

- i) Do you consider that all of the relevant evidence has been taken into account?

Yes. Our organisations, the British Society for Haematology (BSH) and the UK Myeloma Forum, (UKMF) are very pleased that the Committee, having considered the evidence from the ERG, taken into account the price capping scheme offered by the manufacturer, and agreeing that Lenalidomide for myeloma fulfils the criteria of a life extending medicine, has recommended that Lenalidomide and dexamethasone be made available for patients with myeloma at second relapse and beyond.

As previously stated, we consider Lenalidomide to be a well tolerated, effective drug in patients with relapsed myeloma and we are in no doubt as to the importance of and the positive impact the Committee's decision will have on the lives of people suffering with this disease.

- ii) Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence, and that the preliminary views on the resource impact and implications for the NHS are appropriate?

We believe the Committee, after rigorous examination of the all evidence has made the correct decision in recommending that Lenalidomide be made available.

We recognise and appreciate that the Committee has listened and agreed to feedback from stakeholders on a number of specific issues. However, we note that it still expressed some doubts about the costs and disutilities for the adverse effects and anti-thrombosis prophylaxis for Lenalidomide. We take this opportunity to further reassure the Committee that these doubts are unjustified as increasing clinical experience demonstrates to us that side-effects, such as they are, are mostly experienced early in the treatment course and lessen over time. They are very easily and cheaply managed and have proved in reality not to be the issue and challenge as they may have first appeared from the data which emerged from the trials.

We are delighted that the desperate need of patients facing certain death has been acknowledged by the Government and that NICE and the Committee have acted swiftly in implementing the new advice concerning end of life medicines and agreed that Lenalidomide for myeloma at second relapse and beyond meets all the criteria for the new advice to be applied.

- iii) Do you consider that the provisional recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS?

We do believe the recommendations of the Appraisal Committee are sound and constitute a suitable basis for the preparation of guidance to the NHS.

In particular we feel that the capping scheme is simple, will be easy to implement and represents a good deal for the NHS. We understand it is necessary to ensure that NHS resources are used cost effectively and we seek to reassure the Committee that through our professional groups via guidelines, teaching and training, we will make every effort to ensure that the guidance is implemented responsibly and delivers maximum benefit to patients and the NHS.

iv) Are there any equality related issues that need special consideration that are not covered in the ACD?

We are not aware of any equality related issues that need special consideration not covered in the ACD

[REDACTED]

On behalf of UKMF and BSH
Friday, 20 February 2009