

# It's time - for a bipartisan stand-firm

Sydney Morning Herald  
September 28, 2004

Australia can still ensure cheap medicine prices under the free trade deal with the US, writes Tom Faunce.

In late October, with the election over, representatives of Australia and the United States will exchange final letters signifying the start of the free trade agreement between the two countries. The text of the agreement contains many highly contentious ambiguities related to the Pharmaceutical Benefits Scheme, which comes as little surprise, given the protracted and difficult negotiations.

One area of ambiguity is whether drug companies will be able to "evergreen" their patents, enabling them to keep cheaper generic drugs off the market; another is whether the phrase "independent review process" will enable a drug company to seek to overturn a decision of the PBS advisory committee not to allow partial government funding for an innovative drug.

There are likely to be disputes as to whether the agreement allows pharmaceutical companies to advertise directly to consumers and whether the interpretive principles covering pharmaceuticals will be construed to cover "universal access to affordable, essential medicines", which is the first - and primary - principle of our national medicines policy.

It is not unusual for both sides to claim victory following difficult negotiations, as both countries seek domestic political kudos. That the US negotiators believe they succeeded in achieving the strategies necessary to begin "eliminating" our PBS is undeniable.

The Prime Minister, John Howard, admitted on July 29 that "some of the American drug companies did try and get in under the radar" on the PBS.

But there was very little subterfuge in the agenda of the US pharmaceutical multinationals to dismantle our PBS since the US Trade Act of 2002, obliging US negotiators to eliminate government measures that seek to "reference" drug price against competitors for overall community value, that is to control drug prices. A committee of several US drug company representatives, the independent trade advisory committee covering chemicals, pharmaceuticals and health sciences worked closely with the US negotiators.

And when the deal was presented to Capitol Hill, there was no indication that the US had failed to achieve its objectives. In fact, Senator Jon Kyl told the US Senate on July 15 that the free trade agreement with Australia was the first time a US trade deal had "addressed the worldwide problem of prescription drug price controls".

Both countries had "recognised the importance of innovative pharmaceuticals in delivering high-quality health care", he said. To do this they had "agreed to set pharmaceutical prices based on the objectively demonstrated therapeutic significance of the pharmaceutical".

There is a significant divergence of opinion between that US statement and Australian views, as expressed by Howard on November 21 last year, that the "essential character" of the PBS would be protected.

Under the National Health Act, the "essential character" of the scheme is that drug prices are set, not based on how "innovative" the drug is or how much research and development was involved in its development, which is what the US would like to impose, but based on whether it offers benefit to the whole community when compared with an existing product and its price.

Textual ambiguities in the free trade agreement could become a major concern for Australia because the agreement includes a so-called "non-violation nullification of benefits provision". Despised in the world of international trade law, this provision enables the US to start dispute proceedings and threaten trade sanctions where the US is deprived of a commercial benefit it would otherwise have expected under the free trade agreement, even if there has been no violation of any specific part of the agreement.

The recent "evergreening" legislative amendments to the free trade agreement will be interpreted in any dispute hearing as having eroded what the US can claim to be its legitimate expectations in this area.

Given the central place of the PBS in providing low medicine prices, making doubly sure that our position is protected makes sense.

So, in the national interest both major political parties should make a commitment now that whichever side is in power after the election, it will put on record a unilateral interpretive declaration which would clarify Australia's position on the most ambiguous aspects of the agreement relating to the PBS and also other items of national interest such as quarantine and local content.

Making this declaration should be given bipartisan support.

Australia regularly enters treaties following prolonged negotiations, which include interpretive declarations to safeguard our future negotiating position. This was the case recently with the European Science and Technology Agreement, for example.

Including an interpretive declaration does not affect the legal status of the trade agreement, nor would we need the permission of the US to introduce it. Along with the recent evergreening amendments, it may prove an invaluable asset in the inevitable subsequent trade disputes with the US.

US companies will continue to pursue their agenda of "eliminating" the restriction on medicine prices imposed on them by our PBS. Multiple strategies are needed if we are to secure continued low medicine prices for future generations.

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