Hope or hype?

Kathy Redmond ■ EDITOR

Decades of experience have taught us to guard against the temptation to trumpet early impressive results as breakthroughs. Yet some of the comments over the promising results from trials testing Herceptin (trastuzumab) in early-stage breast cancer raise questions about how well that lesson has been learnt.

In a glowing NEJM editorial, Gabriel Hortobagyi, a breast cancer specialist at the MD Anderson Cancer Center in Texas, described the results as "revolutionary", "simply stunning" and "maybe even a cure". Jo Anne Zujewski, director of breast cancer research at the US NCI, said the findings support her belief that breast cancer has become curable in increasing numbers of women.

Predictably, these statements fuelled demand for early access to Herceptin from patients concerned that they would die without this drug and, not surprisingly, sections of the popular press gave over their front pages to champion their cause. Such was the pressure in the UK that the government instructed local health authorities that they should not restrict use of the drug in patients with early breast cancer on the grounds of cost, even though the drug was not licensed for use in this setting, and indeed the manufacturers had yet to submit an application to EMEA.

This decision may return to haunt the UK government when equally compelling and emotional situations arise, as they inevitably will.

In a tough editorial, the *Lancet's* editor, Richard Horton, voiced strong criticism of decisions in the UK and other countries to bypass official approval procedures. He pointed out that available evidence on the drug's safety and efficacy in the adjuvant setting is insufficient to make reliable judgements, particularly since interim results are prone to showing large treatment effects that may not stand the test of time.

Some US-based breast cancer advocacy organisations agree with this assessment and have chastised cancer experts for using the word "cure", because such premature confidence may fuel unrealistic expectations.

We cannot overlook the situation facing either the women newly diagnosed with HER2+ breast cancer right now who are desperate to optimise their chances of survival, or the doctors who must tell their patients that only those who can afford to pay will get the drug. But should we accept that complex decisions on access to cancer therapies are made in haste, in reaction to sensationalist media campaigns?

Faced with the challenge of spiralling healthcare spending there is a need for balanced debate to tease out when, if ever, it is acceptable for a cancer drug to be paid out of the public purse prior to the drug's approval for a specific indication.