

## generics



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# Generically challenged — PBS reforms stunt growth

The new PBS reforms cannot be relied upon to take care of rising costs in pharmacy, especially for those who don't want to play the price/volume game. \*MARK NICHOLSON reports

**T**HE latest PBS (Pharmaceutical Benefits Scheme) reforms offer the pharmacy industry a realistic expectation of a Fifth Agreement, due for negotiation prior to the 2010 election.

Why? Because dealing with one distributor representative, in this case, the Pharmacy Guild offers the Federal Government ease of negotiation, certainty and control throughout the implementation process.

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As it stands, financial modeling of these reforms is not yet possible as the following key details remain unknown or unconfirmed:

- the increase to pharmacy mark-ups and dispensing fee which will be effective 1 August 2008;
- the proportion of items dispensed which will attract the \$1.50 incentive. This is unable to be estimated due to:
  - the F2T medicines list to which it applies not being publicly available;
  - the recently announced price reductions, which are additional to the initial 12.5 per cent reduction once off-patent, will reclassify some drugs into the safety net category which does not qualify for the \$1.50 incentive. This list is also unknown; and
  - unknown timing of patent expiries.

Knowing the exact future financial impact of the reforms is not imperative, however, when it comes to forecasting the

**FIGURE ONE: JR CLIENT DATA EXTRACT**

	Four months ended 31 October		
	2006	2005	2004
Script numbers	14,430	13,995	14,000
Growth	3.1%	0.0%	-1.1%
Dispensary sales	478,602	480,540	463,458
Growth	-0.4%	3.7%	4.4%
Dispensary GP\$	155,604	149,980	134,141
Growth	3.7%	11.8%	3.7%
Dispensary GP%	32.5%	31.2%	28.9%
Estimated generic as a percentage of GP\$	12.7%	12.5%	5.5%
JR Client average expenses growth *Estimate only	8%*	7.4%	6.3%

effect of the changes on the industry, nor is it an impediment to developing a successful business strategy to counteract the changes.

Accordingly this article attempts to explore the economic motives and political drivers behind the proposed PBS reform the expected business impact of the changes and the resultant impact on the generic medicines market.

#### The need for change

In theory, the Australian PBS is a simple system and widely regarded as representing world's best practice, when it comes to both controlling the public cost of medicines and distributing those medicines effectively and efficiently.

As the ultimate payer for those medicines the Government negotiates the listing and cost of medicines on behalf of taxpayers. The Government's representatives in this process (the Pharmaceutical Benefits Advisory Committee and Pharmaceutical Benefits Pricing Authority) conduct a separate negotiation for each new patented drug that is admitted to the system.

Pharmacist's pivotal role within the

supply chain includes being the gate-keeper to those drugs as well as carrying the business risk associated with funding the purchase of stock directly from the manufacturer. When sold the government pays the pharmacy who in turn pays the manufacturer.

When a drug comes off patent, a generic equivalent can be admitted to the system on the same financial terms as the originating drug. In recent years, generic manufacturers have been able to enter, compete and gain Australian market share relatively quickly and cheaply by dealing directly with pharmacists.

Given the PBS is a fixed sale price mechanism and manufacturers are unable to advertise their product, the only way to market for generic drug manufacturers is to discount the price of the product sold to pharmacy. To date this has worked well on two levels:

- pharmacy has delivered on a goal of governments worldwide to promote and grow the generics market as a way of controlling future health costs associated with an ageing population.

It has been a financial imperative for pharmacy owners as expense growth

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would have exceeded gross profit growth without it. The attached table (Figure One) shows a fairly typical JR pharmacy client's data, where script numbers have been fairly stagnant over the last three years. Growth in gross profit dollars have been achieved through increased substitution. Expenses growth has continued unabated due to ongoing rent and wage increases.

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In August 2005, a partial solution was enacted, which was the commencement of a program that triggered a 12.5 per cent price reduction for similarly categorised medicines, each time a patent expired for a drug where a comparable generic medicine existed. However, this did not reform the system, just reduce the amount the Government had to pay.

### Alignment of interests

Therefore, in order to ensure PBS viability into the future a new system needed to evolve. Accordingly it has, and fortunately for the industry, been developed in consultation with the Pharmacy Guild of Australia. As such the new system should:

- deliver ongoing operational cost

- savings from being online and enable data mining;
- enable the introduction of new wonder drugs; and
- financially support an ageing population well into the future.

While the economic rhetoric is sound enough, the political argument is far more compelling, given how much negative press the current commercial arrangements between generic manufacturers and pharmacists has created.

Essentially generic manufacturer discounts have been continually used by the powerful supermarket lobby group to embarrass all concerned.

Thankfully, the distribution system remains operationally strong and, fortunately for pharmacy, highly valued by Prime Minister John Howard (although not necessarily all his Cabinet members).

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The Pharmacy Guild deserves to be congratulated for co-operating with the Government in creating a new and sustainable model.

### The reforms

The key components of the reform involve streaming prescribing of authority prescriptions and the creation of separate lists for PBS medicines.

Streamlined prescribing of authority prescriptions takes effect from 1 July 2007 and will make it easier for doctors to prescribe certain medicines. This easing should provide some level of increase to historical prescribing volumes for those medicines.

This also represents a significant efficiency win for aged care operators whose dispensing/packing operations are regularly disrupted by the issue of expired authorities.

The PBS has also been reinvented, with the creation of separate lists for PBS medicines to F1 (single brand) and F2 (many brands).

F2 will be subject to price reductions:

- 2 per cent per year for three years commencing 1 August 2008 for those where price competition between brands is low (F2A category); and
- 25 per cent once-off reduction where price competition between brands is high (F2T category)—approximately one-third of the total PBS costs currently reside in this category.

Note that these measures will reduce, but not totally eliminate, discounts and are additional to the 12.5 per cent claw back, currently, in place. Further reductions will occur on 1 August, 2009 and 1 August 2012 for F2A and F2T medicines respectively as prices will be further adjusted based on the manufacturer's disclosure of their sale prices to pharmacy.

Effectively the above can be seen to represent a five-and-a-half year phase-out of the majority of generic discounts.

Based on the pharmacy example (Figure One) which produces \$1.435m dispensary turnover, up to \$60k of current generic discounts will disappear. In most similar size pharmacies generic discounts currently account for between one-third and one-half of a total net profit. It is not presently possible to estimate how much will be replaced by the various new measures.

The biggest concerns from these reforms may well rest with hospital and aged care pharmacies whose contractual positions with those facilities are often competitively tendered for with discounts often underpinning the cost of servicing. More than ever before, only volume operators will survive in this sector.

Positively, the price reductions will see more medicines fall into the non-government funded price category. With reduced discount levels the price variances on medicines between warehouse and traditional pharmacies will reduce. While this should reduce the amount of negative press regarding price differences across the industry, it is unlikely to slow the rise of discounters.

PBS Online incentive of 40c per script, or \$20,000 for the industry's average size pharmacy doing 50,000 scripts per year, will be payable from 1 August 2007 which

is one year before any price reductions to the F2 category.

Now that remuneration is confirmed, pharmacy should embrace the cash flow advantages that flow from PBS Online and convert as soon as possible. Note, not all dispense systems are enabled yet to process online.

Expect more reform initiatives to follow as the Health Department commences data mining.

#### Pharmacy incentive

The \$1.50 per premium-free prescription dispensed pharmacy incentive is not a generic incentive but an incentive to foster the dispensing of 'premium-free' drugs.

Government motivation is aimed at reducing cost to government and cost to customer. Brand pharmaceutical companies will no doubt be considering their position regarding maintaining brand premiums. The incentive is payable from 1 August, 2008, which accords with the first round of price reductions.

The size of generic manufacturers' pricing point of difference at pharmacy level will reduce but not be eliminated as, without it, there would be little motivation for a customer to switch or a pharmacy to promote switching.

Brand pharmaceuticals' product prices are based on a worldwide market which means price reductions are only palatable to brand manufacturers to a limit. It has been known for brand manufacturers to withdraw products in foreign markets because of the flow-on effect that could be generated in other countries. Stay tuned!

Government is also currently considering a campaign to promote generics:

- Changes to pharmacy mark-ups and dispensing fee are hoped to counteract the fall in mark-up dollars resulting from a reduced product cost following price reductions. The changes are yet to be released but will be applicable from 1 August 2008.
- Similarly, the CSO funding pool for wholesalers will be increased to counteract the fall in mark-up dollars resulting from a reduced product cost

post the price reductions. Changes to volume/loyalty discounts will not result as the funding pool is sufficient to cover the expected loss.

#### Pharmacy values

While the impact on pharmacy profitability is unknown and subject to the mark-up/dispensing fee announcements, pharmacy owners should prepare for a neutral to small loss position in the short term.

The long term is more uncertain as remuneration has now been partly de-linked from the previously in-built inflationary increases. Additionally the move to a more dominant flat fee remuneration structure will make it easier for Governments of the future to adjust as they deem appropriate. Accordingly those with long term debt need to be mindful of the 5 to 10 year position this may present.

However, do not expect future pharmacy business values to decline. The market remains hostage to demand exceeding supply and this is likely to continue. Control of significant volume will be required in order to negotiate better than market-listed buying terms with manufacturers/wholesalers.

As such the 'pharmacy groups' will continue to seek growth and indeed will be presented these opportunities by wholesalers in preference to first time buyers. The reason is simple—good operators known to wholesalers are more likely to grow volume while also allowing wholesalers to control their costs through improved management/distribution efficiencies.

In addition these groups will improve their own efficiencies and evolve offers that deliver a more sophisticated level of customer relevance than the industry has experienced previously.

#### Summary

Positively, the latest round of PBS reforms offer the Pharmacy industry a realistic expectation of a Fifth Agreement. Why? Because dealing with one distributor representative—in this case the Pharmacy Guild—offers the Government ease of

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negotiation, certainty and control throughout the implementation process.

Negatively, dispensing margins will reduce into the future meaning the number of groups focusing on volume and price will continue to increase.

So, while the Government is yet to announce key financial components regarding mark-ups and is yet to respond to the concerns surrounding generics, the message flowing from the current PBS reform announcements for pharmacy owners is clear—future PBS growth alone should not be counted on to offset expenses growth.

Fortunately though, for those who can't/don't want to play the price/volume game there is a reasonable time period to develop customer-focused income streams from the provision of healthcare solutions (for example, home medicines reviews (HMRs), weight loss and so on). These offerings will and have to evolve/mature during this transition period in order for small, single operator pharmacies to not just remain viable but, indeed, prosper.

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