IN brief

Priority voucher flops

Novartis

Malaria drug Coartem.

The first company to deploy a priority review voucher (PRV) received a complete response letter from the US Food and Drug Administration (FDA) provoking criticisms that the scheme has failed. The scheme was established in 2008 as an incentive for developers of drugs for neglected tropical diseases. Novartis of Basel recently used the only PRV issued so far—granted for the approval of the antimalarial drug Coartem (artemether/lumefantrine) in 2009—to have a 'priority' review of their supplemental biologics license application (sBLA) to the FDA for Ilaris (canakinumab). "We decided to utilize our PRV for ACZ885 (canakinumab) in gouty arthritis because of the significant unmet need that exists despite standard treatment options," says Eric Althoff, head of global media relations. Unfortunately, Novartis received a complete response letter from the FDA requesting additional clinical data to evaluate the benefit-risk profile for use of Ilaris in refractory patients. As Novartis used their PRV (which cost an additional fee of $5,280,000 on top of the sBLA fee) but did not achieve approval of the supplementary indication for Ilaris, industry observers have been quick to suggest that use of this first PRV has been a failure. This is because the potential value of the PRV has been predicted based on additional sales revenue that a company would theoretically receive if approval was achieved at an earlier date. "Some studies have estimated the value of the voucher to be more than $300 million, others have estimated that it would provide a company with approximately four additional months of peak sales of a product," says Nick Cammack, head of GlaxoSmithKline's Tres Cantos Medicines Development Campus in Spain. However, as use of the first PRV has not resulted in increased sales revenues in the short term, many are questioning the voucher's value as an incentive to develop drugs for neglected tropical diseases. Nevertheless, Tim Wells, CSO of the Medicines Malaria Venture in Geneva, remains optimistic of the voucher's value. "Even if only one in ten of the vouchers were deployed successfully, it would still have a book value of tens of millions of dollars. This is enough to help drive innovative clinical development." Cammack adds, "As only one PRV has been awarded, we believe it is too early to draw any conclusions on the effectiveness of PRVs as an incentive." *Bethan Hughes*

European ruling raises specter of mandatory GM pollen tests on honey

Honey producers may be forced to test for exposure to genetically modified (GM) pollen after a decision from the high court of the European Union (EU) in Luxembourg. The court ruled in September that honey found to contain traces of pollen from GM corn must receive regulatory approval before it can be sold in Europe. If interpreted broadly, the decision could have widespread consequences for testing requirements for other agricultural products.

Jaime R. Carrero/AP Photo

A Europeam high court decision could force European honey sellers to test their products for the minute amounts of GM pollen stored by bees in the hive.

The ruling is the result of a complaint from an amateur German beekeeper who in 2005 found traces of genetically modified (GM) pollen in his beehives. The beekeeper kept his apiary near fields where the Bavarian government was growing Monsanto's MON 810 corn, which has been modified to express insecticidal toxins from the bacterium *Bacillus thuringiensis* (*Bt*). The beekeeper was supported by Bündnis zum Schutz der Bienen vor Agro-Gentechnik, a Rosenfeld, Germany–based bee protection group opposed to genetic modification.

Pollen mixing with honey is nothing new. Bees store pollen in the hive as food for larvae, and small amounts of pollen from these storage areas unavoidably mix with honey when beekeepers harvest it. But in its ruling, the European Court of Justice decided that pollen is an "ingredient" in honey. Any food containing a GM ingredient is considered "produced from a GM organism " and therefore regulated, according to European rules. Honey containing GM pollen cannot be marketed without authorization, the court concluded.

The court's 'ingredient' ruling could be interpreted to mean that any farm product—cheese or milk, for example—containing a speck of GM pollen would need authorization before it can be sold. Pollen is easily carried around farms by wind and insects, so anyone making food near GM crop fields could be affected. "Maybe that is what the court meant to imply but that would mean Europe would thus ban all growing and all field testing of agricultural biotechnology because nobody is going to go spend the time and effort to get authorization for every food product," says Drew Kershen, a law professor at the University of Oklahoma in Norman.

European member states are awaiting a response from the European Commission, which will interpret the ruling. "At the moment all we know is that pollen from MON 810 is not allowed to be in honey," says Klaus-Dieter Jany, a member of a panel on food contact materials, enzymes and flavorings for the European Food Safety Authority, and is the former director of the Center of Molecular Biology at Max Rubner-Institut in Karlsruhe, Germany. Germany imports most of its honey and authorities plan to test apicultural products from countries such as Argentina where MON 810 corn and other GM crops are widely grown, Jany says.

The chances of finding any kind of GM pollen in honey produced in Germany is "very low," says Joachim Schiemann, head of the Institute for Biosafety of Genetically Modified Plants at Julius Kühn-Institut in Quedlinburg, Germany. Commercial cultivation of MON 810 was banned in Germany in 2009. And there are only about a dozen experimental field trials of GM plants in Germany, most of which are confined to two locations, Schiemann says. But the crop is commercially grown elsewhere in the EU, including Spain, Czech Republic, Romania and Portugal.

The case also raises the question of how pollen from wild plants will be treated, says Mark Buckingham, a spokesperson for St. Louis–based Monsanto. Pollen found in honey is unlikely to come from a single crop or plant, and some pollen may come from wild plants that have not undergone the safety assessments of those produced through genetic modification. "Our position is that our MON 810 product is safe," Buckingham says. "The safety of MON 810 is confirmed by multiple regulatory approvals, including those in the EU, and by up to 15 years of successful commercial use and consumption of MON 810 corn products in the EU and around the world."

If the ingredient ruling applies not only to GM pollen, but also to pollen generally, honey sellers may be forced to test their products for pollen and label them accordingly, says Schiemann. "That might have dramatic consequences for beekeepers," he says. **Emily Waltz** *Nashville, Tennessee*