Drug companies' lobbying of ministers has little effect on NICE

Andrew Jack *pharmaceutical correspondent, Financial Times*

Aggressive lobbying of government ministers by drug companies seeking to overturn the judgments of the body that advises on the use of treatments by the NHS in England and Wales has had little effect on its decisions.

Minutes of civil service meetings obtained by the *Guardian* (Sep 28, p 1) under freedom of information laws show that during the eight months to May this year senior executives from 10 drug companies met ministers to

criticise the National Institute for Health and Clinical Excellence (NICE).

Since its creation seven years ago NICE has been attacked by drug companies, doctors, and patients' groups whenever it recommends against reimbursement of new drugs in the NHS—largely on the grounds that their relative effectiveness is modest or their cost excessive.

An international consensus is growing that to improve health and tackle escalating healthcare

costs a more systematic "health technology assessment" is needed of precisely the sort that NICE provides.

At a meeting in October last year, Pfizer, the world's largest drug company, hinted at disinvesting from the United Kingdom, where it has a substantial research centre at Sandwich in Kent. "Pfizer ... noted that there is complacency in some quarters of Whitehall regarding their continued investment in the UK," the minutes read.

However, the most striking conclusion from the documents obtained by the *Guardian* was that drug companies' lobbying had proved largely ineffective. NICE rejected Pfizer's inhaled insulin product Exubera for NHS reim-

bursement and recommended its Alzheimer's drug donepezil hydrochloride (Aricept) only in very restrictive circumstances.

Eli Lilly lobbied in vain for pemetrexed (Alimta), its treatment for the asbestos related cancer mesothelioma, and Johnson & Johnson pushed for a "fast track" approval of bortezomib (Velcade) for bone cancer, resulting in a preliminary negative opinion from NICE.

The health department said in response to the *Guardian* story: "It's perfectly normal for ministers and officials to meet with a wide range of stakeholders, not only drug companies, to discuss a variety of issues. This in no way compromises the appraisal process." ■

Italy debates end of life decisions

Fabio Turone *Milan*

An open correspondence between a terminally ill man and the Italian president, Giorgio Napolitano, has spurred a public debate in the country about euthanasia and "living wills."

The letter to the president—entitled "Dear President, I want euthanasia"—was written by Piergiorgio Welby, an Italian of Scottish descent, who has advanced muscular dystrophy and is now confined to bed and attached to a ventilator.

He wrote, "Until two months and a half ago my life was certainly full of difficulties, but for a couple of hours every day, with the help of the computer, I could write, read, research, and meet with some friends over the internet."

"Now I feel like I fell in an abyss and am unable to find a way out. Every day it gets worse; I am increasingly weak and tired. I watch TV, waiting for the time of the lorazepam tablet so I can sleep and feel nothing, hoping I won't wake up the next morning."

President Napolitano, who was elected last May by the new centre left coalition government, expressed "sincere understanding and solidarity" and wished for a "sensible and thorough" discussion.

The correspondence brought polarised reactions, even within the centre left coalition. "Denying euthanasia to someone who is lucidly asking for it is pure and simple torture," said the former health minister and famous oncologist Umberto Veronesi.

But the president of the Senate, Franco Marini, a Catholic member of the coalition, warned that "euthanasia is not going to be discussed in the Senate."

Currently Italian law punishes doctors who practise euthanasia with prison terms of up to 15 years.

Now, despite the turmoil about euthanasia, the Senate's health commission, chaired by the transplantation surgeon Ignazio Marino, has begun to hear the eight bills presented so far about advance directives and life prolonging treatments. The final draft is expected to be voted on by the parliament by March 2007.

Piergiorgio Welby: "Every day it gets worse"

GMC recommends scrapping medical majority on its council

Clare Dyer *legal correspondent, BMJ*

The General Medical Council is to recommend scrapping the automatic majority of doctors on its governing council. This would end the longstanding principle of self regulation of the medical profession in the United Kingdom.

The 35 member governing council has agreed that "despite the constitutional changes that we have made in recent years, the professional majority on the council undermines confidence in our independence and because of that it impacts adversely on our ability to regulate effectively."

It wants to move to a "balanced composition" reflecting its four main stakeholders: patients and the public, doctors, doctors' employers, and doctors' educators and trainers. None of the four groups will have an in-built majority.

The change could see equal numbers of lay and medical members, spelling the end of the "professionally led regulation" now delivered by the GMC, 40% of whose council members are lay people.

The proposal will be put forward in the council's response to the reforms recommended by the chief medical officer for England, Liam Donaldson, in his report *Good Doctors, Safer Patients* (BMJ 2006;333:163). The

response will be finalised at the council meeting on 1 November. If ministers agree, the change, which goes further than the recommendations in Professor Donaldson's report, would need secondary legislation to bring it into effect. A move to a lay majority, which is not currently on the cards, would need primary legislation.

The GMC's president, Graeme Catto, said that the doctors' regulatory body had been "a source of controversy" over the past five to 10 years among groups that needed to have confidence in it. "The issue for us is what could we do that would allow us to command confidence over the next 10 years."

He said that the council needed to be independent of government and of any department of state, though it should be accountable to parliament. It should also be independent of any particular group among its constituencies.

"We need to be equal and even handed in dealing with them [the constituencies]," he said. "We want to end up with a balanced council, and we would not necessarily see an in-built majority for any one of those groups."

Also up for discussion is a move to an appointed or largely appointed council. ■