The New Zealand Herald
nzherald.co.nz

Pharmaceuticals Story

Sarah Meads and Thomas Faunce: Bill risks medicine price rise

5:00AM Wednesday May 09, 2007

New Zealand drug prices will rise and cheap generic medicines will be marginalised if a proposed law setting up the Trans-Tasman Regulation of Medicines goes through Parliament.

A controversial bill now before the House aims to create a single Australia-New Zealand safety regulator for medicines.

However, the bill incorporates patent obligations which Australia took on under the Australia-United States Free Trade Agreement. In 2004, Pharmac said these obligations could increase the cost of medicines to New Zealand taxpayers by $30 million to $45 million each year - 6 per cent of its yearly drug expenditure - and that it could restrict the availability of some products.

These patent obligations would affect drugs and might be extended to medicines that can be bought without a prescription. The availability of many of these products is threatened by other sections of the bill.

The single agency proposed in the Therapeutic Products and Medicines Bill would be formed out of the existing Australian body that regulates safety of medicines in several Australian states. This body, together with the Australian equivalent of Pharmac, has undergone substantial changes to comply with patent obligations established by the free-trade agreement with the US.

The obligations in US agreements are more extensive than multilateral World Trade Organisation agreements, where such obligations would not be tolerated. This is important because New Zealand's patent law and its obligations under its trade agreements are different from Australia's in key areas.

The proposed single agency will want to apply the same patent rules to medicines irrespective of which country they are for. "Linkage evergreening" rules applying to pharmaceutical patents are an important example of the patent law changes that New Zealand could inherit through the back door if this bill is approved.

In developed countries, the sale of medicines is controlled by two separate mechanisms. One regulator checks safety and quality of new medicines. A separate body governs the commercial exploitation of intellectual property rights.

However, under the bill, when an application is made by a generic manufacturer to the safety and quality regulator, patent information must be supplied. The regulator is then obliged to notify patent-holders when they have received an application for a generic version of their product.

Applicants who misrepresented patent information would face far harsher penalties than if they misrepresented the product. That puts higher importance on commercial rights than safety.

Linkage makes the medicines safety and quality regulator an informer, and supervisor, of private property rights, a task it is not equipped to perform.

Such linkage evergreening provides the firm holding a patent over a "blockbuster", or high sales volume drug, with new mechanisms for extending the duration of their patent royalties.

That means being able to block further applications, reducing competition and delaying the entry of cheaper drugs.

The Canadian Government recognised such potential harm when it signed the North American

free-trade agreement - it fought linkage and created a separate organisation, the Office of Patented Medicines and Liaison, to supervise such claims. The Australian Government also introduced anti-evergreening amendments.

These are of controversial effect and will not apply to New Zealand under the transtasman agency. Pharmac has asked the Government to completely remove linkage provisions, for in New Zealand at present there is no requirement to supply patent information and regulation of medicines and patenting are rightly viewed as separate processes.

Moreover, New Zealand patent law encourages "springboarding", which enables generic manufacturers to bring medicines to the market five years sooner than Australian law would allow.

Pharmac has also asked for clarification of other patent obligations in the bill that are ill-defined. These may affect patent extension, fast-tracking, data exclusivity, parallel imports and compulsory licensing.

If the bill's agenda is trade, the Labour Party, its key sponsor, should insist that the obligations inherited in the Australian-US agreement are carved out of the bill unless New Zealand receives equivalent benefits.

Although Prime Minister Helen Clark has renewed New Zealand's invitation to the US to consider a free-trade agreement, its priority for the US will be even lower if trade obligations the US would seek have already been accepted through the back door.

At best, the bill involves giving away important "bargaining chips" the Government could use in other trade-related deals, without capturing health gains or direct trade benefits for New Zealand citizens.

The international community is moving towards a treaty on health technology safety and cost-effectiveness assessment, which is surely a viable long-term alternative to the transtasman agency.* Sarah Meads is a development consultant in international trade and public health. Dr Thomas Faunce is senior lecturer in the Medical School and College of Law at the Australian National University.

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