



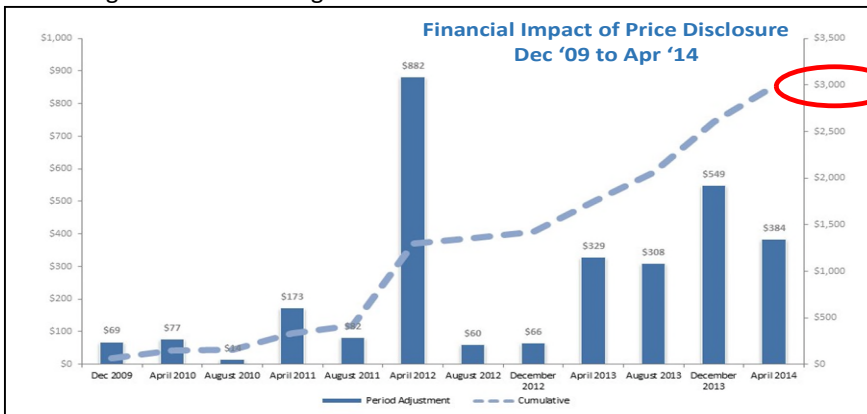
FACT SHEET

The Devastating Impact of Cost Cutting on the Generic Medicines Industry

Think before irreversible damage occurs to the generic medicines industry in Australia

The PBS is sustainable

There is no doubt that a sustainable model for funding medicines via the Pharmaceutical Benefits Scheme (PBS) has been delivered. Numerous reforms continue to generate PBS savings.



Including the PBS price cuts of \$2.2 billion in August 2008 and the ongoing price disclosure cuts of \$3 billion depicted in the graph above, total PBS savings to date are \$5.2 billion. **More than \$18 billion in PBS savings are forecast from 2008 to 2017.**

The PBS is sustainable. The Federal Government's budget papers show that spending on the PBS grew only by an average of 2.7% per year in real terms over the past decade, compared to 4.8% per year growth in overall health spending.

Last financial year PBS spending actually dropped 3.5% in nominal terms, or \$356 million – this shows recent reforms are effective, delivering significant savings.

Current PBS savings are unplanned

The price disclosure policy is delivering more than the Government's own forecasts. Successive Federal Budget reviews continue to disclose billions of dollars of additional savings – there have been \$8.8 billion of expenditure downgrades (see chart opposite) announced by Government since 2011.

Accelerated price disclosure is having a devastating impact on the generic medicines industry - more than any other sector.

The reforms disproportionately damage the generic medicines industry model placing at risk a viable generic medicines industry and jeopardising patient access to medicines. Policy changes are urgently required.

The savings threaten industry viability

Manufacturers are paid less than \$2.00 for many essential medicines listed on the PBS. Currently, generic medicines manufacturers are supplying more than 200 products at below cost.

2012 and 2013 saw an unprecedented number of generic medicines launches but the generic medicines sector experienced zero growth. In fact, sales revenues for the sector actually declined. This is due to the current price disclosure policy.

Savings from price disclosure impact the entire business of generic medicines companies.

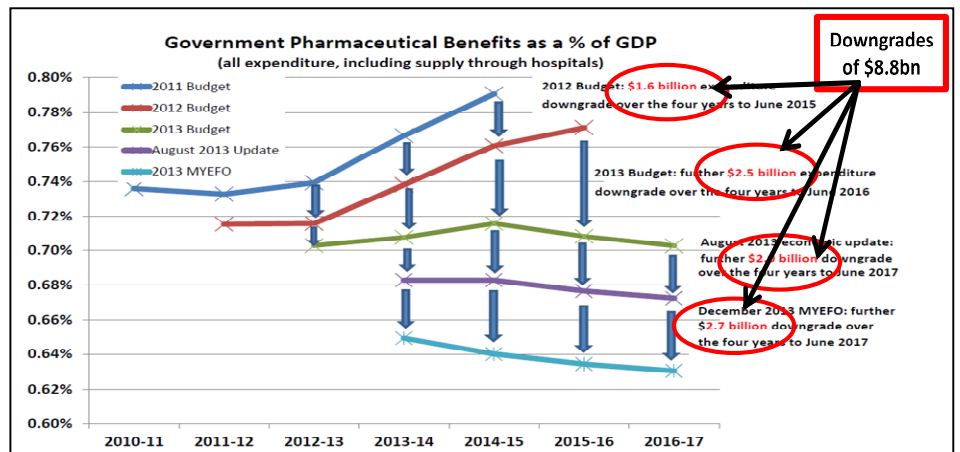
On 1 April 2014, over 120 medicines will have their prices cut by up to 90% as a result of price disclosure, with the

top five price reductions including important medicines such as:

- Medicines to treat cancer - Docetaxel (90% reduction), Oxaliplatin (60% reduction)

and Topotecan (56% reduction);

- Valaciclovir to treat herpes (56.5% reduction);
- Fluconazole to treat fungal infections in people with HIV (53% reduction).





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No more reform

PBS reform is delivering more savings than expected and to avoid inflicting irreversible damage to the generic medicines industry, it is important that there are no more damaging price cuts to generic medicines. GMiA calls on Government to think before irreversible damage occurs to the generic medicines industry in Australia.

Fact - Recent reforms have ensured the PBS is financially sustainable.

Fact – Since 2008, more than \$10 billion in price cuts have occurred. More than \$18 billion in PBS savings are forecast from 2008 to 2017.

Fact - These reforms have damaged the generic medicines industry more than any other stakeholder.

Fact – Accelerated price disclosure provides generic medicines manufacturers only 2 years in which to recoup the cost of bringing a medicine to market.

Fact - A number of medicines will simply not become available in Australia, limiting the choice for Australian doctors and patients.

Fact – Accelerated price disclosure will irreversibly impact jobs, manufacturing, and the value add of a highly educated workforce.

Australia needs a best practice PBS

It is imperative that if Australians want a best practice PBS, we should not aim for the 'cheapest' scheme or cherry-pick elements from other countries.

...“aggressive government pricing policies in New Zealand have led to multiple and repeated medicine shortages whilst generating only modest savings for its Government. This overwhelming focus on cost containment at the expense of health outcomes has drawn strong criticism from New Zealand’s medical community and patient groups.”¹

A best practice PBS provides a stable industry with fair remuneration from the PBS and is an essential foundation for the entire medicines industry in Australia.

There are 100 million prescriptions dispensed for generic medicines each year in Australia, but by world benchmarks the figure should be 180 million. Reaching this target would deliver significant savings to the PBS.

¹ Medicines Australia – Submission to the National Commission of Audit – Nov 2013

Potentially invalid patents are costing the PBS hundreds of millions of dollars. There are more than 20 medicines with patents under active challenge at present.

The follow on benefits from a stable generic medicines industry are important for the nation and include:

- Making medicines affordable and generating significant savings to Government and the public
- Ensuring supply continuity
- Freeing up PBS funds for innovative medicines
- Stimulating economic development, high skilled jobs, clean manufacturing, and exports.
- Incentivising further innovation
- Helping patients achieve quality use of medicines.

How the price cuts work

Before all valid patents on an originator medicine expire, the original brand company has 100% of the market. The time period immediately after loss of market exclusivity is the opportunity for the generic medicines industry to receive a return on invested funds.

Generic medicine manufacturers invest three to six years and an estimated \$4 million to bring a new generic medicine to market. When the generic medicine enters the market there is an automatic statutory price reduction of 16% applied to all brands of the medicine. This generates immediate savings for government.

Suppliers of generic medicines offer their product to pharmacists at prices lower than the Government approved price to compete for market share. At regular time points, price disclosure brings Government prices in line with market prices, benefiting taxpayers and consumers. This yields stepped price cuts to Government over time and **is delivering savings.**

There is a limited time window for suppliers of generic medicines to recoup their investment from entering the market and this timeline has tightened significantly with further accelerated price disclosure which will start 1 October 2014. Effectively, the time to recoup initial investment has been reduced from 3 ½ years to 2 years as depicted in the graph below.

If costs cannot be recouped in this short period, generic medicines manufactures will be forced to make commercial decisions not to bring these medicines to the Australian market which will impact on supply and choice for doctors and patients.

