSSPS N IRELAND - COMMENTS ON ACD
HEALTH TECHNOLOGY APPRAISAL **MULTIPLE MYELOMA- BORTEZOMIB-ACD**
Dr Martin Eatock ,Chair Belfast City Hospital, Oncology/ Haematology Drugs and Therapeutics Committee – on behalf of DHSSPS NI

I disagree with the ACD recommendations for bortezomib in its licensed indication. The clinical effectiveness of bortezomib cannot be in doubt that this is acknowledged in the ACD. Furthermore the committee have not rejected its use on cost effectiveness grounds. The recommendation appears therefore to be based upon the lack of clarity regarding the position of bortezomib in the pathway of care for patients with myeloma.

I believe this is perverse as the management of patients, where there is a potential choice of therapies, will depend on the relative toxicities of those treatments, clinical effectiveness, and patient factors such as pre-existing comorbidity. It would not have been unreasonable for the committee to suggest that bortezomib should be restricted for use in patients where the use of high dose dexamethasone would be considered an appropriate treatment option, given that this was the standard treatment arm of the APEX trial which confirmed the clinical effectiveness of bortezomib.

In randomised phase II trials where Time to Progression is the primary endpoint of the trial it is increasingly common for patients receiving standard care to cross over to the experimental treatment where this has shown an advantage. This crossover occurs because of ethical considerations. Therefore if the committee accept that time to progression is a valid primary endpoint in a clinical trial they should accept the data as presented. Crossover will always make analysis of some secondary endpoints such as overall survival difficult to analyse satisfactorily.

The committee suggest that they believe the manufacturers estimate for cost effectiveness of £38,000 per QALY is an underestimate and that they were not persuaded that bortezomib was cost effective compared to current standard treatments used in the NHS. If this is the prime reason for not recommending bortezomib this should be stated in section 1.

Finally, given the ongoing trials of bortezomib in multiple myeloma, and the data which will be available from these in the near future, the suggested review date of 2009 is too late to adequately react to a rapidly changing clinical environment. Without early review of the final appraisal (assuming the recommendations in the ACD remain unchanged) patients with myeloma may be significantly disadvantaged compared to other parts of Europe or even the British Isles.

Deadline for comments to NICE 14 August 2006.