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## Australia's low-cost drugs threatened by US trade deal

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SYDNEY, AUSTRALIA

### **On Friday, Parliament approved a new free-trade agreement - with caveats.**

A model approach that allows Australians in some cases to pay even less than Canadians for prescription drugs may be jeopardized by a new free-trade agreement with the United States.

The Pharmaceutical Benefits Scheme (PBS), which last year collectively negotiated to supply Australia's drug needs at a price tag of only \$ 3.7 billion, has been hailed by the World Health Organization as a benchmark by which other countries' health programs are judged.

Prime Minister John Howard insists that the popular program will not be affected by the trade agreement, passed Friday by Parliament after weeks of controversy. But critics say the deal could undercut the generic drug industry that is key to the discounts achieved by the PBS and its emulators around the world.

"Once you break up the system it stops being a model, and the Americans will be more confident about telling [other] countries what they should do," says Peter Drahos, a professor of intellectual law at the Australian National University. "Those countries will have to rework their own PBS, which is a much harder thing to do."

According to Mr. Drahos, countries like Malaysia and Thailand, which is currently negotiating a free-trade agreement (FTA) with the US, will be at risk if the trade deal goes into effect on January 1, 2005.

Under Australia's current scheme, the price of a new drug is referenced to the cheapest product of its type. If the new drug does not provide any more benefits, then it gets the same base-line price. As a rule, the greater the benefits and the fewer the side effects, the more the government is willing to subsidize higher prices.

In this equation, drug prices fall when a patent expires and a cheap generic alternative becomes available.

The new FTA, however, may slow the emergence of cheaper drugs. Under the deal, generic drugmakers must notify patent owners when they are applying to enter the market.

The provision sparked concern in Australia that US-based drug companies would use the notifications to tweak their old drug in order to extend the patent - a process called "evergreening." The trade deal would also give US firms a review mechanism to challenge a

drug's rejection by the independent Pharmaceutical Benefits Advisory Committee (PBAC).

David Henry, a former PBAC official, says manufacturers want to sell drugs at higher prices even if there are no obvious benefits.

"Saying 'no' to a drug is tough, because the manufacturers will bring in medical specialist groups who often side with the industry, [and] PR companies, issue press releases, and even petition politicians to apply pressure ... to accept the drug," says Mr. Henry, who teaches Clinical Pharmacology at the University of Newcastle.

'No free lunch'

Manufacturers have long argued that Australia is not paying its fair share for drugs.

On a visit here last January, Sen. Jon Kyl (R) of Arizona delivered a strong message to the Australian people.

"There is no such thing as a free lunch. Somebody has to pay for the research and development of these miracle drugs, and if we are all paying only the marginal cost - the cost of producing the one millionth pill - then there isn't going to be sufficient return for the companies to do the investment," he told the Australian Broadcasting Corporation at the time.

Price hikes are enormously unpopular here - especially in an election year - and the government has strongly denied that the FTA will adversely affect the drug program.

"Our prime minister has given assurances that prices are not going to rise," says Brendan Grabau, consultant pharmacologist at Deakin University in Melbourne. "And for prices of prescription drugs to rise, approval must come from the health minister who has the final say on a PBAC recommendation, and that must be passed by both houses of Parliament."

The opposition Labor Party had threatened to nix the deal before it pushed through two amendments, one designed to safeguard against bogus patent extensions.

Drug companies, under Labor's amendments, will be required to issue a certificate to show that they are acting in good faith when they try to block a cheap generic drug from being introduced into the market. If the information they provide is found to be misleading then they are liable to face up to \$ 7 million in fines.

"We would have preferred that the PBS was not a part of the FTA at all, but now that it is, this amendment will go some ways to lessening gross misconduct, but will not be able to stop 'evergreening' altogether," says Dr. Mukesh Haikerwal, the vice president of the Australian Medical Association.

The government, anxious to ink a free-trade deal that it predicts will boost Australia's economic growth up to \$ 4.3 billion a year and create 30,000 jobs, reluctantly agreed to these demands late last week.

But Prime Minister Howard warned that the US may find the amendments inconsistent with the free-trade agreement. US officials over the weekend reserved the right to review the legislation before the FTA goes into effect on January 1, 2005.

However, a media representative at the US consulate in Sydney told the Monitor that since the Australian legislation is separate from the FTA, the amendments are unlikely to present a problem to Washington unless they contradicted the essence of the agreement.

A template for US FTAs?

Australia's health program accounts for only one percent of the global drug market. But the deal may set a wider precedent.

According to critics of the trade deal, the US has been going around the world trying to stitch up bilateral trade deals which bypass agreements to aid universal access to medicine stipulated in the current round of global trade talks.

And it's not just countries with whom the US want to do business which will be affected by the current deal, but their poorer neighbors as well, because experts say the deal does not explicitly emphasize the importance of generic drug manufacturers in expanding access to healthcare.

"This affects place like Papua New Guinea which is suffering from a crisis involving AIDS," says Thomas Faunce, a professor of law at the Australian National University.

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