European Union could create incentive for new drug treatments

September 10 2010

Drug companies may be more willing to develop treatments for neglected diseases including malaria, tuberculosis and leishmanaiasis if the European Union would adopt a "priority review voucher" reward system.

The vouchers would give a company accelerated regulatory review of one of its other drugs as a reward for developing a treatment for a neglected disease.

Although these diseases affect more than 1 billion people, they occur most frequently in developing nations, providing little financial incentive for pharmaceutical companies to create and test new treatments.

Writing in the Sept. 11 issue of The Lancet, professor David Ridley of Duke University's Fuqua School of Business and Alfonso Calles-Sánchez, a patent expert with the Spanish Patent Office and former pharmaceutical policy maker at the European Commission, propose a European Union version of the priority review voucher system instituted in the United States in 2007.

The EU voucher would provide priority regulatory review through the European Medicines Agency, as well as accelerated pricing and reimbursement decisions by EU member states.

For example, "If you develop a new drug for malaria, your profitable cholesterol-lowering drug could go on the market a year earlier," global

health philanthropist Bill Gates explained at the 2008 World Economic Forum in Davos. "This priority review could be worth hundreds of millions of dollars," Gates said.

The U.S. voucher was originally proposed by Ridley and Duke colleagues Jeff Moe and Henry Grabowski in a 2006 article in the journal Health Affairs. Legislation to create the U.S. priority review voucher system was sponsored by Sens. Sam Brownback and Sherrod Brown and authorized by Congress in 2007.

"By allowing a company to sell its profitable drug sooner, an EU voucher system also would increase the time during which the company could enjoy patent-protected sales," Calles-Sánchez said."The voucher would not, however, delay generics because it would not extend the patent expiration date."

A company that receives approval for a new neglected disease treatment in both the U.S. and EU could receive vouchers in both regions that, combined, could be worth hundreds of millions of dollars in additional sales of a future blockbuster product, the researchers estimate. Vouchers could be sold or transferred between companies, making them valuable as potential revenue sources or assets to make firms more attractive as buyout targets.

"Scientists are aware of molecules that could potentially treat neglected diseases, but they have been mostly unable to make a business case for spending millions of dollars testing those molecules," Ridley said. "A European voucher would provide a strong incentive for organizations to use their knowledge and resources to treat conditions that might otherwise be ignored."

Novartis received the first U.S. priority review voucher in 2009 following FDA approval of Coartem, a treatment for malaria. Several

more companies have treatments in late-stage clinical testing that may qualify for vouchers.

"The U.S. voucher and other new incentives have motivated firms to begin clinical testing, but it will take several years for these treatments to reach patients. We expect another voucher to be awarded in the U.S. within the next five years, and after that we could see a new treatment every year," said Ridley. "Given the enormous burden of these diseases, the new treatments could relieve a lot of suffering."

"A European priority review voucher system, combined with the U.S. system, would provide an extraordinarily powerful incentive for companies to invest in treatments for neglected diseases," Calles-Sánchez added.

Provided by Duke University