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NICE: friend and foe

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It was not without a sense of irony, I expect, that the UK government chose to christen its drugs watchdog with the acronym NICE (National Institute for Health and Clinical Excellence), surely aware of the controversies to follow and the oxymoronic mileage it would grant the media. Myeloma is an incurable bone marrow cancer affecting 8,000–12,000 people per year in England and Wales and has been one of the recent victims of a negative NICE appraisal. The Institute acknowledges that bortezomib (Velcade®; Ortho Biotech, High Wycombe, UK), the first innovative treatment to be licensed for myeloma in well over a decade, is a clinically important and effective treatment for patients with relapsed myeloma, but has deemed it not cost-effective enough to be considered appropriate for use on the National Health Service (NHS).

In the current drugs approval system we have a reality in which cost-effectiveness can outweigh clinical importance. I accept that the NHS has finite resources, and agree that the introduction of new drugs should be subject to appropriate scrutiny. Further, NICE does a commendable job within its predetermined remit. The existing procedures that are in place, however, often do not translate into fair and sensible treatment availability on the NHS. The Velcade® decision leaves relapsing myeloma patients with only experimental or unlicensed alternatives. In seeking clinical excellence, the NICE system can perversely subject patients to treatments that lack the gold standard evidence base that it insists scrutinized drugs possess. Consequently, there is a real possibility that the NHS is wasting money on less effective treatments—or on avoidable palliative care and hospitalization—rather than investing in treatments backed by sound clinical evidence.

This situation has clearly arisen from, and been exacerbated by, two principal factors. To begin with, the remit within which the government asks NICE to operate is inadequate. To assess treatments using a 'one size fits all' method is ineffectual: the quality-adjusted life year (QALY) threshold is arbitrary and ambiguous, and set cost limits do not permit assessment of treatments covering the entire disease spectrum. Secondly, on a more holistic front, the 'cost-effectiveness' consensus varies across public sector regulators (for example those with responsibility for road, rail, health, or the nuclear industry). Vast resources are fed into some industrial pursuits, such as train protection systems and nuclear clean-up schemes, often at poor value for money, resulting in illogical disparities in spending across differing areas of need. Health regulatory expenditure is often the recipient of tighter constraints than its counterparts.

An intelligent debate on the workings of NICE and the wider issue of equitable public spending is required.

Sensible solutions are within reach for technologies that are clinically effective and within the grasp of QALY-ordained cost-effectiveness. The granting of time-bound conditional approval of treatments, with ongoing collection and audit of clinical results—including response and quality of life data—to further inform value for money, and a pharmaceutical–government risk-sharing scheme, ought to be important components of NICE reform. Involving the Institute earlier in the licensing process and in the design of clinical trials would further improve the UK drugs approval system, and public controversy can be minimized with a commitment to greater transparency in NICE decision-making processes.

In moving forward, political will is imperative. An intelligent debate on the workings of NICE and the wider issue of equitable public spending is required. It is promising that 2007 will see both a Health Select Committee inquiry into the remit of NICE and an open public consultation by the Institute itself; Myeloma UK will certainly be using both forums as platforms to campaign for change. We hope that 2007 will see the first step towards dynamic and sensible reform.

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Competing interests
The author has declared associations with Ortho Biotech. See the article online for full details of the relationship.

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