NATIONAL PHARMACEUTICAL SERVICES ASSOCIATION

PBS Reform – National Health Amendment (PBS) Bill 2010

Submission from NPSA
(National Pharmaceutical Services Association)
representing Full Line Pharmaceutical Wholesalers

Overview

NPSA strongly recommends to Government that it introduces an adjustment mechanism to compensate the pharmaceutical wholesalers for the negative flow on impact of the savings sought to be achieved from the PBS Reforms (2010) proposed in the National Health Amendment (PBS) Bill 2010. This is critical for the ongoing survival of the Wholesale industry, without which the daily access to medicines (on which the Medicines Act is based) would not be possible.

Under the Fourth Guild Agreement, 3% of the wholesale margin was removed from pharmaceutical wholesalers and a portion of that savings was put into the Community Service Obligation fund (CSO). Wholesalers had to sign up to the CSO fund in order to access a share of the fund and participation was based on the basic principle that medicines had to be available within 24 hours anywhere in Australia.

In 2006, the Government introduced PBS Reform (2006) - which introduced price disclosure and price reductions so that the price the Government pays for PBS medicines more closely reflected the actual price at which medicines were being sold.

Then, the National Health Amendment (PBS) Bill 2010 introduces further PBS price reductions agreed in a Memorandum of Understanding between the Australian Government and Medicines Australia (MA MOU) announced in the 2010 Federal Budget. Referred to in this submission as PBS Reform (2010).

Under both of these reform arrangements, there is a flow on reduction in wholesaler remuneration.

When the price of a PBS medicine is reduced, the dollar value of the wholesaler mark-up (set as a fixed 7.52%) is automatically reduced.

Reductions in PBS prices have a flow on impact on wholesalers that is outside the scope of the MA MOU. Similarly, the wholesale mark-up is incorporated in the Guild Agreement. Wholesalers were not a party to either negotiation and therefore do not believe that the impact of the reduction in the value of the wholesale margin on wholesalers, the entire supply chain or patients has been fully considered.

<u>All PBS Reform price reductions have an unaccounted for and unintended impact on wholesalers.</u>

By way of illustration:

- Consider an off patent medicine which currently has a PBS Price to Manufacturer of $30;
- The wholesale mark-up paid by Government is $2.26 (a wholesale mark-up of 7.52% on the PBS Price to Manufacturer)
- Assume that currently a discount is offered by the PBS supplier to pharmacy customers of 20%. This comes off the PBS Price to Manufacturer of $30.
- If price disclosure results in say a 20% cut in the PBS Price to Pharmacy, then the wholesale mark-up will also be reduced by 20%. i.e. the wholesale mark-up is reduced to $1.81.
- Despite there being no change in the costs to distribute product, wholesalers incur a cut in revenue in this example of 46c or 20% which translates into reduced overall earnings.
- To make up this 20% reduction in earnings, wholesalers need to offset the cuts through cost savings or by increasing wholesale prices to pharmacy.

Even before the introduction of the PBS Reform (2010), the 12.5% generics price cuts and the PBS Reform (2006) were continuing to create “shock” for the sector. PBS Reform (2010) will therefore lead to further unintended consequences for the sector and patients. Confronted with aggressive price reductions, wholesaler options will be constrained as follows:

- Under the Community Service Obligation arrangements, each wholesaler undertakes to supply the full range of PBS medicines within 24 hours to all pharmacies in Australia at fees that are not higher than the approved price to pharmacy paid by Government – i.e. the maximum wholesale fee payable by pharmacy in the above example is $2.26 before the price change, and $1.81 after the price change.

- Market forces within the very competitive three player national full line wholesaler market only allow for manageable incremental changes. In contrast, the price changes from PBS Reform (2006 and 2010) are not incremental. Currently there are three national full line wholesalers of relatively equal size in Australia. There are serious pressures within the sector and these have been the subject of significant recent media coverage.

- The quantum of the impact that wholesalers need to adjust for pursuant to PBS Reform (2006) represents around three-quarters of the current profit earned by the full-line wholesalers (Professor Ian Harper, Access Economics – Attachment 2 – “Summary of Presentation”). The quantum of the impact that wholesalers need to adjust for with the addition of PBS Reform (2010) is now closer to 100% of the current profit earned by the full line wholesalers.

In 2006, when faced with the flow-on risks of PBS Reform (2006), the Government introduced pharmacy and wholesaler support arrangements:-

3.2 Pharmacy and wholesaler support arrangements

Additional funding of $69 million over three years will be added to the Community Services Obligations (CSO) Funding Pool to compensate pharmaceutical wholesalers for the impact on the wholesale margin resulting from the new pricing arrangements. Wholesalers are eligible to access the CSO Funding Pool if they can demonstrate that they meet specified service standards.

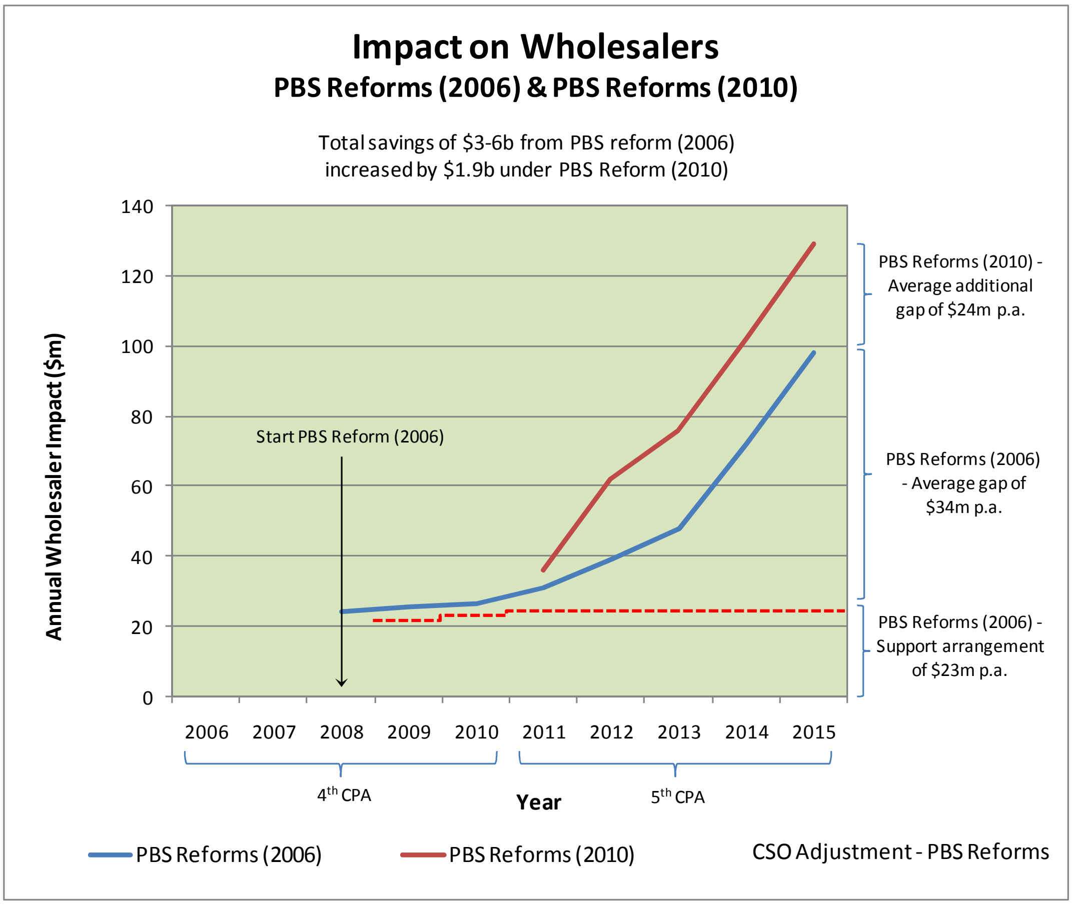
Under these support arrangements, the Government was able to reduce the price of PBS medicines without causing unnecessary stress on the sector.

NPSA strongly recommends that the Government introduces further adjustment mechanisms to underpin the savings sought to be achieved from the reforms.

By way of illustration, in April 2012, pursuant to the minimum 23% price reduction, wholesalers need to either absorb the impact or recoup an additional $5,600 per pharmacy per annum to maintain what are already inadequate returns. This is unrealistic in the current climate.

The full quantum of the adjustment to be made by the wholesalers (over 2010-2015) is graphed below. The full financial impact of the package of reforms that the wholesale sector needs to adjust to is as follows:

- $19 million per annum due to the ongoing impact of the 12.5% measure
- $3.8 million per annum due to the loss of indexation in year one of the Fifth Community Pharmacy Agreement
- $34 million per annum (in addition to the current CSO funding) due to PBS Reform (2006)
- An additional $24 million per annum due to PBS reform (2010).



1. NPSA

The National Pharmaceutical Services Association (NPSA) is the peak organisation representing the interests of the full line wholesale pharmaceutical industry and CSO Distributors. Full line wholesalers distribute to 5,000 pharmacies throughout Australia, and carry and distribute the full range of PBS medicines sold in pharmacies. Full line wholesalers supply medicines on a just-in-time basis at a set maximum price to pharmacy regardless of whether the pharmacy is located in a metropolitan, country or remote area of Australia.

Full line wholesalers employ around 3000 people across Australia and have more than $2 billion invested in the pharmacy supply chain. To be eligible to receive CSO payments, a CSO Distributor must sign a Deed and commit to the following minimum service standards:

- supply of PBS medicines to any community pharmacy;
- ensure that its volume of sales of PBS medicines to its rural and remote pharmacies is not more than 10% below the industry average;
- supply any brand of any PBS medicine requested to community pharmacies;
- hold stock of at least one brand of every PBS medicine, plus at least two generics;
- supply any brand of any low volume PBS medicine, including in single units, where requested and ensure that its volume of sales of low volume PBS medicines is not more than 10% below the industry average;
- supply any PBS medicine, in any quantity, at or below the Approved Price to Pharmacist or Claimed Price;
- supply PBS medicines to any community pharmacy, within 24 hours from the regular order cut off time, where requested (some extremely remote areas excepted); and
- offer a daily delivery service to any community pharmacy as part of standard service delivery infrastructure.

Full line wholesalers therefore underpin the achievement of the objectives of the Government's National Medicines Policy which aims, amongst other things, to ensure that all consumers receive "timely access to the medicines that Australians need, at a cost individuals and the community can afford".[1] That is wholesalers:

- Ensure that Australians enjoy equity of access to medicines with next day, if not, same day delivery;
- Provide facilities for rapid supply of urgent and emergency medication for patients via pharmacy (including pandemic services as illustrated during the recent Bird Flu pandemic); and
- Drive quality, safety and efficiency standards in the supply chain from medicine manufacturers through to pharmacies and thus help keep the cost of medicines at a level "the community and Government can afford".

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[1] Department of Health and Ageing 2008, 'National Medicines Policy', 24 July, available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/nmp-objectives-index.htm.

2. Background to Wholesaler Funding Arrangements

A wholesale margin/wholesale mark-up is paid by Government pursuant to the Pharmaceutical Benefits Scheme (PBS) pricing arrangements and the Fifth CPA. The wholesale margin is calculated as a percentage of the "approved PBS price to pharmacy" for PBS medicines. Under the Fifth CPA, the distribution of PBS medicines is funded by a payment to pharmacies equal to 7 per cent of the "approved PBS price to pharmacy".

This represented a 30% reduction in the wholesale margin of 10% which applied in the Third CPA that ended on 30 June 2006. This reduction in the wholesale margin delivered savings to the PBS of $180 million per annum over the period of the Fourth CPA and continues to deliver savings today.

It is important to note that under the constant percentage fee model contained in past CPA's, revenue obtained from supply of high volume medicines to more profitable markets was used, in part, to fund timely delivery of low volume PBS medicines and delivery of PBS medicines to rural and remote regions of Australia.

During the Third CPA these arrangements were increasingly threatened by the growth of direct suppliers and short line wholesalers, who contested for sales with full line wholesalers, in the more profitable markets. This reduced the revenue available to full line wholesalers to enable viable distribution of low volume PBS medicines and the distribution of PBS medicines to rural and remote regions.

The introduction of the CSO Funding Pool in the Fourth CPA was designed to rectify this situation by directly remunerating those distributors that were able to meet the CSO service standards for the extra costs they incurred in meeting these standards.

The reduction in the wholesale margin from 10% to 7% was used to fund the CSO, although in fact, Government clawed back a $30 million saving per annum as the CSO Funding Pool was originally set at $150 million per annum.

The CSO is a fixed pool that is indexed annually and allocated to CSO Distributors based on CSO sales volumes each month. This reduction in wholesaler funding occurred at the same time that new minimum service standard and compliance criteria were introduced on the wholesalers' operations. The service standards were established by the Government to secure timely supply of all medicines to all pharmacies, generally within 24 hours. In turn, wholesalers are now unable to avoid the high cost services that underpin patient access to PBS medicines in the course of pursuing reduced costs.

Under the Fifth CPA, the wholesale margin and CSO arrangements are ongoing.

3. Generics Measure - 12.5%

In April 2005 the Government's 12.5% generic measure was introduced. Since then, the price of all medicines within a reference group have been reduced by an immediate 12.5% when a generic is introduced.

On 16 November 2006 the Government announced further changes to the PBS (PBS Reform – 2006). From 1 August 2007, PBS medicines were classified into 3 broad groups and the pricing reforms (i.e. reductions) differed across the 3 groups.

The PBS price cuts were in addition to the price cuts underway and ongoing pursuant to the 12.5% measure and were directed at the achievement of increased savings to Government by reducing the price of PBS medicines received by manufacturers. However, the PBS price cuts have and continue to have consequential effects on the margins received by wholesalers of PBS medicines.

Economic Insights estimates that funding for the wholesale distribution of PBS medicines will be reduced by $85 million – $95 million due to the 12.5% measure for the period 2010 to 2015.

Pursuant to the MA MOU this percentage will increase from 12.5% to 16%.

4. Forecast Impact of PBS Reform (2006)

When PBS prices are reduced, wholesalers experience a direct flow on reduction in their wholesale margin remuneration as they earn a fixed percentage on the reducing PBS dollar value of the medicines supplied. PBS price reductions mean wholesalers must supply medicines for reduced remuneration even though the costs associated with the supply of the medicines generally increase. Thus, absent any compensation, PBS pricing reform would reduce the profitability of the wholesale distribution of PBS medicines.

In recognition of the significant foreshadowed impact on wholesalers, in November 2006, an agreement was reached between the Government and CSO Distributors to pay support funding of $69 million into the CSO Funding Pool over the period 1 August 2008 to 31 July 2011 ($22 million in 2009, $23 million in 2010 and $24 million has been absorbed into the Fifth CPA).

The NPSA believes that PBS Reform (2006) will have an ongoing negative effect on the funding available for the wholesale distribution of PBS medicines. To estimate this impact CSO Distributors engaged Economic Insights to estimate the reduction in wholesale funding that would flow from the PBS Reform (2006) over 2010 - 2015.

Economic Insights estimates that funding for the wholesale distribution of PBS medicines will be reduced by $285 million for the period 2010 to 2015 due to PBS Reform (2006) alone.

From the perspective of the full line wholesale sector, this quantum represents a significant proportion of the total profits for the sector over the same period The magnitude of this funding reduction is unprecedented and the sector is not in a position to absorb it. Such a reduction in profit puts wholesale distributors under significant financial strain given the very competitive and low growth market distributors operate in. As wholesalers rely on profit margins of half a percent after tax, reductions in the actual quantum of wholesale funding per medicine supplied has a significant direct impact on wholesaler financial returns.

CSO Distributors are obliged to continue to meet their community service obligations and are therefore limited in their ability to absorb reductions in wholesale funding through cost savings from reduced service standards.

5. PBS Reform (2010)

Under the MA MOU the forecast impact on wholesalers is forecast to be increased by $24 million per annum on average over 2010 – 2015.

The total impact of the various price reduction measures is therefore equal to $498 million over 2010 – 2015 as follows:

- **12.5% - $95 million**
- **PBS Reform (2006) $285 million**
- **Partially offset by additional CSO funding of $115 million (net impact $170 million)**
- **PBS Reform (2010) - $118 million**

NPSA does not believe that the PBS Reform (2010) savings calculations or the Fifth CPA savings calculations incorporate the PBS Reform (2010) impact on wholesalers and seeks a mechanism by which the sector can adjust.

6. Additional Matters

Transition Arrangements – 1 April 2012

Under the PBS Reform (2010) arrangements, significant stock losses are forecast to be experienced by wholesalers on 1 April 2012. The transition arrangements to manage the price reductions on 1 August 2008 were problematic for manufacturers, wholesalers and pharmacies and the losses experienced by wholesalers through stock devaluations were significant.

When prices are reduced, wholesalers are at risk of holding stock that reduces in value significantly overnight. This risk is very real in the face of the need to forecast stocking requirements in a manner that ensures that wholesalers are able to deliver medicines to pharmacies generally within 24 hours of when the order is placed whilst working with manufacturers and delivery lead times to each distribution centre around Australia. With pharmacists also needing to keep their stocks low when price reductions are imminent, the management skills of the CSO Distributors are critical to ensure that patient access remains timely and viable.

There is always a significant stock devaluation effect on wholesalers as stock needs to be held over the transition period in order to meet patient demand and CSO service standards.

Any stock held on the date of the price reduction can then only be sold at the lower price notwithstanding its higher purchase price. The notice period provides an opportunity to reduce, but not avoid or eliminate, the magnitude of this stock devaluation.

In the lead up to price reductions, the buying patterns of pharmacists change significantly as they attempt to minimize their stock holdings. This makes management of inventory and service levels extremely difficult. CSO Distributors have long lead times which add to the difficulty of minimising stock holdings while maintaining service levels.

The above estimates of the costs to wholesalers of PBS Reform do not include these stock losses. It is essential that wholesalers are reimbursed by manufacturers in respect of the loss on stock value as at the date of the PBS price changes to ensure that patients are not impacted by the reform arrangements.

❖ Timing of Pricing Changes

The PBS Reform arrangements do not provide a sustainable arrangement for the management of price reductions within the supply chain. It is critical that patients are not impacted by the measures and that they can obtain their medicines when they need them.

The experience of wholesalers is that some manufacturers reduce their prices to wholesalers early to ensure a smooth transition and then make an adjustment for any stock on hand that was purchased at the higher price when the price change comes into effect.

On the other hand, some manufacturers make no arrangements to smooth the transition and this makes it impossible for CSO Distributors, which are committed to timely supply of all PBS medicines, to protect themselves from stock losses or to ease the burden on pharmacy or patients.

This lack of consistency causes uncertainly and needs to be addressed. It causes timely supply of medicines to be vulnerable when prices are reduced. For example, if the price of a medicine is reduced from say $30 to $20 then the loss incurred per medicine on hand on the date of the price reduction is $10. The stock loss in this example is significantly higher than the wholesale margin paid by the Government for the supply of this medicine (e.g $2.10 before the price change and $1.40 after the price change) and cannot be absorbed by wholesalers.

NPSA Recommends

NPSA strongly recommends that the Government introduce an adjustment mechanism in favour of pharmaceutical wholesalers to underpin the savings sought to be achieved from the PBS Reforms (2010) proposed in the National Health Amendment (PBS) Bill 2010.

Under the PBS Reform (2010) arrangements, wholesale fees are cut. At the same time, under the Fifth CPA and the CSO, wholesalers are constrained from passing on wholesale fee cuts as they are bound to maximum prices to pharmacy.

The MA MOU addresses the manufacturer issues while the Fifth CPA contemplated the foreshadowed impact of PBS Reform (2010) on pharmacy. Wholesalers were not represented in the negotiations of either of these agreements notwithstanding their role in the supply chain and under the National Medicines Policy, yet the likely impact of the combined arrangements on the wholesale sector is enormous.

The NPSA therefore seeks an adjustment arrangement to ensure that patients continue to access timely supply of the full range of PBS medicines as follows:

- $34 million per annum due to the shortfall from PBS Reform (2006)
- $24 million per annum due to the impact on wholesalers of PBS Reform (2010) – the subject of the National Health Amendment (PBS) Bill 2010.

NPSA Submission Attachment 1: *130510 NPSA Press Release*

NPSA Submission Attachment 2: *Access Economics "Summary of Presentation"*