mount importance is the requirement to keep public health care at the highest scientific level, based on evidence and medical competence.

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SHOULD REGULATORS BE CONCERNED WITH PHARMACOECONOMIC ISSUES?

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Risk–benefit analysis should be the only basis for approval or registration of a new agent. However in addition to this, in Sweden, for example, there is an obligation to promote cost-effective use of drugs based on written information or workshops that include subscribers. The National Institute of Clinical Excellence (NICE), a special health authority of the British National Health Service, deals with issues of cost and reimbursement. Regulators may think of considering cost effectiveness when they request data to substantiate efficacy of new anticancer agents as long as patients are provided with best possible treatment. If, however, society is not prepared to pay for new products, then they should not be developed.

The goal of regulators is to limit unnecessary queries because they needlessly increase the price of new drugs. A tradeoff exists between quality of data and cost and data quality cannot be lowered below some point. Industry dislikes segmented pricing, but, particularly in the case of drug combinations, costs are prohibitive for many countries. Differential pricing, based on the region where a drug is being marketed, is one way to maximise income. Regulatory authorities should take this factor into account as they consider registering or licensing new anticancer therapies.

Oncology involves a very special group of drugs. Is a new drug development model for oncology drugs required to get them to the market more quickly? Is conditional or accelerated approval the best means to do so? In theory, conditional approval should work although it is a relatively new process. Linking conditional approval to conditional reimbursement, however, needs to be very carefully evaluated as it should be possible to reassess the cost–benefit of a conditionally approved therapy and take it off the market if the cost–benefit analysis is not favourable (although it would be a very difficult situation).

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THE ETHICS OF PHARMACOECONOMICS FROM THE PATIENT'S PERSPECTIVE

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This discussion on pharmacoeconomics involves not only industry and academia, but also real people who have cancer. Some people are treated and cured, but many have to live with the disease. Results of a keypad voting survey[1] regarding the patient access to anticancer therapy of 104 cancer advocates in May 2005 are shown in Table 1.

Interestingly, 100% of respondents from France indicated they knew of no one who had been refused access to a cancer treatment because of cost, whereas 100% of those from Poland responded that they did. Clearly, cost is a factor, and the ability to access new anticancer therapies varies greatly across Europe. Patients do not think like consumers, though, because they do not care about price; they just want the best treatment.

Therefore the question is that if a significant number of people in Europe are not able to access technologies, what is the point of developing or testing them? To ensure that real people can benefit from new drugs means eliminating barriers to access, which include the high price tag of the drugs and the time it takes for registration or licensure. Clinical trials, regulatory agency review and health technology assessments (HTAs) all take time, but patients with life-threatening disease often do not have that luxury.

The goals of new-drug development should be to provide patients everywhere with timely access to safe and effective therapies and to ensure that patients are not put at undue risk by taking innovative medicines. Thanks to the informed consent process, patients understand risk and many are willing to accept it by participating in clinical trials, even if they might not benefit directly. Nevertheless, placebo-controlled trials present challenges because patients generally desire the opportunity to take a potentially effective drug. Patients are likely to benefit from the regular monitoring provided during clinical trials, but their

Table 1 – Results of a keypad voting survey of cancer advocates, 2005

Survey item	Response (%)
Are you aware of any cancer drugs that are not available in your country but are available in others?	
Yes	54
No	46
If yes, why is the drug not available?	
The drug(s) are not licensed in my country	39
The public health authority will not reimburse the drug(s)	56
Physicians will not prescribe the drug	0
Do not know	5
Do you know of anyone who has been refused access to a cancer treatment, because it was considered too expensive?	
Yes	51
No	49