Generic explosion or implosion?

LAST JANUARY **MARK NICHOLSON*** LOOKED AT THE GENERIC LANDSCAPE. WITH THE PBS REFORMS FAST APPROACHING HE PROVIDES FURTHER ANALYSIS AND HOW TO AVOID THE FALLOUT.

Many pharmacists are alarmed at the looming price cuts associated with PBS reform measures under way, yet are unaware that measures negotiated by the Pharmacy Guild of Australia largely offset associated reductions in income. Also offsetting these income reductions are an ageing population and the relatively static number of pharmacies.

KEY POINTS

- The 1 August 2008 25% F2 price cuts are offset by benefits negotiated by the Guild.
- Pharmacies have been given some time to adapt to lower dispensary profitability.
- Areas to improve profitability include increasing generic substitution as patents expire.

However, it is imperative that both PBS and non-PBS income streams are developed to achieve profit growth sufficient to at least match rapidly growing overheads.

If you look at what's happened overseas in more mature markets the writing is on the wall for Australian pharmacies to confront the way they operate.

Last December UBS released a report detailing its 'Global Pharmaceuticals' outlook for this year. What stands out is that between now and the end of 2012 US$78bn of sales will be drained from US and European big pharma through generic switching (about 25% of current combined market size for those companies). During the same period almost US$40bn of profits will be drained. Approximately 75% of those losses will be due to patent expiries while at the same time the 'R&D pipeline visibility is low', UBS predicts.

This wake-up call was also reinforced by Citigroup Stockbroker's report of April, last year. On average big pharma sales worth US$10bn per annum will face generic competition (refer Figure 1) Citigroup's US generics analyst estimated.

And in Australia 50 drugs are due to come off patent by 2010 with an estimated market value of $1.7bn, according to a 'Reuters Insight Study'.

This further contrasts with a PBS currently valued at around $7bn (including patient contribution) with the same report estimating generic substitution representing 11% of value and 28% of total prescription volume. On further analysis JR pharmacy clients' data supports these figures.

Brand pharma does not have its head in the sand, however, and is preparing for the first round of cuts to come from the PBS reforms.

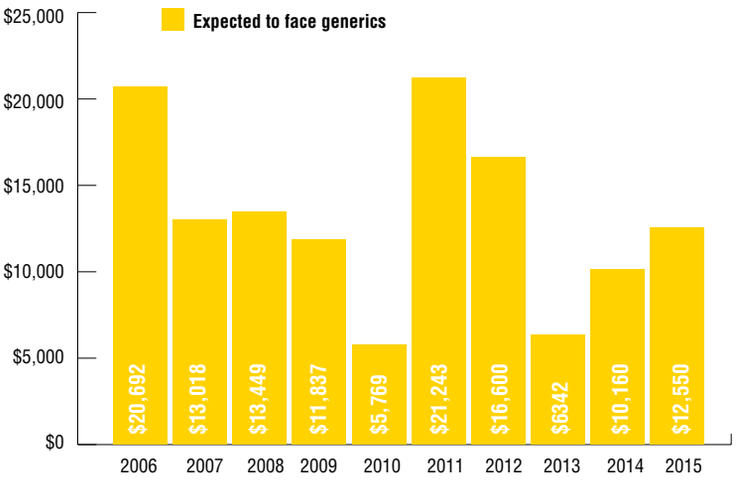
In summary the reforms include:

- **evolution of the PBS into F1, F2A and F2T medicine groups;**
- **price disclosure requirement when a new brand lists in the F2 group;**
- **price reductions commencing 1 August 2008 for F2 medicines—2% per annum over three years for F2A drugs and 25% for F2T drugs (note the existing 12.5% price reduction still applies to similarly categorised medicines when a comparable generic is listed).**

Brand pharma is going to face significant changes to its business and see reduced profits given the dearth of new blockbuster drugs. As a result there have already been job losses aimed at mitigating the income squeeze.

If the new government does not deviate from what the reforms were meant to achieve—create 'headroom' to list new drugs—this is clearly in brand pharma's favour. In addition, the single brand patented F1 medicines will be excluded from the reference pricing system which had operated prior to the reform package.

FIGURE 1: **Global sales of branded products to face generic competition, 2006–2015**



SOURCE: Company records, FDA, court documents, IMS, Citigroup Investment Research

THE GOOD NEWS

The good news for pharmacy is that most of the potential short-term pain will be eased by some increases to mark-up on high and low-cost drugs, a $0.15 dispensing fee increase and the $1.50 incentive for dispensing premium-free scripts, all applying from 1 August 2008. These are additional to the PBS Online incentive of $0.40 per script which came into effect 1 July 2007.

In many cases the reforms will mean little change for consumers as approximately 80% of PBS prescriptions are dispensed to concessional card holders who pay no more than $5.00 per prescription and the remaining 20% pay a maximum of $31.30. For this category there will be some change because the price cuts combined with generics competition and inter-pharmacy competition will force some cheaper medicines off the PBS and into the sub $31.30 section.

Wholesalers will also receive an offsetting adjustment as a result of the price cut (due to reduced mark-up base) by having the CSO funding pool increased by $69m over three years.

The level of generics usage in Australia is mostly driven by inducements at the pharmacy level. Therefore, in order to gain traction, generics manufacturers will need to keep margin differences sufficiently wide to gain increases in market penetration. At the same time sustaining workforces is a costly exercise for generics manufacturers. In some cases it may not be viable to deliver small-volume, low-cost generic alternatives.

Again in what seems like a twist of fate, under the new system it is actually more likely that fewer, not

more, alternatives will exist. This will certainly be the case in the hospital sector, where there are fewer competitors in a market that accounts for one-eighth of the PBS.

NEGATIVES

But the manufacturers may not be so satisfied.

Prior to the introduction of the reforms, Australia fared well against similar countries (US, UK, Canada, Ireland and NZ) when comparing the level of government expenditure on medicines. (Refer to Figure 2 comparing government pharmaceutical expenditure per person and Figure 3 comparing pharmaceutical expenditure as a percentage of total health expenditure).

Following implementation of the reforms the government originally estimated a saving of $580m in the first four years (say 2% of current annual PBS cost) or $3bn over 10 years (say 4% per annum of current annual PBS cost). This is a massive saving considering the base cost includes the somewhat fixed supply chain costs of pharmacist and wholesaler remuneration.

OUT IN THE OPEN

For those who have already joined the dots this converts to an estimated average saving per annum to the government of $145m in Years 1 to 4, which rises steeply per annum to $400m in Years 5 to 10. These later savings will be achieved partly through the 12.5% price cuts as medicines come off patent and when a generic alternative lists. This moves a drug from F1 to F2, triggering the 'Weighted Average Disclosure Pricing' (WADP) mechanism where most of the government's savings are likely to accrue.

This mechanism requires the manufacturer of each new brand being listed to disclose its 'net into store' prices to government. The definitions are broad and unforgiving—so, all rebates, bonus stock and so on must be incorporated by the manufacturer when determining the true sale price to pharmacy. Penalties for incorrect disclosure are severe. The key points include:

- **F2A disclosure began 1 August last year with the first possible price cuts to be introduced from August 2009.**
- **F2T disclosure begins from 1 January 2011, with the first round of price cuts perhaps commencing August 2012.**
- **Pharmacists will be given at least six months notice of a price decrease.**
- **In January 2011, F2A and F2T groups will be combined into one group—F2.**
- **Once a manufacturer begins disclosure for a product it is a continuous regime with potential price cuts occurring on an annual basis depending on market forces.**
- **Price cuts will only occur where the weighted average net into store price is more than 10% lower than the listed price.**

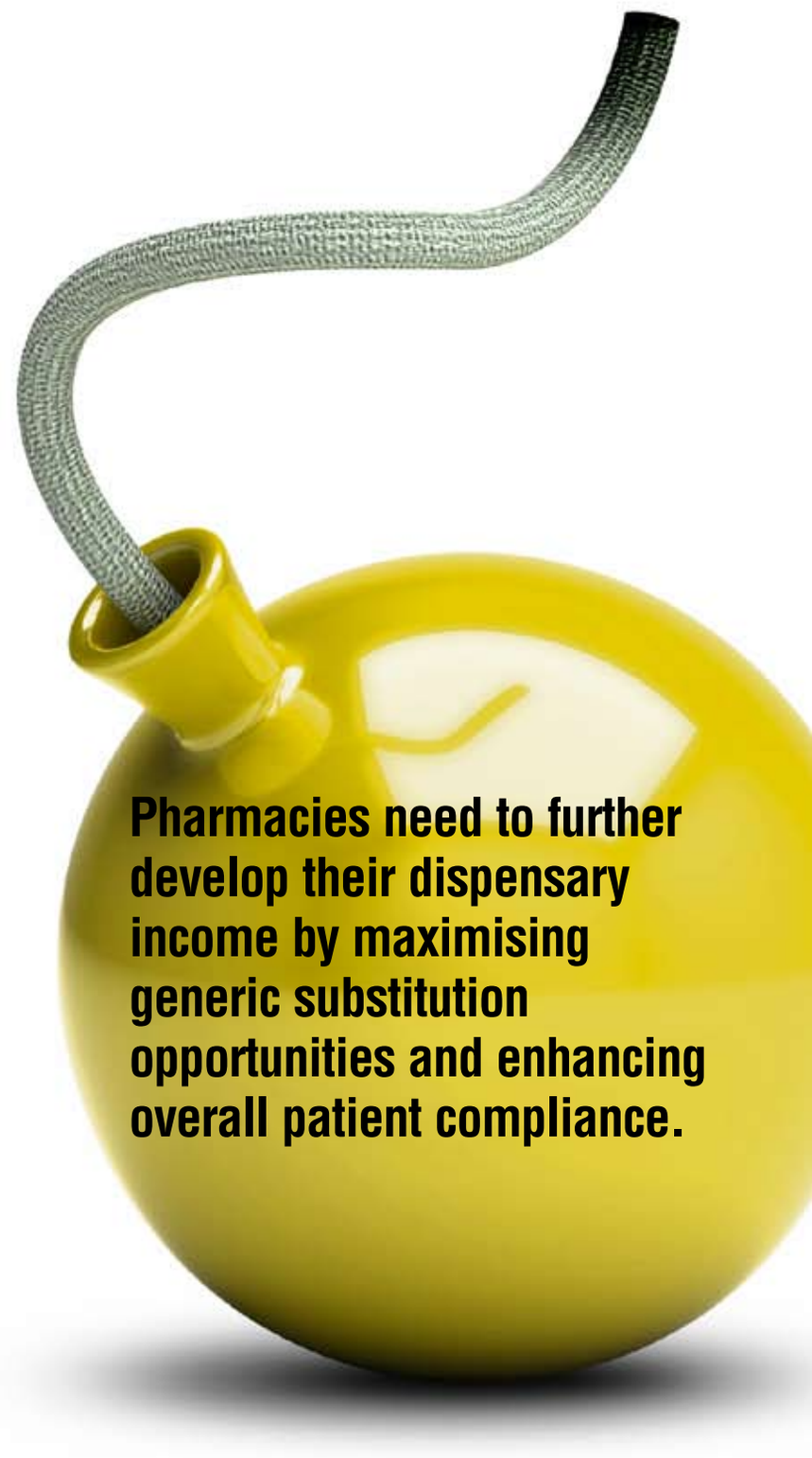
Consider the example: The price difference is 8% which is less than the required 10%, therefore no price reduction would result. However,

Example

New brand product lists after patent expiry offering 40% discount and achieves 20% market share by volume.

Supplier	PTP (*)	Market Share (%)
Originator	$100 (ie PBS list price)	80%
Generic	$ 60	20%
New Price under WADP	$ 92	

* Price to Pharmacy



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if the originator did not enter into price disclosure the new price would become the $60.

Given newly listed products to F2 will be generic equivalents, it is expected that (as has historically occurred) the only possible way to gain market share is through offering a lower price to pharmacy than their competitors.

As can be seen from the previous example, without higher priced competitors opting in and voluntarily disclosing, the price cuts will be more severe. It is expected most manufacturers will begin disclosing once the government notifies them that a manufacturer of another brand has started disclosing, although the market has already seen some multinational brand pharma companies elect not to participate due to the high cost of compliance associated with the entire disclosure process.

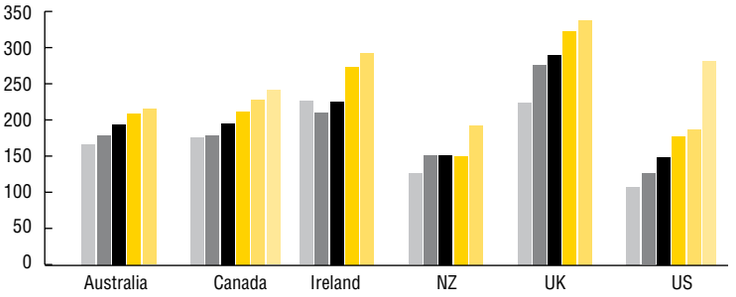
Clearly aggressive early pricing tactics by new product entrants may create long-term problems depending on the amount of market share gained and the response by competitors.

THE FUSE IS ALIGHT

The continual ratcheting down mechanism on price through WADP is unlike any other price control mechanism at the government's disposal. At this stage its commercial effect is unclear. It takes years for new entrants to build market share, yet any price advantage they may bring to the market place will be quickly eroded through WADP.

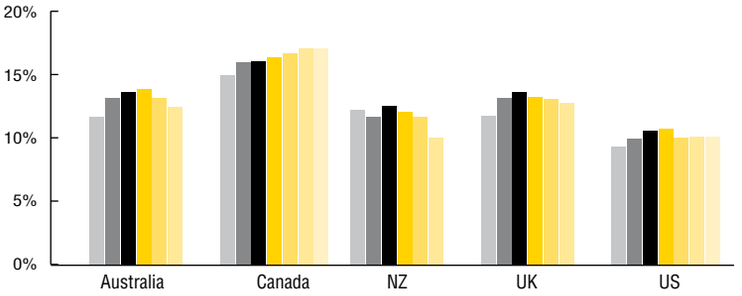
New products listed on or before 1 December 2007 in the new F2A category will probably have the first round of price cuts delivered in August 2009 (less than 18 months away). Even though the aggressive price cuts to F2T have been the cause of most discussion to date, the F2A category via WADP carries its own harm.

FIGURE 2: **Government pharmaceutical expenditure per person ($US)**



	2001	2002	2003	2004	2005	2006
Australia	166	179	194	209	215	na
Canada	176	179	195	212	228	241
Ireland	226	210	225	273	292	na
New Zealand	126	152	151	150	192	na
United Kingdom	224	276	290	322	338	na
United States	108	126	149	177	187	281

FIGURE 3: **Total pharmaceutical expenditure as a percentage of health expenditure**



	2000	2001	2002	2003	2004	2005	2006
Australia	11.6%	13.1%	13.6%	13.8%	13.1%	12.4%	na
Canada	14.9%	15.9%	16.0%	16.3%	16.6%	17.0%	17.0%
New Zealand	12.2%	11.6%	12.5%	12.0%	11.6%	10.0%	na
United Kingdom	11.7%	13.1%	13.6%	13.2%	13.0%	12.7%	na
United States	9.3%	9.9%	10.5%	10.7%	10.0%	10.1%	10.1%

NOTE: no data available for Ireland. SOURCE: Pharmacy Guild of Australia

This is because the F2T product list is fixed apart from any new entrants that are interchangeable with existing F2T medicines. This means that all new brand listings (ie: arising from patent expiries or new competitors to existing F2A products) from now on will enter the F2A category and (despite the orderly 2% price reduction over the next three years) be subject to potentially aggressive WADP price reductions from August next year.

FLOW-ON EFFECT

This will be felt most severely (but not only) in the hospital pharmacy sector where margins are thin and many products were originally placed in F2A due to the low competition and/or low discount/volume characteristics of the acute-care marketplace. Should a new entrant aggressively price their product to obtain market share (which may well be obtained via emerging hospital-owned pharmacy dispensaries rather than pharmacist-owned hospital pharmacies) the subsequent downward adjustment to price could prove disastrous to businesses which are built on high volume and low margin.

The supply chain efficiencies in these markets would deliver a subsequent downward adjustment to price that could prove disastrous to these businesses because they are built on high volume, low margin and high substitution. The effect will flow on to community pharmacy over time as these items become more commonly used.

AVOID THE FALL-OUT

The intricacies of the PBS make it difficult to predict whether maximising generic substitution rates will be sufficient to offset the inevitable WADP price cuts. Without it the loss of profit may be substantial but depends on the ongoing level of competition between generics manufacturers.

Fortunately, the Guild's negotiations resulted in a staged introduction and significant offsets. WADP was unavoidable because the government's stated position was that price disclosure was not negotiable. Its effect on generics manufacturers and particularly brand pharma will be more severe than on pharmacy whose volume sales of generics will rise rapidly.

CARPE DIEM

Although the fuse is now well alight there is still sufficient time for pharmacies to evolve and avoid the fall-out from the impending PBS reforms.

Pharmacies need to further develop their dispensary income by maximising generic substitution opportunities and enhancing overall patient compliance. Developing customer-focused, health-related income streams which better leverage pharmacy's healthcare status will go some way to provide the necessary fortress of future growth. ■