NICE to rule on influenza flu drug zanamivir

Gavin Yamey *BMJ*

The British pharmaceutical industry will start to move out of Britain if the government makes the environment antagonistic to its interests, Sir Richard Sykes, chairman of GlaxoWellcome, predicted on Monday.

Sir Richard's comments, on BBC Radio 4's *Today* programme, came after it was reported that the National Institute for Clinical Excellence (NICE) was about to recommend to the health secretary, Frank Dobson, that GlaxoWellcome's new influenza drug zanamivir (Relenza), should not be available on the NHS.

Sir Richard said that his company was not threatening to pull out of Britain, but he warned: "If [the government] continues to make the environment antagonistic to this industry then obviously it will start to move elsewhere. It is something which needs to be taken into consideration." He added that although 94% of his company's business was abroad, about 50% of its research work was conducted in Britain.

His remarks suggest that there will be a savage struggle between the new institute and the industry whenever the institute tries to restrict the introduction of a new drug.

The institute, which is undertaking a full eight month assessment of zanamivir, set up a special rapid assessment committee, chaired by its chief executive, Andrew Dillon, to produce preliminary guidance on the drug before a possible autumn or winter flu epidemic. The committee met twice in September and invited representatives from GlaxoWellcome to attend its second meeting.

Under the institute's rules, the manufacturer of any drug that is being assessed has the right to appeal to the institute's board, before any interim guidance is submitted to the secretary of state. GlaxoWellcome has just done so.

The crux of the argument over zanamivir hinges on whether trials have proved that the drug is effective in high risk patients, such as elderly people, or those with chronic respiratory disease. In its appeal, GlaxoWellcome has presented the institute with a new pooled analysis of its data, claiming that they show that the drug does benefit high risk patients.

Sir Richard, moreover, told the *Today* programme that the drug had been tested in 6000 patients. Only a small proportion of that number had come from high risk groups, because it was hard to enrol people from such groups into trials, but the numbers enrolled had been sufficient.

But Dr Robert Pearson, the company's associate medical director, said at a press conference in September: "We can't make any claims for its use in high risk groups" (11 September, p 659).

Professor Rory Collins of the Clinical Trials Services Unit in Oxford commented that "ideally trials should be done in as wide a range of patients as possible. Part of the rationale, on the part of the drug companies, for not recruiting elderly patients is that their side effect profile may be worse. There's also a tendency to try and exclude people with other diseases, with the fear that comorbidity will show up as a side effect." □

Full story in News Extra at ww.bmj.com

Japan's worst nuclear accident leaves two fighting for life

Joe Lamar *Tokyo*

Forty nine people were exposed to radiation—two with a potentially lethal dose—after Japan's worst nuclear accident struck a uranium processing plant on 30 September.

The accident occurred at a facility run by JCO, an affiliate of Sumitomo Metal Mining, in Tokaimura, 70 miles north west of Tokyo, as a result of an attempted short cut.

In the process of purifying reactor fuel, workers were supposed to use an automatic pump to mix up to 2.4 kg of enriched uranium with nitric acid. Instead, they manually used a stainless steel bucket and mixed 16 kg of the fissile material.

The uranium reached a critical mass at 10 35 am and set off an uncontrolled chain reaction that emitted radiation for almost 20 hours.

The three workers who carried out the operation reported seeing a blue flash—the Cerenkov radiation that is emitted during a critical reaction—before collapsing with nausea. They were rescued by colleagues and taken to a local hospital by emergency services.

According to doctors, two of the men were exposed to more than the 7 sieverts of radiation that is considered lethal: Hisashi Ouchi, aged 35, and Masato Shinohara, aged 29, received 17 sieverts and 10 sieverts respectively. Their supervisor, Yutaka Yokokawa, aged 54, was irradiated by 3 sieverts.

After the men were taken to the National Institute of Radiological Sciences in Chiba, just east of Tokyo, tests on Mr Ouchi and Mr Shinohara showed their lymphatic blood count had plunged to almost zero. Symptoms included nausea, diarrhoea, and dehydration.

Three days after the accident the two men were transferred to the University of Tokyo Hospital for transfusion operations that were seen as the only hope of reactivating their blood producing functions.

At the time the *BMJ* went to press, Mr Ouchi was due to receive peripheral stem cells from his brother and Mr Shinohara was to have a transfusion from congealed umbilical cord blood. David Kyd, a spokesman for the International Atomic Energy Agency, based in Vienna, said that the chances of the two men surviving were slim. □

Full story in News Extra at ww.bmj.com

AP PHOTO/KATSUMI KASAHARA

A man has his radiation level checked in Tokaimura, Japan