

IN brief

Norway's swift bail out

The Norwegian government has unveiled a rescue package for the biotech industry as part of a national financial rescue plan. The stimulus package worth NOK20 (\$2.87) billion contains explicit measures worth about \$400 million to support the biotech industry and prevent companies from going bankrupt. The government's move came in response to a proposition made by the Oslo Cancer Cluster, an industry and research cluster representing 25 Norwegian groups. Over half of the group's member companies, which together have more than 50 oncology products in the pipeline, were in danger of running out of cash in the next 12–18 months. In other countries where similar requests have been made, the response has been slow (*Nat. Biotechnol.* **27**, 1, 2009). "The Norwegian government understood that they had to react quickly," said Jónas Einarson, chairman of the Oslo Cancer Cluster. Key measures in the package include a tripling of the funds allocated to innovations loans for biotech and information technology, an additional \$279 million for the government-owned fund Argentum to invest in private venture capital funds focusing on life sciences, and extra tax breaks for individual small-to-medium enterprises. "Norway has a small but growing industry with a very strong pipeline, mostly in the oncology sector," says Einarson. "The Norwegian government wants to make sure that this fragile industry survives the ongoing financial crises." *Nayanah Siva*

Green fuels thrust

By 2020, all road transport fuel in Europe must include 10% from renewable sources, be it from biofuels, hydrogen or green electricity. The European Parliament's decision, reached last December, is a step down from the original aim of sourcing 10% of transport fuels from biofuels alone. Across the Atlantic, the US Department of Energy announced \$200 million in funding from 2009 to 2014 for pilot and demonstration-scale biorefineries to develop cost-effective biofuels such as bio-butanol, 'green gasoline' and advanced biofuels technologies, such as algal biomass. But first-generation biofuels manufacturers have been trading at an all-time low. In January, Pacific Ethanol, of Sacramento, California, suspended operations at one of its sites, and last November, the world's largest corn-based ethanol producer, VeraSun Energy Corporation, of Sioux Falls, South Dakota, filed for bankruptcy citing huge losses and a \$1.5 billion debt. The situation for corn ethanol producers could arguably improve as the US gears up to accommodate the 36 billion gallons per year of annual domestic renewable-fuel production stipulated in the Energy Policy Act. "Corn ethanol is not going away anytime soon," says Pavel Molchanov, analyst at Raymond James in St. Petersburg, Florida. "With the current costs and low rates of return, I see no real investment going into the sector apart from VC [venture capital] and public money, so it will take some time to figure out the economics of second-generation technologies."

Victor Bethencourt



Anne Marie Rogers in the UK launched a legal action against her local health authority in 2006 after she was denied Herceptin to treat early-stage breast cancer. NICE guidelines restricted the drug's use to 'exceptional circumstances', but guidance has since been revised to include all HER2-positive breast cancer patients.

But Exeter University's Taylor thinks that the biotech industry needs to face up to the fact that some form of HTA will be applied in all major markets. "The movement is bound to spread: as far as governments are concerned, they are interested in cost effectiveness because they can't pay for everything. The question will be, Does this drug give you more healthcare bangs for your healthcare bucks?"

Negative rulings by NICE are leading companies to strike 'creative pricing' or 'risk-sharing' deals to meet the institute's cost-effectiveness criteria. Examples include Velcade (bortezomib) for treating multiple myeloma,

for which manufacturer Johnson & Johnson of New Brunswick, New Jersey, reimburses the NHS for patients who do not respond, and Lucentis (ranibizumab), for which the NHS pays for the first 14 injections and manufacturer Genentech of S. San Francisco pays if more treatment is required.

Although these are portrayed as risk-sharing deals, Keiron Sparrowhawk, partner at the pricing and reimbursement consultancy PriceSpective, believes that they are merely a form of discounting. "The industry is prepared to do it when it doesn't have to lower the list price," he said. This is important because although the UK represents just 6%

Box 1 How does NICE judge cost-effectiveness?

To decide if the UK's NHS should pay for a drug, NICE assesses the treatment's additional cost over that of the current standard therapy, set against the extra health benefits it confers. The tool for comparing the value or health gain of different drugs is the quality-adjusted life year, or QALY, which, at its crudest, measures the increase in life expectancy and quality of life derived from any treatment.

The main difficulty with QALYs is that this measure does not take account the severity of the underlying condition. A second major problem is the question of who decides what is an acceptable cost per QALY. Any drug with a cost per QALY below £20,000 will automatically get the nod; those between £20,000 and £30,000 will need additional evidence; and it is rare for drugs with a cost per QALY of over £30,000 to be approved.

Given an unacceptable price per QALY, there are two ways forward for companies to get NICE's approval: provide more compelling data for benefits or lower the price. In Australia, negotiating price is an explicit part of the HTA process. Similarly, in France the clinical added value, as determined through an HTA, is the key factor in agreeing on a price.

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