approved in Zambia — $168 million for eight climate projects — are "small change", he says. The approvals include a wetlands resilience programme in Peru, climate-resilient infrastructure in Bangladesh and a scheme of 'green bonds' to finance sustainable energy ventures in Latin America and the Caribbean, but seven of the schemes will not receive money until they meet further project-specific conditions.

Developed nations may be reluctant to transfer their money to the fund, says Timmons Roberts, who studies climate change and economic development at Brown University in Providence, Rhode Island. "Many developing countries and NGOs believe that the funding should all flow through the GCF," he says. "However, contributor countries have always defended their ability to funnel their funds through channels they control, whether through their own bilateral agencies (like USAID) or through dedicated World Bank funds."

LACK OF TRANSPARENCY

There are also concerns about how the GCF is run, says Wu, who attended the Zambia meeting as a permitted 'civil society observer'. Wu is worried that indigenous communities were not adequately consulted before the approval of $6.2 million for the Peruvian wetlands programme, for example. GCF documents say that a consultation was carried out, but for this and for other projects, the fund has no independent verification of its claims, says Andrea Rodríguez Osuna, who works in Mexico City for the non-profit environmental law organization AIDA and was also present in Zambia.

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Nor is the GCF transparent about its processes, Rodríguez Osuna adds. "The fund has no information disclosure policy and no accountability mechanism, yet the board is approving project proposals," she says.

For the eight projects approved at the board meeting, for example, only proposal documents were publicly available (and in the case of two private-sector projects, only a summary). "These are hardly the unbiased sources of information needed to evaluate a project's merits or any potential negative impacts," Wu says. Project reviews made by the fund's board and by an independent technical advisory panel are not publicly released, and GCF officials repeatedly failed to answer questions asked by *Nature* for this article.

For some, another contentious issue is that the GCF is flowing its money mainly through international organizations, such as multilateral or private banks such as the World Bank and Deutsche Bank — rather than sending it directly to institutions in developing countries where the projects are taking place.

The GCF is still new and is seriously understaffed, Rodríguez Osuna adds; and observers hope that their worries are teething problems. Its executive director, Héla Cheikhrouhou, has promised "many more projects under development".

Claims have already been made that rich nations are upscaling public climate funding. But experts say that there is little clarity on whether the cash is new money, or being re-routed from elsewhere, such as from overseas development assistance funds. "Definitions of what constitutes new money haven't been agreed on," says Barbara Buchner, who leads CPI's global finance programme in Venice, Italy.

There is one thing is for certain, Buchner says — total finance for low-carbon energy projects and for adapting to and mitigating climate change is far short of estimates of the need. "We need trillions, not billions," she says. ■

POLICY

Brazilian courts tussle over unproven cancer treatment

Patients demand access to compound despite lack of clinical testing.

BY HEIDI LEDFORD

A court in the Brazilian state of São Paulo has cut off distribution of a compound that is hailed by some as a miracle cancer cure — even though it has never been formally tested in humans.

On 11 November, to the relief of many cancer researchers, a state court overturned earlier court orders that had obliged the nation's largest university to provide the compound to hundreds of people with terminal cancer. Although the reversal applies only to requests for the drug by residents of São Paulo state, administrators at the university estimate that it covers about 80% of the orders they have received for the compound.

The compound, phosphoethanolamine, has been shown to kill tumour cells only in lab dishes and in mice (A. K. Ferreira *et al. Anticancer Res.* **32,** 95–104; 2012). Drugs that seem promising in lab and animal studies have a notoriously high failure rate in human trials. Despite this, some chemists at the University of São Paulo's campus in São Carlos have manufactured the compound for years and distributed it to people with cancer. A few of those patients

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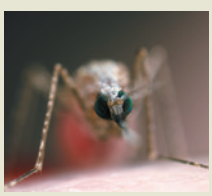

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CECILIA BASTOS/USP

Phosphoethanolamine capsules were manufactured at the University of São Paulo.

have claimed remarkable recoveries, perpetuating the compound's reputation as a miracle cure.

Dismayed by this unofficial distribution of phosphoethanolamine, the university's administration moved in September 2015 to shut it down. Patients took the university to court, and in October 2015, Brazil's Supreme Federal Court ruled in favour of one plaintiff who wanted the right to try the compound. A lower court then began granting orders for the university to provide it to others. University officials say that they were soon overwhelmed by more than 800 requests.

"The decision not only ignored the opinion of medical specialists, but also overlooked the fact that the drug has only been tested on animals," says bioethicist Volnei Garrafa at the University of Brasilia. "Such court decisions bring false expectations for patients and their families, creating turmoil in society and confusion between what is safe and what is not."

The Brazilian constitution guarantees universal access to health care, and it is common in Brazil for patients to turn to the courts to access drugs that the state health-care system does not dispense because of their cost, says Garrafa. But phosphoethanolamine presents a different situation, he adds, because it is not really a 'drug' at all. It is not approved by Brazil's National Health Surveillance Agency.

Those who argue that people who are terminally ill have a right to try experimental medicines saw the decision earlier this year as a significant victory. But to the university administration, drug regulators and cancer researchers, it showed blatant disregard for the basic scientific principle that a drug should be demonstrated to be safe and effective before being given to patients outside of a clinical trial.

"It's a violation of the autonomy of the university," says Marco Antonio Zago, a physician and president of the University of São Paulo. "We are seen as a factory to produce something that we do not believe should be done."

Phosphoethanolamine is an important building block of the lipids that make up cell membranes. The compound can also act as a molecular signal that activates certain cellular processes. Although some studies do suggest that the compound may kill cancer cells in isolated cells and mice, it is not entirely clear how the compound brings about this response. Biochemist Durvanei Augusto Maria at the Butantan Institute in São Paulo believes that the compound may be imported into tumour cells and, once inside, trigger processes that cause the cell to self-destruct. Immunologist James Venturini at São Paulo State University and his colleagues have found that phosphoethanolamine may modulate the immune system's response to cancer or affect cell division (M. S. P. de Arruda *et al. Braz. Arch. Biol. Technol.* **54,** 1203–1210; 2011).

But to justify using phosphoethanolamine in people, Venturini says, one would have to rigorously test it in a series of clinical trials using human volunteers. "I strongly believe that double-blind, randomized clinical studies are necessary," he says.

And even before such trials, further preclinical studies would have to be done, says Jailson Bittencourt de Andrade, secretary for research-and-development policy at Brazil's science and technology ministry. The ministry plans to fund those studies, he says, and has already asked several research laboratories in the country to do the work. If those tests and subsequent clinical trials are successful, he says, the ministry will also fund the research needed to scale up phosphoethanolamine production to the quantities and quality needed for an approved drug.

That process will take years. In the meantime, lawyers representing people with cancer have vowed to appeal against the latest ruling. If those appeals succeed, de Andrade worries that people will not wait until all the tests are completed, and may even abandon conventional treatment in favour of phosphoethanolamine. "Many patients have come forward and said they have tried the drug and it has worked for them," he says. "So the other patients and their families — they want phosphoethanolamine now." ■ SEE EDITORIAL P.410

TIMEKEEPING

Leap-second decision delayed

Nations fail to agree on whether to scrap an adjustment that keeps official time in sync with Earth's rotation.

BY ELIZABETH GIBNEY

A leap second is gone in the blink of an eye. But a decision on whether to ditch these occasional time insertions — which keep official time synced with Earth's rotation — has been delayed for at least eight years.

This month, the International Telecommunication Union (ITU), which bears responsibility for defining official Coordinated Universal Time (UTC), was expected to reach a consensus. But representatives who discussed the issue at the World Radiocommunication Conference in Geneva, Switzerland, failed to agree on whether the leap second's costs outweigh its benefits.

Leap seconds, which occur once every few years, are necessary because Earth's rotation is slowing in an unpredictable way. Without them, the time of day when the Sun is at the highest point in the sky would drift by about one minute over about 100 years. However, these extra seconds have to be programmed into electronic systems manually and can upset systems that ▶