Free Trade Negotiations, the PBS, and Pharmaceutical Prices

The Relevance of the Australian Pharmaceutical Market to an AUSFTA

There has been ongoing speculation as to whether, and if so how, the Commonwealth Pharmaceutical Benefits Scheme (PBS) might be affected by US–Australian Free Trade negotiations. The US pharmaceutical industry has been concerned about the role played by the PBS, and other arrangements in Australia, in lowering the profitability of the US industry in Australia. The following Australian arrangements would be counted by the US industry as candidates for negotiation:

• the mechanisms determining the prices offered to manufacturers for pharmaceuticals subsidised on the PBS

• the regulations restricting 'direct to consumer' advertising of pharmaceuticals, and

• arrangements allowing generic drug manufacturers to gain approval to produce drugs, and to begin preparations, while the drugs are still under patent.

Three questions can be asked of these:

1. Do they fall within the US objectives for AUSFTA negotiation?

2. What would the impacts be for Australians if these arrangements were modified in line with US industry interests?

3. Which of these arrangements would require legislative or regulatory amendment, if they were to be modified?

Pharmaceuticals and US Objectives for AUSFTA

Arguably, there is scope within the US’s objectives for Free Trade negotiations to place all of these on the negotiating table. Three of the US objectives are particularly relevant.

One objective seeks to ‘address issues of anti-competitive business conduct, state monopolies, and state enterprises’.

Another seeks to ‘reduce or eliminate artificial or trade-distorting barriers to US investment in Australia’.

A third seeks to ‘have Australia apply levels of (patent) protection (for undisclosed test data and other information) … in line with U.S. law’.

Anti-competitiveness

**The PBS**: The PBS is virtually the sole large purchaser in Australia of pharmaceuticals from local and overseas manufacturers. It is therefore in a position to offer comparatively low prices for their pharmaceuticals. Just as a monopoly will contribute to high asking prices for goods, the absence of competition from other buyers will contribute to low prices being offered to purchase goods. The PBS could be argued to be anti-competitive in this respect.

Artificial Barriers to Trade and Investment

**The PBS**: Recommendations about the prices to be offered to manufacturers for pharmaceuticals subsidised on the PBS, are made by the Pharmaceutical Benefits Pricing Authority (PBPA). These recommendations are made in accordance with administratively agreed pricing procedures and criteria. Greatest weight is given to the clinical and cost-effectiveness of the pharmaceutical compared to other relevant treatments.

Because PBS prices are determined under administrative rules rather than free market conditions, this might be viewed as imposing ‘artificial’ constraints on profit, trade and investment.

**Advertising Restrictions**: Australia restricts direct-to-consumer promotion of medicines. These restrictions could also be viewed as artificial constraints on how the US industry conducts its trade.

**Pharmaceutical Patent Protection**

Australian law allows patents on pharmaceuticals to be protected for up to 25 years. It is possible, at times during this period, for non-patent holders such as generic drug manufacturers, to gain access to information about a pharmaceutical, or approval from the Therapeutic Goods Administration (TGA), in order to manufacture it under a generic brand name when the patent expires.

The US industry would argue that Australia could go further in protecting data exclusivity rights.
Impacts of Changing these Australian Arrangements

The overriding interest of the US pharmaceutical industry in having these aspects of the Australian pharmaceutical market changed, is to increase its profits. Those increased profits would be gained through Australians spending more on pharmaceuticals in the following ways:

Changes to PBS purchasing: If the PBS were not the sole large purchaser in Australia, or if the PBS 'cost-effectiveness' purchasing criteria were weakened, the unit prices paid for pharmaceuticals by the Commonwealth would be likely to increase.

It has been estimated that if current PBS pricing controls were not in place, the extra paid by the Commonwealth for pharmaceuticals would be as much as $2.4 billion per year. These extra costs would be born by Australians, either directly through increased co-payments, or indirectly through higher taxes or reduced spending on other Commonwealth programs.

Changes to advertising rules: The aim of direct to consumer advertising is to increase consumer demand for medicines thereby increasing sales. Relaxation of advertising restrictions in the US resulted in a 41.7 per cent increase in sales of heavily promoted medicines compared to 14.4 per cent increases for other medicines. There is a risk that people will seek medicines where they are not therapeutically needed, or seek pharmaceutical remedies where cheaper lifestyle options would do or be better.

Delaying access to patents: Off-patent drugs sold under generic brand names are usually cheaper than when they were under patent. The availability of generic brand versions of a drug presents considerable competition and is a force for lower prices. Delaying others' access to pharmaceutical patent information, or impeding their capacity to prepare for generic production, would cost Australians more by delaying the onset of lower prices. It has been estimated that the additional cost to Australians of delaying the entry of generic competition for five selected drugs, would be more than $1.12 billion over four years.

Legislative Amendments?

Which of these Australian pharmaceutical arrangements, if modified, would require legislative amendment, and which not?

The Therapeutic Goods Act 1989 has provisions dealing with data exclusivity rights for therapeutic goods such as pharmaceuticals. Australian pharmaceutical patents are also regulated by the Patents Act 1990. Any changes to pharmaceutical patent protection or data exclusivity rights would be likely to require the amendment of either or both of these Acts, or their associated regulations.

The Therapeutic Goods Act imposes restrictions on direct to consumer advertising of medicines in Australia. Any changes to this arrangement would be likely to require the amendment of that Act, or its associated regulations.

The Pharmaceutical Benefits Pricing Authority's price negotiating criteria are administrative arrangements only, and are not based in legislation or regulations. Changes to those criteria would not, therefore, require legislative or regulatory amendment.

However, if these criteria were changed so that drugs could be priced at a level where they no longer qualified as comparatively 'cost-effective' additions to the PBS, this could compromise the initial recommendation to list those drugs for PBS subsidy. In accordance with the National Health Act 1953, the recommendation to list a drug for PBS subsidy must be made with regard to its cost-effectiveness.

What is to Gain?

There would be significant disadvantages for Australia's system of pharmaceutical supply if any of the above changes were made. This is not to deny that in the wider context of AUSFTA bargaining and trade-offs, concessions might be made in one area of trade, with an eye to gaining advantages in others. At this stage of negotiations, parties still seem to be at an impasse over agriculture. Added to this, the price of pharmaceuticals in the US is also a significant US domestic issue. This suggests that the US side in AUSFTA is unlikely to be swayed by purely Australian concerns.

2. A generic drug is an out of patent drug sold under a 'generic' brand name.

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