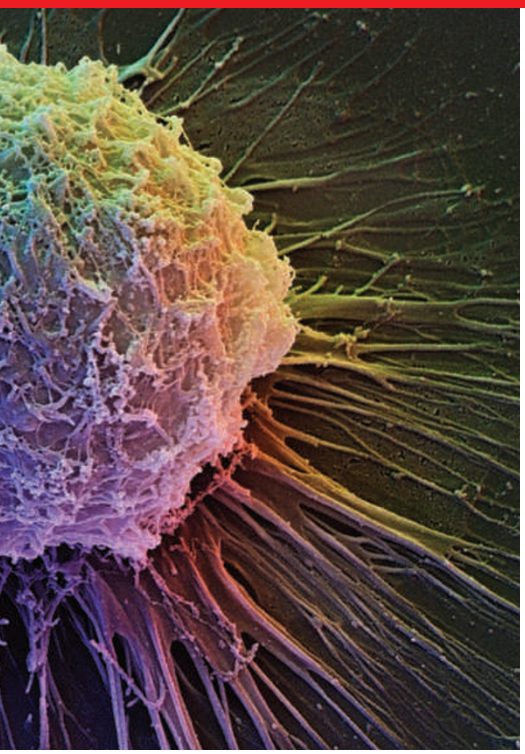

Mark Kay, a geneticist and stem-cell researcher at Stanford University School of Medicine in California, says he would have liked to see the guidelines embrace stem cells derived outside the reproductive context. Still, he says, the draft effort "is a step in the right direction".

Meri Firpo, who uses stem cells in diabetes research at the University of Minnesota in Minneapolis, says that "there are issues that probably need clarifying". Among them, she says, is whether lines derived from embryos created from donated sperm or ova would qualify. They do not under guidelines adopted in the past by the US National Academies. ■

Meredith Wadman

UNITAID's plan to launch a 'patent pool' by the end of this year that would allow multiple companies to license their anti-HIV drugs in return for royalties. This initiative would speed up the development of new antiretroviral combinations, she says, by providing access to a broader range of drugs than the GSK–Pfizer alliance affords.

Last year, Swiss company Roche abandoned its HIV research altogether, but GSK has denied speculation that the new venture is a prelude to its HIV division being sold off. "Both GSK and Pfizer are focused on building a business that has a profitable and sustainable long-term future," says Janet Morgan, director of UK science communications at GSK. "This transaction is about creating a stronger combined business, not about an 'exit strategy'." ■

Declan Butler

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Fees delay pharmed drug

Human tests of a potent antibody against HIV have been delayed by up to a year because of wrangling over the application to run a clinical trial in Europe, *Nature* has learned.

The consortium behind the project, which uses genetically modified (GM) tobacco plants to make the monoclonal antibody 2G12, now hopes to make its application in June. If approved, it will be the first academic-led clinical trial in Europe of a drug produced in a GM plant.

The Pharma-Planta consortium of 28 academic institutions and 4 small companies was awarded €12 million (US$15.6 million) in 2004 by the European Commission to carry out a five-year project to develop plant-derived pharmaceuticals for HIV, rabies and tuberculosis. One of the project's goals is to help improve the regulations that govern the production of drugs in plants, a potentially cheaper and more efficient technique than conventional manufacturing methods.

Internationally, only a handful of clinical trials of such drugs are under way, and there are currently no plant-pharmed drugs on the market. Scientists hope that improving the regulations will help to stimulate 'pharming' research in Europe. "Establishing regulation at an early stage is critical for new technologies," says Julian Ma, a molecular immunologist at St George's Hospital Medical School, University of London, UK, and leader of the consortium.

"The EMEA is blocking developments in this area."

In 2006, the team approached the European Medicines Agency (EMEA), which grants permission for marketing medicinal products in Europe, to discuss their project. "No one in Europe had made any decisions about molecular pharming, and the EMEA needed to develop overarching guidelines so that there is uniformity across Europe," Ma says.

But the group soon hit a roadblock. The EMEA insisted that any further meetings and discussions would be classed as formal scientific advice sessions, which at the time they provided for a fee of €35,000. "For an academic consortium that is publicly funded, this fee is astronomical and unaffordable," says Ma. The EMEA's scientific advice is sold to prospective applicants seeking marketing approval for a product, to help them ensure they meet the agency's safety and quality requirements. That advice does not guarantee that applications will be successful.

In contrast, the Medicines and Healthcare products Regulatory Agency (MHRA), the UK body responsible for ensuring the quality and safety of medicines and devices, charges up to about £4,600 (US$6,700) for similar advice, whereas the US Food and Drug Administration levies no charge.

Although the EMEA provides a 90% discount for small companies, it has no such policy for universities. After negotiating with the consortium, the EMEA agreed in 2008 to grant a 50% discount — on an increased advice fee of €75,500, which came into effect on 1 April this year.

The researchers chose not to pay the fee, and focused on developing guidelines with the European Food Safety Authority on risk assessment of drugs produced by GM plants, which the authority expects to publish in the next few months. The consortium also sought scientific advice from the MHRA, to which they now intend to submit their clinical-trial application.

The EMEA did not answer *Nature*'s specific questions about their interactions with Pharma-Planta, but confirmed in a statement that although "there are no specific fee reductions for universities", universities could submit a request for a fee reduction which will be considered and granted "in exceptional circumstances".

Since Pharma-Planta approached the EMEA, the agency has developed new pharming guidelines, which came into effect in February 2009. Unlike previous regulations, these account for the fact that the conditions for growing drugs in plants are intrinsically variable, and so the same standards of drug manufacture expected of cell-culture and fermentation systems cannot apply. But university researchers still face the EMEA's fees if they want advice on pharming projects, which Ma believes is a significant barrier to translating future academic research in the area.

Marc van Montagu, the president of the European Federation of Biotechnology, says it is "essential" that the EMEA reduces its fee for universities. "The EMEA is blocking developments in this area with their exorbitant bill," he says. ■

Natasha Gilbert

See Editorial, page 946.

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