



We don't have to be a year behind

→ Kathy Redmond ■ EDITOR

Late last year, US patients with advanced renal cell cancer gained access to an oral multi-kinase inhibitor, Nexavar (sorafenib) – the first new drug approved for this disease in the last 10 years. Manufacturer Bayer had filed an application for approval with the European Medicines Agency (EMA) around the same time as its application to the US Food and Drug Administration (FDA). However, the company states that, pending a favourable review, it does not expect the agent to become available to patients in Europe until late 2006 – nearly one year later than in the US.

In January 2006, Pfizer secured FDA approval for its multi-tyrosine kinase inhibitor Sutent (sunitinib) for the treatment of gastro-intestinal stromal tumours (GIST) and advanced renal cell cancer. Pfizer had submitted its marketing approval application for Sutent to EMA last autumn, but a decision is not expected until later this year.

Patients with advanced renal cell cancer have a poor prognosis and few therapeutic alternatives. The FDA granted fast track status to both products because of their potential to provide important therapeutic benefit over currently available therapies. They made a decision on Nexavar in 162 days and on Sutent in 148 days. Similar patients in Europe, however, still face significant delays in accessing two potential-

ly life-extending drugs that have already been deemed approvable by a leading regulatory agency. Strangely there is no public outcry about this, in total contrast to the scenario currently being played out with Herceptin (trastuzumab).

Europe is lagging a long way behind the US in terms of cancer drug approval times. In some countries, pricing and reimbursement negotiations create additional delays. A new fast-tracking assessment procedure was introduced by EMA in November 2005 for drugs of major therapeutic benefit that address significant unmet need. The accelerated assessment procedure reduces the time limit for the evaluation of drugs from 210 days to 150 days. At least 80 of these days must be allocated to scientific analysis of the data.

However, the translation and decision-making procedures that follow can add a further two to three months to a drug's approval time, as decisions go back and forth between EMA, the member states and the Commission.

Recent attempts to speed this process have been little more than a trimming exercise. Commission officials and legislators alike have failed to weed out unnecessary bureaucracy, which continues to impede patient access to innovative cancer drugs in Europe. The European cancer community has a responsibility to help policy makers redress this unjust situation.