

News

Generic drugs 'put at risk'

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TRADING BLOWS Medicines

Academics and generic drug makers yesterday backed Labor's claim that the free-trade deal would make it harder to register low-cost generics to high-priced patented drugs.

But they warned that Labor's proposed safeguard measures would not be enough to solve the problem and said the FTA must be rewritten.

Generic manufacturers complain that a clause in the FTA will force them to prove that no patents exist anywhere in the world on drugs which are presented for approval to the Therapeutic Goods Administration.

They say this will allow big pharmaceutical companies to keep out rivals to their patented products by lodging patent applications in Australia and other jurisdictions.

Even if the patent applications are eventually dismissed, the tactic, known as "evergreening", raises costs and imposes delays on generic-drug makers who often lack the resources of the big drug makers.

The chairman of the Generic Medicines Industry Association, representing six large generic companies in Australia, John Montgomery, said evergreening could have a significant, costly impact on the government's \$6 billion pharmaceutical benefits scheme for prescription drugs.

For instance, the second most expensive drug to taxpayers, the anti-cholesterol medicine Zocor, comes off patent next June, potentially saving taxpayers as much as \$250 million a year if cheap generics enter the market.

The \$1.2 billion complementary medicines sector also believes the FTA could harm it.

"Because complementary medicines are regulated as drugs in Australia, we are concerned about further limitations on the approval process for our products under the FTA agreement," Marcus Blackmore of Blackmore's vitamins said yesterday.

The industry and legal experts dismissed the ALP's proposal to discourage evergreening by introducing an offence with high penalties for spurious patent claims.

ANU law professor **Peter Drahos** said because of complexity in patenting it would be costly to bring successful prosecutions.

Professor Drahos, who says the FTA will raise the cost of the PBS by \$1.5 billion over the next four years, argues this process will be "costly, time consuming and uncertain" for small generic companies.

The ALP has also called for close monitoring to ensure that drug companies do not abuse another clause in the FTA which gives them the right to an independent review of decisions on whether to list their drugs on the PBS.

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