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A deal on the horizon

Leaders have finally thrashed out the European Union budget for the next seven years. But how much money will go to research is yet to be confirmed.

After almost 26 hours of intense debate last week, European leaders have finally agreed on the total European Union (EU) budget for the period 2014–20. Scientists can breathe a sigh of relief — but concerns cannot be dismissed just yet.

The deal allocates €125.6 billion (US$168 billion) for initiatives to increase Europe's competitiveness and strengthen employment. That includes the budget for the Horizon 2020 research programme, which will fund basic research through the European Research Council (ERC) and applied science through other projects.

The total funding for competitiveness over the next seven years has increased by more than 37% compared with the EU budget for 2007–13. European scientists and research lobbyists have cautiously welcomed the deal, which hints at a reasonable settlement for research given Europe's current tight economic climate. As described on page 159, the deal currently sets aside around €69 billion for Horizon 2020. But that could change in coming weeks, as ministers thrash out the fine details of the agreement and the European Parliament also has its say.

The deal agreed on 8 February follows intense lobbying by scientists across the continent to protect the research budget after EU leaders failed to see eye to eye at budget talks in December. Hard-line governments including those of Britain and Germany were looking for a substantial slash to EU spending plans. Lobby groups including Euroscience, which is based in Strasbourg, France, and scientific leaders including Helga Nowotny, president of the ERC, urged decision-makers to safeguard the €80-billion research budget suggested by the European Commission.

Analysts have already begun to crunch the numbers to work out what the competitiveness budget could mean for research. According to estimates by Wolfgang Eppenschwandtner, executive coordinator of Initiative for Science in Europe (ISE), an independent science-advocacy group based in Heidelberg, Germany, the lobbyists will not get everything they wanted. The question is, on what will they lose out?

In the agreement, decision-makers said that a priority of EU spending should be to strengthen research and innovation. Horizon 2020 and the ERASMUS for All programme — which includes funding for graduate students to study abroad — have been promised more money in their yearly budgets than was provided for research and the ERASMUS programme in 2013.

Given this rhetoric, says the ISE, a research budget of €69 billion represents the worst-case scenario. In the best case, Horizon 2020 could actually be awarded between €75 billion and €78 billion.

Standing in the way of the best-case scenario are the financial commitments that EU leaders have already made from the 2014–20 competitiveness budget. They have set aside €29.3 billion for building transport, energy, broadband and digital-services infrastructure as part of the Connecting Europe Facility. They have also allocated €6.3 billion for the Galileo global-navigation satellite system; €2.7 billion for ITER, the experimental fusion reactor being built in Cadarache, France; and €3.8 billion for the Global Monitoring for Environment and Security Earth-observation satellite. Taking into account all the other initiatives that the competitiveness budget must also cover, not all that much money is actually left in the budget for research.

One possible way to free up more funds would be for the EU to pay for its agriculture research, proposed at about €4 billion, from the agriculture budget instead of the competitiveness budget. Still, even lobbyists pushing for this idea say that it is not clear whether it is legal or possible given administrative constraints.

"The lobbyists will not get everything they wanted. The question is, on what will they lose out?"

Ultimately, the final outcome for research depends on minsters' interpretation of the edict that Horizon 2020 will get a real increase over funding levels in 2013.

Keeping in mind that before the budget talks, rumours were circulating of even deeper cuts to research, scientists and lobbyists have done well to secure research funding of at least €69 billion. But the fight is not yet over. ■

Preventive therapy

Stem-cell trials must be made easier, so that treatments can be based on real data.

Last November, a Nevada court convicted two men of fraud for selling ineffective stem-cell treatments to people chronically ill with, among other disorders, multiple sclerosis or cerebral palsy.

According to the US Food and Drug Administration (FDA), one of the men, Alfred Sapse, targeted extremely ill patients with a method that he claimed to be proprietary — implanting portions of placental tissue into the abdomen. Sapse, the agency says, knew that he needed FDA approval for such a procedure. He didn't have it. He claimed to be a doctor but didn't have a licence. The other defendant, the physician who performed the procedures at Sapse's bidding — on some 34 people in Las Vegas — knew "that it would not benefit the patients". The pair "conducted no meaningful follow-up with the patients who underwent the implant procedures". They did "not use any of the money for laboratory research, animal studies or human clinical studies relating to the short- and long-term effects of the implant procedures". (Sapse made US$1 million from the treatments; he spent $700,000 of that on gambling and personal expenditure.) At least two patients suffered infections, and it is not clear what damage others might have incurred. In November 2006, the FDA issued a warning letter, telling the pair to stop. But they continued.

The incident shows the cavalier attitude with which many fraudsters

approach the promising yet immature field of stem cells. It also shows the importance of the FDA's regulatory role. Yet, as described on page 166, that role has been questioned by a Texas stem-cell-therapy company. The firm, Celltex Therapeutics in Houston, has demonized the agency to its patients, some of whom seethe at what they see as government intrusion.

The situation with Celltex is different from the Sapse case — the Texas company believes in its treatments, its doctors are real and its stem-cell manufacturing was registered with the FDA, for example. But the quality of the stem cells that Celltex used was not ensured, and follow-up on patients seems not to have been rigorous.

Celltex frames its dispute with the FDA as a conflict between a brave company that wants to offer cutting-edge medicine to desperate patients and a tyrannical bureaucratic ogre that is holding it back. But some of the facts don't fit that simple narrative.

Patient care is about more than intervention. It demands top-quality processing facilities, systematic administration of therapies and meticulous follow-up, so that informed decisions can be made for current and future patients. If Celltex wanted to be the standard-bearer for a new form of cell-based therapy, if it wanted to have a showdown with a federal agency by demonstrating that regulations stand in the way of scientific progress and patient health, it should have produced the best evidence of safety and efficacy that it could muster. That would have stimulated an interesting and constructive debate and created real pressure for change at the FDA.

Certainly, there is room for the FDA to improve the regulation of stem cells. The large clinical trials that the rules currently demand are so expensive that many researchers and biotechnology companies cannot afford to conduct them. To ease that problem, the agency could explore expanding its 'compassionate use' clause, which allows individual patients to pay for drugs that are being used in FDA-approved trials. Alternative funding mechanisms, perhaps involving national insurance programmes, could be used to help offset the costs to patients and to those who perform the trials.

To enact such a change, the FDA would probably need more money to ensure that companies are serious about developing medicines and not simply seeking a loophole to increase profit. Increased FDA funding could also enable the agency to waive or reduce fees paid by the (usually small) biotechnology companies that develop the treatments. Organizations including the Alliance for Regenerative Medicine in Washington DC have been working with the FDA to create a regulatory environment more conducive to the development of stem cells.

"Patients are ready to take risks and clinical researchers are ready to do studies."

More broadly, there has been a boom in people going abroad to receive stem-cell treatments. The World Health Organization (WHO) has taken a stand by issuing guidelines on how to regulate cell transplants. National authorities could actively engage with the WHO to ensure that those guidelines are effective.

All involved want to speed up the introduction of stem cells into the clinic. Patients are ready to take risks and clinical researchers are ready to do studies. Funding bodies should step up with money to help.

The matter is urgent. After the FDA turned up the heat, Sapse went to Mexico for three years before his arrest in 2010. Celltex is moving there now. The longer it takes to develop a workable and affordable system in nations such as the United States, the more patients will travel for treatment to countries where there are even more unknowns. ■

Damage control

Planning for extreme events must incorporate not just infrastructure but societal preparedness.

When officials in New York City began to piece together how Superstorm Sandy had managed to flood the subway last October, they found that the storm had driven a bundle of lumber from a construction site right through a plywood barrier built around one of the entrances to the South Ferry subway station. It was a seemingly random act of violence, but in reality, the barriers probably never stood a chance. With a standing-water height of up to 1.5 metres at Battery Park on Manhattan's southernmost tip, the rising tide skirted a second plywood blockade and poured over a waist-high concrete wall at another entrance.

Preparing for hurricanes is hard. But the fact that core infrastructure in a global metropolis such as New York was protected by plywood should trigger alarms. South Ferry is a reminder of just how ill-prepared New York was for a storm of this magnitude — and it underscores the scale of the challenge ahead.

It wasn't supposed to be this way. New York City has engaged scientists while working to reduce emissions and prepare for a warmer world. In 2008, Mayor Michael Bloomberg created the New York City Panel on Climate Change, and in August the city council gave the panel a permanent place in its long-term planning process. *PlaNYC*, a planning document that offers a vision of what the city will look like in 2030, includes a comprehensive chapter on climate change. But none of this prepared the city for Sandy. Nor could it have — the surge that Sandy brought ashore was off the charts.

Legions of scientists are now assessing what happened and projecting future risks. The latest, and perhaps best, estimate, based on models by researchers at Princeton University in New Jersey and the Massachusetts Institute of Technology in Cambridge, is that the storm surge at Battery Park was a 1-in-500-year event. But the size of a surge is not the only measure of a dangerous storm, nor is Battery Park the only location that matters. Scientists also know that the baseline is changing with the climate. All of which leaves the city, its residents and businesses in the unenviable position of rebuilding in the face of an uncertain future.

As this process unfolds, several lessons can be learned from Sandy (see page 162). In many places, premises erected under newer building codes survived the storm with only limited damage at ground level. A new generation of waterfront parks and developments also weathered the storm quite well, showing that there are ways to manage the risks of occasional flooding. But given the predicted sea-level rise and the likelihood of more powerful storms in the future, a more comprehensive strategy is clearly needed.

Some positive signs have emerged. The Federal Emergency Management Agency is updating the city's flood maps, and the city has announced steps to strengthen its building codes. As directed by Congress last year, the agency will also be incorporating long-term climate projections, including for sea-level rise, into its rate structure for the federal flood insurance programme. Until now, the programme has served as a government subsidy for risky coastal development — so risky that private insurance companies refused to enter the market.

One of the big questions facing the region is whether to spend billions of dollars on a storm-surge barrier. Scientists and engineers should clearly include a barrier in their analysis, but a surge is just one of many threats posed by many kinds of storm. Moreover, how fast New York bounces back will depend not only on damage to infrastructure but also on the strength of social networks and the general health of the communities affected. Farther afield, as sea levels rise, coastal cities will have little choice but to learn to live with more water than they are used to today. ■

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