NICE to issue faster guidance on use of drugs by NHS

Susan Mayor *London*

The National Institute for Health and Clinical Excellence (NICE), which advises the NHS in England on the use of medical treatments, has developed a more rapid process for assessment that will be used initially for lifesaving medicines, including several cancer drugs.

The new "single technology appraisal" process will enable NICE to develop guidance on drugs selected for rapid assessment within eight weeks—much more quickly than the current average of 18 months. It will initially be applied to lifesaving drugs that have already been licensed and to new lifesaving medicines close to the time that they first become available.

In the faster appraisal system, NICE will ask for a single submission of evidence from the

manufacturer of the drug being appraised. The institute will then independently assess this evidence and move rapidly to the final stage of the process—in which organisations can appeal against the decision—in cases for which the draft recommendations are in agreement with the drug's licence. Currently, after deciding the scope of the appraisal, NICE commissions an independent academic centre to report on the published evidence, which is then considered by an independent committee.

Their appraisal is widely circulated for comment before the final guidance is produced. Patients' and carers' groups, bodies representing health professionals, and the manufacturers of the drug being appraised are also invited to submit evidence.

The new appraisal process will initially be applied to 14 drugs—13 of which are cancer drugs—that have already been referred to NICE. These include docetaxel (Taxotere) for breast cancer; paclitaxel (Taxol) for breast cancer; rituximab (MabThera) for non-Hodgkin's lymphoma; trastuzumab (Herceptin) for breast cancer; and bortezomib (Velcade) for multiple myeloma. NICE estimates that the more rapid process will result in guidance being published 6-15 months earlier than with the existing process, with more than half of appraisals being published at least eight months earlier.

The first guidance developed using the new process will appear by June 2006, NICE hopes. Guidance on bortezomib and trastuzumab (subject to it being granted a licence by regulatory bodies) will appear shortly afterwards.

Delays in the development of NICE appraisals—particularly in relation to cancer drugs—have

attracted widespread criticism because they have led to delays in the use of drugs by the NHS. Andrew Dillon, chief executive of NICE, said, "We are aware of the need for timely advice on the use of new medicines, particularly for life threatening conditions such as cancer. The proposals we have set out mean NICE can deal with the current backlog much quicker than planned and that we will be able to issue guidance to the NHS rapidly in the future, once a drug is licensed."

Joanne Rule, chief executive of the cancer information charity CancerBACUP, said, however, "These proposals represent a bold reform package for the future, but they don't solve the problem of the backlog of new cancer treatments currently held up at NICE." She added, "NICE should issue interim guidance on cancer treatments already approved for use in Scotland, and it's crucial that the government make it crystal clear that doctors can prescribe licensed cancer drugs now." □

Merck cleared in personal injury case against Vioxx

Susan Mayor *London*

The pharmaceutical company Merck has won a personal injury court case associated with its cyclo-oxygenase-2 inhibitor rofecoxib (Vioxx) in the United States, a jury ruled in Atlantic City last week. This is the second case to be brought against the drug giant out of more than 6000 claims expected from people or their relatives who say they were harmed by rofecoxib. Merck lost the first case.

In the most recent case, the state court jury found by an eight to one vote that Vioxx had not caused Frederick Humeston, a 60 year old Idaho postal worker, to have a heart attack in September 2001. The plaintiff had alleged that he had had a heart attack as a result of intermittent use of Vioxx over a two month period.

The jury also concluded unanimously that the company had properly marketed Vioxx. It

found that Merck had given doctors adequate warning about possible health risks and did not commit consumer fraud in marketing the drug. It reached its decision after just over one day of deliberation after a seven week trial.

In a statement, Jim Fitzpatrick, a member of Merck's defence team, said, "We presented a case that was solidly based on scientific evidence." He continued, "Frederick Humeston would have suffered a heart attack when he did whether he was taking Vioxx or not. In addition, Merck presented evidence that showed that it carefully studied Vioxx before and after [Food and Drug Administration] approval, and consistently made the results of those studies available to the FDA and the medical community."

In the first US personal injury court case regarding Vioxx, heard in August this year, a Texas jury ruled that Merck should pay \$253m (£146m; €216m) after ruling that the drug had contributed to a man's death and that the firm had been negligent (\$24.4m for economic loss and emotional anguish and \$229m in punitive damages). This was later reduced to about \$26m under Texan law, which

limits damage payments. The company is appealing against the ruling (*BMJ* 2005;331:471, 3 Sep).

Merck is facing more than 6400 further Vioxx lawsuits in the US. Kenneth Frazier, senior vice president and general counsel of Merck, said in a statement that the company would "vigorously defend them one by one over the coming years." He added, "Merck acted responsibly—from performing extensive clinical trials comparing Vioxx to NSAIDs [non-steroidal anti-inflammatory drugs] or placebo

in almost 10 000 patients prior to approval, to monitoring the medicine while it was on the market, to voluntarily withdrawing the medicine when we did." Rofecoxib was withdrawn in September 2004 after a study showed that it doubled the risk of heart attack or stroke if it was taken for longer than 18 months. The risk was thought to be due to increased risk of thromboembolism.

The next US Vioxx personal injury trial is scheduled to begin in federal court in Houston on 28 November. □

Frederick Humeston hugs his wife after the hearing in New Jersey