



Submission to the Department of Health and Ageing

**Effects of Reforms to the Pharmaceutical
Benefits Scheme**

November 2009

Table of Contents

| | |
|---|---------------|
| Executive Summary | - 1 - |
| Summary of Recommendations..... | - 7 - |
| About Medicines Australia | - 8 - |
| The Objectives of PBS Reforms..... | - 9 - |
| PBS Reforms bolster an already Sustainable and Efficient PBS..... | - 9 - |
| Getting Price Disclosure Right..... | - 12 - |
| Patient’s Timely Access to New Medicines should be the Key Priority..... | - 13 - |
| <i>Separation of the PBS into the F1 and F2 formularies is pivotal to delivering future savings and ensuring continued supply of new medicines.....</i> | <i>- 13 -</i> |
| <i>Access to Medicines Working Group.....</i> | <i>- 15 -</i> |
| <i>Cabinet Threshold.....</i> | <i>- 18 -</i> |
| Unintended Consequences of Legislation | - 19 - |
| <i>Patient Premiums.....</i> | <i>- 19 -</i> |
| <i>Exemptions to legislated price Reductions</i> | <i>- 20 -</i> |
| Patients have Benefited from PBS Reform Overall..... | - 21 - |
| PBS reform is delivering a more competitive generics market..... | - 22 - |
| Conclusion..... | - 23 - |
| Appendix A – The Impact of PBS Reforms on PBS Expenditure and Savings – Centre for Strategic Economic Studies, Victoria University – Summary | - 25 - |
| Appendix B – Section 84AH of the National Health Act 1953..... | - 29 - |

Executive Summary

In November 2006, the Australian Government announced the Pharmaceutical Benefits Scheme (PBS) Reform measures. These were the most comprehensive reforms to the PBS since its inception over 60 years ago.

The objectives of the PBS reforms were to ensure a financially sustainable PBS whilst enabling the continued listing of new innovative medicines on the PBS in the future. This is done by enabling Government to generate significant savings for the taxpayer over time by exposing multi-brand medicines to market competition whilst ensuring new medicines can remain and continue to be listed on the PBS due to pricing predictability. Price setting for new medicines will continue to be achieved through rigorous cost-effectiveness evaluation with initial prices set by reference to existing medicines on the PBS.

The reforms were also designed to ensure that new medicines continue to be listed on the PBS for Australians in the future. A range of measures were introduced to secure the sustainability of bringing new medicines to Australia including the creation of the Access to Medicines Working Group (AMWG).

Medicines Australia members supported these reforms (despite the significant impacts on their off-patent revenue base) in return for stability in PBS policy. This means a stable and predictable business environment for companies to continue listing new innovative medicines on the PBS, funded by the headroom created from savings in the off-patent medicine market.

PBS Reform Bolsters an Already Sustainable and Efficient PBS

Overall, Australia has historically spent, and continues to spend, significantly less on pharmaceuticals than the majority of OECD countries both relative to size of economy and as a proportion of total health system expenditure¹. According to the OECD Australia pays the lowest prices for originator medicines relative to economy wide-prices amongst all OECD countries².

Historically, the Australian taxpayer through the PBS has paid more than the OECD average for off-patent medicines. However, PBS reforms will provide lower priced off-patent medicines through market competition. This will bolster the sustainability of the PBS with estimated savings to Government of \$6 billion over the 10 years from 2008-09 to 2017-18 (Appendix A).

This is double what the Government had projected when the reforms were announced in 2006. **The pharmaceutical industry will provide \$8.43 billion in savings to the PBS over 10 years with the innovative pharmaceutical industry providing \$5.96 billion of the savings, with the remaining \$2.47 billion coming from the generics industry.**

¹ OECD *Health Data 2009*, Statistics and indicators for 30 countries.

² Pharmaceutical Pricing Policies in a Global Market, *OECD Health Policy Studies 2008*, P164

The Victoria University's Centre for Strategic Economic Studies (CSES) report into the impacts of PBS Reforms projected expenditure on the PBS compared with overall GDP will remain stable at 0.68-0.74% of GDP over the coming years to 2013-14³.

It is the industry's contention that:

- the savings from the PBS reforms should be properly accounted for in the Government's budgeting process to avoid future unnecessary and unjustified cutbacks to the PBS affecting industry and patients; and
- PBS reforms have provided and will continue to facilitate a sustainable system into the future – one which provides ongoing market driven savings to Government and continued access to new medicines for Australian patients.

Getting Price Disclosure Right

The price disclosure arrangements for multiple brand medicines on the PBS, whereby the Government reimbursement price tracks the actual market selling price, will deliver half of the \$6 billion in savings the Government should receive over the next 10 years as a result of the PBS reform package.

The accurate and efficient administration of price disclosure will therefore have a major influence on the success of the PBS reforms. However, the administration of the price disclosure arrangements to date has been unsatisfactory and suggested improvements have gone unheeded.

If Government is to realise the full potential of price disclosure, it needs to ensure that the administration of the price disclosure arrangements operate accurately and efficiently, and that the industry has confidence in the price disclosure process.

In addition, the only current recourse that an affected company has to resolve questions of fact or process regarding a price disclosure outcome is the judicial system, a route already taken by one company following the very first round. This case highlights the need for an administrative resolution process for price disclosure, as recommended by Medicines Australia several years ago. The case also revealed the importance of devoting sufficient administrative resources to administer price disclosure correctly.

The initial delay in implementing the first round of price disclosure price reductions due to administrative issues has resulted in an estimated \$6 million of savings not being realised by the Government.

Timely Access to New Medicines for Patients should be the Key Priority

Medicines Australia strongly views timely access to new medicines for all Australians key to a successful and sustainable PBS. Since the introduction of PBS reforms, new medicines have continued to be listed on the PBS. However, many of these medicines have experienced significant delays before listing and the time taken to list a new

³ Victoria University , *The Impacts of PBS Reforms on PBS Expenditure and Savings*, Sustainability of the PBS, 2009, P13

medicine continues to increase. Only 55% of medicines applying for PBS listing get a positive recommendation to list within a year⁴.

The time taken to listing increases by up to 12 months if Federal Cabinet is required to approve the listing of a new medicine on the PBS. It is not clear that PBS reform has improved the environment for listing new medicines at this time.

Separation of the PBS into the F1 and F2 formularies is pivotal to delivering future savings and ensuring continued supply of new medicines

The separation of the pricing of PBS medicines into single brand medicines (F1 formulary) and multiple brand medicines (F2 formulary) is a crucial component for the overall sustainability of the PBS, particularly for the listing of new and innovative medicines.

The separation of the formularies acknowledges that there are two markets within the PBS – a single brand innovative medicines market and a multiple brand commodity medicines market. This allows Government to realise savings where brand competition exists in the commodity market. This could not be achieved under the reference pricing arrangements which existed before the reforms took effect.

However, measures such as the current therapeutic group policy undermine this predictability and the policy intent of PBS reforms. The therapeutic group policy is a legacy from the days of reference pricing arrangements – arrangements which prevented the Government from achieving appropriate savings from the multi-branded medicines market and risked supply of single brand medicines to patients. **The therapeutic group policy and supporting legislative provisions in the National Health Act should be removed.**

Access to Medicines Working Group

Establishing the Access to Medicines Working Group (AMWG) was one of the significant measures for industry introduced as part of the PBS Reforms. The overarching objective of the AMWG is to consider issues regarding timely and appropriate access to new medicines on the PBS⁵. Medicines Australia strongly supports the continuation of the AMWG, as a critical vehicle for initiatives to be developed so that timely medicine access is delivered for patient benefit.

The AMWG has examined a range of PBS listing issues since its inception, including the potential impact of price reductions on the listing of new medicines, streamlining the PBS listing process, improved information for the community concerning new medicines being considered for PBS listing, and measures to reduce the time to listing new

⁴Figure 1 Cumulative PBAC recommendation percentage for initial major submissions by calendar year 2004-2008, *PBAC Outcome Indicators 2008*, P12.

⁵ Department of Health and Ageing, <http://health.gov.au/internet/main/publishing.nsf/Content/amwg> [Accessed 20 November 2009]

medicines. This is a key part of PBS reform and will provide important benefits for Australian patients.

However, while an important part of PBS reform, the initiatives developed or the outcomes identified by the AMWG have yet to be meaningfully progressed. While understandable given the time required to canvass these complex issues, the pharmaceutical industry is keen to see faster progress concerning implementing improvements to the PBS listing process.

Cabinet Threshold

The \$10 million threshold at which Cabinet approval is required was established in 2001 and has not been adjusted to reflect changes in the economy or even indexed to inflation. By failing to adjust the threshold over time the listing of an increasing number of new medicines is likely to be delayed in the future.

The requirement that Cabinet approve the listing of any medicine costing more than \$10 million per annum can additionally add more than 12 months to the time it takes for some medicines. During this time Australians are denied subsidised access to life-saving drugs meaning longer periods of debilitating illness for patients, time off work, increased use of other health services and, in some cases, such delays can literally be life threatening.

Data from the Department of Health and Ageing showed that even a small increase in the threshold to \$20 million would have more than halved the number of medicines requiring Cabinet consideration from 2002-03 to 2007-08.

In addition to improving patient access to new medicines, relieving Cabinet time pressures and removing a regulatory burden for some medicines, Medicines Australia believes that increasing the threshold will not cost the Government any additional money.

Limiting Unintended Consequences of Legislation

The PBS reforms included provisions aimed at protecting patient access to low volume single branded medicines used for treatment of small unique sub-populations and restrictions on patient premiums aimed at ensuring that patients would not incur increased costs as a result of PBS reform.

However, both of these measures had unintended consequences. The way the Department of Health and Ageing has chosen to interpret the legislation regarding low volume medicines has led to the delisting of some strengths of medicines. This has led to patients in some sub-populations, such as children, missing out on subsidised treatment options.

The restrictions imposed on companies' ability to change their premiums on their products are unnecessary and have not only restricted the way companies price their products in the private market, but have also made it more difficult for companies to

reduce or remove their premiums. This also has the effect of limiting competition in the multi-branded medicine market and means that patients will miss out on intended price reductions.

Government needs to review the exemption legislation and patient premium restrictions to remove these unintended consequences.

Patients have Benefited from PBS Reform Overall

Patients are benefiting from PBS reform for a number of reasons.

Firstly, the PBS reforms will enable future Australian governments to continue subsidising new innovative medicines on the PBS whilst further improving the scheme's financial sustainability. This means that Australians will have affordable access to the range of new therapies being developed by the pharmaceutical industry now and in the future. This is important given Australia's ageing population.

Whether Australians do ultimately benefit from PBS reform in this way depends in part on whether system improvements to listing new medicines are implemented and the extent to which future Australian governments are prepared to fund new medicines. PBS reform further bolsters an already efficient and sustainable system.

Secondly, patients will also benefit from PBS reforms through lower medicine prices. CSES estimates that the direct savings to patients will be \$420 million over 10 years (2008-09 to 2017-18). These lower prices for medicines come about from the mandatory and price disclosure price reductions initiated by government policy and delivered by the pharmaceutical industry – both originator and generic manufacturers.

As more patents expire for some PBS listed medicines into the future, patients will benefit from further price reductions through price cuts resulting from multi-brand competition. IMS data indicates that worldwide, US\$120 billion worth of medicines will lose patent protection and be subject to brand competition in the next 5 years⁶. PBS reform will allow these significant savings to be realised for patients and the taxpayer over the coming years.

PBS Reform is delivering a more competitive generics market

One of the policy objectives of PBS reform was to drive a more competitive generics market and more competitive generic pricing in Australia. Prior to PBS reforms, the price paid by Australians for off-patent generic medicines was comparatively high by international standards⁷.

The PBS reform package introduced price disclosure to the PBS to lower the price paid by government for off-patent medicines on the PBS and it was industry's understanding that it would require 3-4 years to fully implement the price disclosure arrangements.

⁶ New Market Segmentation, *IMS Health MAT Dec 2008*.

⁷ Figure 4.A1.1. Retail price – economy-wide price level differentials for original and generic pharmaceuticals 2005 OECD, *Pharmaceutical Pricing Policies in a Global Market 2008*, P164.

This provided a transition phase (2008 - 2011) allowing sponsors to adapt to the new model.

The first three rounds of price disclosure price reductions have been calculated and is estimated to save the Government \$102 million from 2009-10 to 2012-13 through the Government adjusting the PBS reimbursed price to reflect the 'actual market price'. Importantly, these measures did not impede the critical market principles of competitive neutrality: all manufacturers, both originators and generic companies, were equally affected.

Since the reforms, there is also evidence of increased competition in the 'generics' market with the number of 'premium free' medicines increasing from 68% prior to PBS reform (2007-08) to 74% post PBS reform implementation (2008-09).

Given these trends, it is not desirable or appropriate for any additional policy measures to drive further generic competition, particularly any measures that would create a sectoral imbalance.

Conclusion

The PBS reform will bolster an already sustainable and efficient PBS delivering savings to Government of \$6 billion dollars from 2008-09 to 2017-18, double the \$3 billion the Government estimated in 2006. Patients will benefit from lower medicine prices and continued listing of new innovative medicines as a result of PBS reform.

However, patient access to new and innovative medicines is contingent on the Government ensuring that PBS reform measures are administered efficiently and accurately providing policy stability, and business certainty and predictability. This will encourage the innovative pharmaceutical industry to continue to seek listing new and innovative medicines.

Summary of Recommendations

Medicines Australia Recommends that the Government:

1. remove from the National Health Act 1953 the therapeutic group policy provisions to restore pricing predictability in F1 as this will provide industry with business certainty to list new medicines on the PBS;
2. implement the AMWG initiatives in the near future to realise efficiencies in the PBS listing process and decrease the time taken to list new innovative medicines on the PBS;
3. increase the threshold at which Cabinet approval is required for the listing of a medicine on the PBS from the current \$10 million to \$35 million, and index future adjustments to reflect economy-wide prices;
4. acknowledge and incorporate the full savings from PBS reforms into its Budget estimates;
5. work with industry to ensure that the administration of the price disclosure process is accurate and efficient thus ensuring that savings from price disclosure will be realised;
6. work with industry to implement a formal price disclosure dispute resolution and audit process to avoid delays implementing further price disclosure price reductions;
7. work with industry to review the restrictions on removing or lowering patient premiums at the same time as a legislated price reduction so companies can pass on lower prices to patients;
8. work with industry to review the s84AH exemption arrangements to permit the listing of multiple strengths of a single branded medicine formulations to ensure continued access of these medicines to treat small unique sub-populations (as originally intended); and
9. *not* introduce any additional policy measures to direct market share for generics companies in the off patent market so that a competitive off-patent market is maintained.

About Medicines Australia

Medicines Australia represents the innovative medicines industry in Australia. Our member companies comprise more than 80 percent of the prescription pharmaceuticals market, and are engaged in the research, development, manufacture, supply and export of prescription medicines.

Medicines save lives, reduce and cure disease. Medicines Australia is committed to enhancing the health of Australians by providing access to medicines of the highest quality, safety and efficacy.

The pharmaceutical industry is a key industry in Australia which provides benefits to both Australians' health and the health of Australia's economy. Pharmaceutical companies are constantly working on bringing new effective medicines to patients and invest around \$860 million in research and development each year.

Our Association represents a high technology, knowledge-intensive industry, contributing significantly to the Australian economy as an employer and exporter. The industry sells over \$11 billion worth of medicines domestically and directly employs over 14,000 people in Australia. In 2007, Australian pharmaceutical manufacturing exports totalled \$3.9 billion.

Medicines Australia represents the innovative medicines industry by:

- participating in health and industry policy development.
- building and maintaining relationships with Government to ensure the continuation of a viable pharmaceutical industry.
- actively engaging with key consumer groups to better understand their needs and issues and educating the general community about the industry in Australia.
- administering the Code of Conduct which sets the standard for the ethical marketing and promotion of prescription medicines.
- working along with other health professional organisations to discuss issues of mutual concern.

The Objectives of PBS Reforms

In 2007, the Australian Government, with support of the Parliament, passed the most comprehensive package of changes to the PBS since its inception in 1948. The reforms implemented structural changes to the PBS intended to facilitate its long term sustainability.⁸

PBS Reform split the PBS into two distinct formularies: medicines which were not exposed to brand competition at the molecule level (F1); and off-patent medicines which were exposed to multiple brand competition (F2).

The division of the PBS into two formularies enables the Government to extract significant savings for the taxpayer by encouraging more market competition in the off-patent market without undermining the pricing predictability for, and value of patented medicines in F1. Efficient price setting and control in F1 continues to be achieved through rigorous cost-effectiveness evaluation.

These reforms were carefully negotiated between Government, the Australian pharmaceutical industry, community pharmacy, doctor groups and patient groups, with the specific objective of using the savings generated by market competition to fund the PBS listing of the latest, most innovative and cost-effective medicines as they became available.

At the time of its implementation, the Australian Government estimated that PBS Reform would deliver \$3 billion worth of savings to the tax payer over 10 years. More up-to-date modelling suggests that savings to the Government will be closer to \$6 billion.

PBS Reforms bolster an already Sustainable and Efficient PBS

Successive governments have been concerned with growth in the PBS and have frequently highlighted medicine prices and the listing of new medicines as its major cause. However, it is important for governments to avoid viewing growth in the PBS as a negative fiscal impost. Spending in the PBS is an important investment in the health of all Australians and the PBS is an important tool in ensuring a healthy and productive population.

Furthermore, it must be noted that PBS growth and the noted causes of that growth has not translated to increased revenues for companies. For example, in 2008-09 growth in PBS expenditure was over 10% however, the growth in pharmaceutical manufacturers revenue for PBS medicines was only half that at 5%⁹.

⁸Tony Abbott, Minister for Health and Ageing, Media Release: *PBS Reform*, 16 November 2006, http://www.healthactive.gov.au/internet/main/publishing.nsf/Content/pbs_reform_02feb07.htm, [Accessed 19th November 2009]

⁹ *IMS Health API - 12 Months to August Data*.

Therefore it is reasonable to assert that recent growth in the PBS is attributable to factors other than medicine prices and the listing of new medicines. Other factors contributing to PBS growth include increases in demand resulting from population growth and an ageing population. A recent significant rise in the number of Concession Card holders and continued annual increases of community pharmacy dispensing fees also contribute to growth in PBS expenditure.

Even before the introduction of PBS Reform however, Australia enjoyed one of the most efficient and sustainable schemes in the OECD for providing its citizens with universal and equitable access to medicines.

Certainly, any debate on the sustainability and efficiency of the PBS must take into account the following facts:

- Every single medicine funded on the PBS since 1993 has been found to return more to Australia in terms of health and economic benefit than it costs due to the listing requirement that it be determined to be “cost-effective” No other component of the health system has such an in-built guarantee of sustainability and efficiency.
- Australia has historically spent, and continues to spend, significantly less on pharmaceuticals than the majority of OECD countries both relative to size of economy and as a proportion of total health system expenditure¹⁰.
- According to the OECD, Australia pays the lowest prices for originator medicines relative to economy wide-prices amongst all OECD countries¹¹.

The long term sustainability and efficiency of the PBS was further bolstered by the introduction of PBS Reforms. When the reforms were announced in 2006, the Government initially estimated that they would generate saving of \$3 billion over 10 years. Many outside of Government with knowledge of the terms of trade in the pharmaceutical market place believed this figure to be a significant underestimate.

The Pharmacy Guild of Australia commissioned independent modelling of the impact of PBS Reform and concluded that the savings figure is likely to be \$7.4 billion over 10 years¹².

In March 2009 Medicines Australia commissioned the Centre for Strategic Economic Studies (CSES) at Victoria University to analyse the impact of the PBS reform measures since their introduction and for the next decade. CSES was asked to analyse trends in overall PBS expenditure and to report on how reforms have affected stakeholders; namely, government, community pharmacy, pharmaceutical wholesalers, pharmaceutical manufacturers and other suppliers, and patients.

¹⁰ Figure 1.5. Share of pharmaceutical expenditure in total health spending and in GDP 2005, *Pharmaceutical Pricing Policies in a Global Market 2008*, P28.

¹¹ Figure 4.A1.1. Retail price – economy-wide price level differentials for original and generic pharmaceuticals 2005, *Pharmaceutical Pricing Policies in a Global Market 2008*, P164.

¹² Pharmacy Guild Media Release, *Taxpayers Reap Benefit from PBS Reforms* <http://guild.org.au/content.asp?id=2592>, [Accessed 10 November 2009]

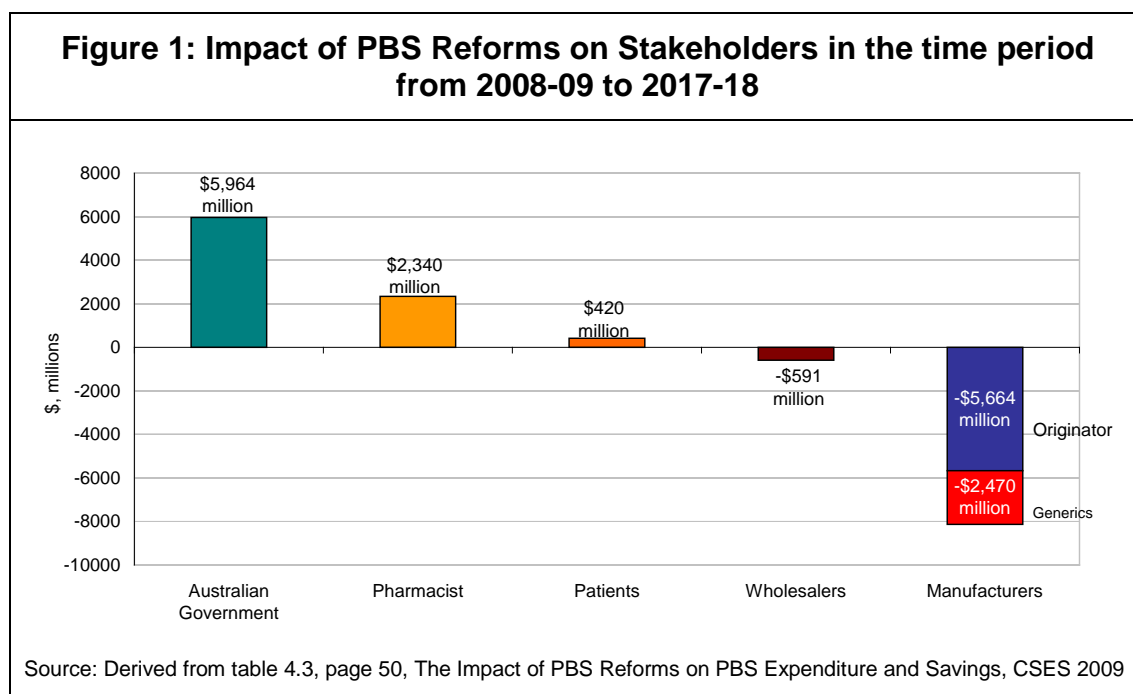
The CSES report concludes that the true saving to be delivered by PBS reforms is likely to be double the original Government estimate.

Over ten years from 2008-09 to 2017-18, CSES estimated that PBS reforms will deliver \$6.4 billion to taxpayers and patients. This figure comprises:

- a **\$8.13 billion net saving at the expense of the pharmaceuticals industry**
- a \$5.96 billion net saving to the Government
- a \$591 million net savings at the expense of Wholesalers¹³
- a \$2.34 billion net cost to compensate community pharmacy¹⁴.

Importantly, PBS Reform is set to deliver patients a saving of \$420 million from reduced out-of-pocket costs.

Figure 1 illustrates the magnitude of these savings:



Finally, the CSES report also concludes that the PBS will continue to be sustainable into the future. The report assessed that the PBS will continue to track between 0.68% and 0.74% as a percentage of GDP to 2013-14, a range from which it has not deviated over the past many years¹⁵.

¹³ Excluding additional funding of \$69 million over three years for the Community Services Obligation (CSO) Funding Pool to compensate wholesalers.

¹⁴ Assumes that the pharmacy compensation package continues beyond 30 June 2011 (though precedent)

¹⁵ Victoria University, The Impacts of PBS Reforms on PBS Expenditure and Savings, *Sustainability of the PBS*, 2009, P13.

It is important that the true magnitude of the savings to be delivered from PBS Reform be recognised by the Government and its agencies.

The initial \$3 billion worth of savings that the Government originally estimated is a significant underestimate, and a revised figure needs to be built into the PBS forward estimates. To this end Medicines Australia is prepared to work with the Government to identify the true figure of the savings.

Medicines Australia Recommends that the Government:

- **acknowledge and incorporate the full savings from PBS reforms into its Budget estimates.**

Getting Price Disclosure Right

The additional \$3 billion in estimated savings is projected to be obtained by extracting the price reductions generated by market place competition. The mechanism designed to achieve these savings is the PBS Price Disclosure policy. In essence, this policy seeks to align the price paid by the Government for multi-branded medicines with the price these medicines are actually sold to pharmacies for in the market. Discounting to pharmacies occurs in the marketplace as a result of generic companies competing for greater market share and, as the Pharmacy Guild has identified, this discounting will be subject to change as a result of PBS reform. The price disclosure policy works to ensure that a significant portion of that discount is passed on to the tax-payer, whilst still allowing community pharmacy to appropriate a fair share of the benefit.

The policy has been phased in since 2007, but from 1 January 2011, all new brands of medicines listed on the F2 formulary will be required to have disclosed the price they are sold to pharmacies.

The success of the PBS Reform is highly contingent on the accurate and competent administration of this policy by the Government. It is vital that Price disclosure is administered in an efficient and competent manner if sufficient savings (headroom) are going to be created for the future PBS listing of new innovative medicines.

Despite being fundamental to the ultimate success of PBS Reform, the implementation of price disclosure has so far been characterised by a number of administrative errors that have led to significant delays in the realisation of savings.

Medicines Australia has long been concerned about the absence of a formal price disclosure dispute resolution and audit process. As the price disclosure policy is designed to extract savings facilitated by companies' discounting practices, it is vital that the calculations and data used by the Government to determine price alterations can be verified, and that any resultant disputes can be resolved in a transparent and fair manner.

At the present time, the only recourse that a sponsor has to resolve questions of fact or process is the judicial system, a route already taken by one company following the very first round of price disclosure related price reductions. The court not only found in favour of the company, but also highlighted a number of administrative anomalies that

demonstrated standard operating procedures were not followed. The delay in implementing the first round of price disclosure price reductions has resulted in an estimated \$6 million of savings not being realised by the Government.

Medicines Australia maintains that this outcome could have been avoided had the Government introduced a formal dispute resolution and audit system. More than 12 months ago, KPMG provided the Government with an options paper for the introduction of such a scheme. Whilst Medicines Australia provided feedback on the paper, no further work has been forthcoming on the matter.

Medicines Australia again urges the Government to work with the industry to ensure that administration of the Price Disclosure policy is efficient and accurate. In particular, it is imperative that a formal dispute resolution and audit process be introduced to validate, and ensure confidence in the administration of the policy.

Medicines Australia Recommends that the Government:

- **work with industry to ensure that the administration of the price disclosure process is accurate and efficient thus ensuring that savings from price disclosure will be realised.**
- **work with industry to implement a formal price disclosure dispute resolution and audit process to avoid delays implementing further price disclosure price reductions.**

Patient's Timely Access to New Medicines should be the Key Priority

Medicines Australia strongly views timely access to new medicines for all Australians key to a successful and sustainable PBS.

Since the introduction of PBS reforms, new medicines have continued to be listed on the PBS. However, many of these medicines have experienced significant delays before listing and the time taken to list a new medicine continues to increase. Only 55% of medicines applying for PBS listing get a positive recommendation to list within a year¹⁶.

The time taken to listing increases by up to a further 12 months if Federal Cabinet is required to approve the listing of a new medicine on the PBS. It is not clear that PBS reform has improved the environment for listing new medicines at this time.

Separation of the PBS into the F1 and F2 formularies is pivotal to delivering future savings and ensuring continued supply of new medicines

It is important to note that CSES estimates that Medicines Australia's members will deliver \$5.6 billion of savings to the Government from price reductions to medicines in F2. This is not an insignificant figure by any standard. Nonetheless, the innovative

¹⁶ Figure 1 Cumulative PBAC recommendation percentage for initial major submissions by calendar year, 2004-2008, *PBAC Outcome Indicators 2008*, p12.

pharmaceuticals industry agreed to absorb this substantial loss of revenue in return for what it believed to be the provision of a predictable and stable pricing market for new medicines within F1.

This predictable and stable pricing market is important for companies seeking to conduct business in Australia. Decisions about whether to seek listing for new medicines, and ongoing business investment in Australia are directly affected by confidence and assurance in this market

Business confidence in the important F1 pricing market is severely undermined by legislative provisions that permit the Government, at any point in time and without consultation with affected parties, to form Therapeutic Groups between different medicines. The decision to form a Therapeutic Group effectively dissolves the boundary between F1 and F2 as all medicines in the Therapeutic Group will be moved to F2 regardless of patent status once one member of the group is exposed to generic competition.

This means that on-patent medicines will be forced to take mandatory price cuts well before a sponsor had anticipated, without any provision for consultation or negotiation with the affected company. In addition, given the unpredictability of how, when or why a therapeutic group is formed, companies have little advance warning of when their medicines will be adversely affected by this policy. Such pricing uncertainty has led to other problems regarding pricing in the past (e.g. additional patient premiums, policy failures, savings objectives not being met).

Additional therapeutic groups are also likely to lead to companies deciding not to submit medicines for listing on the PBS. They may also result in companies seeking higher prices through a cost-effectiveness listing during the PBAC process to protect themselves from possible inclusion in a therapeutic group at a later date.

Furthermore, medicines belonging to a therapeutic group will also typically be exposed to a form of reference pricing based on the Weighted Average Monthly Treatment Costs - another policy that leads to unpredictability in pricing for companies.

Medicines Australia and its member companies believe that the ongoing formation of therapeutic groups breaches the principles of PBS Reform. It undermines predictability in F1 to such an extent that it becomes difficult for companies to operate effectively in the Australian market. It also acts as a disincentive for investment in R&D, clinical trials, and production in Australia. Indeed, the formation of new therapeutic groups work to undermine the viability of the industry in Australia, thus contravening an important principle of the National Medicines Policy.

This breach of a previously negotiated principle undermines business confidence in the Australian market and **makes it more difficult for companies to bring new medicines to the PBS with any certainty**. These outcomes will only work to diminish patients' ability to access new medicines.

Medicines Australia Recommends that the Government:

- **remove from the National Health Act 1953 the therapeutic group policy provisions to restore pricing predictability in F1 as this will provide industry with business certainty to list new medicines on the PBS.**

Access to Medicines Working Group

As part of the PBS reforms package, the Department of Health and Ageing and Medicines Australia agreed to form the Access to Medicines Working Group (AMWG). The purpose of the AMWG is to:

1. Provide strategic oversight of joint activities undertaken by the Department of Health and Ageing, and Medicines Australia to enhance the PBS processes.
2. Consider issues relating to timely and appropriate access to effective new medicines on the PBS following the PBS reforms.

Since its inception the AMWG has provided one written report to the Minister for Health and Ageing (available at www.health.gov.au/internet/main/publishing.nsf/Content/amwg-interim-report.) comprising a series of discussion papers on agreed areas of prioritisation.

These included:

- The effects of statutory price reductions for medicines in F2 on the listing of new F1 medicines;
- Managing uncertainty of evidence in the Pharmaceutical Benefits Advisory Committee (PBAC); including the potential introduction of “Coverage with Evidence Development”, a policy that permits a listing on the PBS contingent upon the provision of additional evidence at a future date; and
- Streamlining the Therapeutic Goods Administration (TGA) registration and PBS listing process for new medicines.

Work in all these areas and others have continued, and the AMWG is due to submit its second report to the Minister early in 2010.

Whilst Medicines Australia believes that the AMWG has achieved a number of milestones since its inception, it remains concerned that little progress has been made in achieving the most important outcome to both industry and patients: a reduction in the time that it takes to achieve a TGA and PBS listing of a medicine in Australia. Far from decreasing, the most recent data suggest that the time it takes for a reimbursed medicine to be made available to patients in Australia is growing.

Medicines Australia acknowledges that the TGA business reforms, after some initial delay, are beginning to take shape. It is anticipated that these reforms should help reduce the time required to achieve TGA registration from current time of 12 or more months to approximately 7 months.

The industry also welcomes the AMWG “streamlining pilots” currently underway. Both of these pilots explore ways to reduce the current high rate of “re-submission churn” that characterises the PBS listing process. It is hoped that by identifying potentially complex submissions early and allowing more time for companies to resolve gaps in information, data, or evidence, significant delays in listing by the PBAC will be reduced.

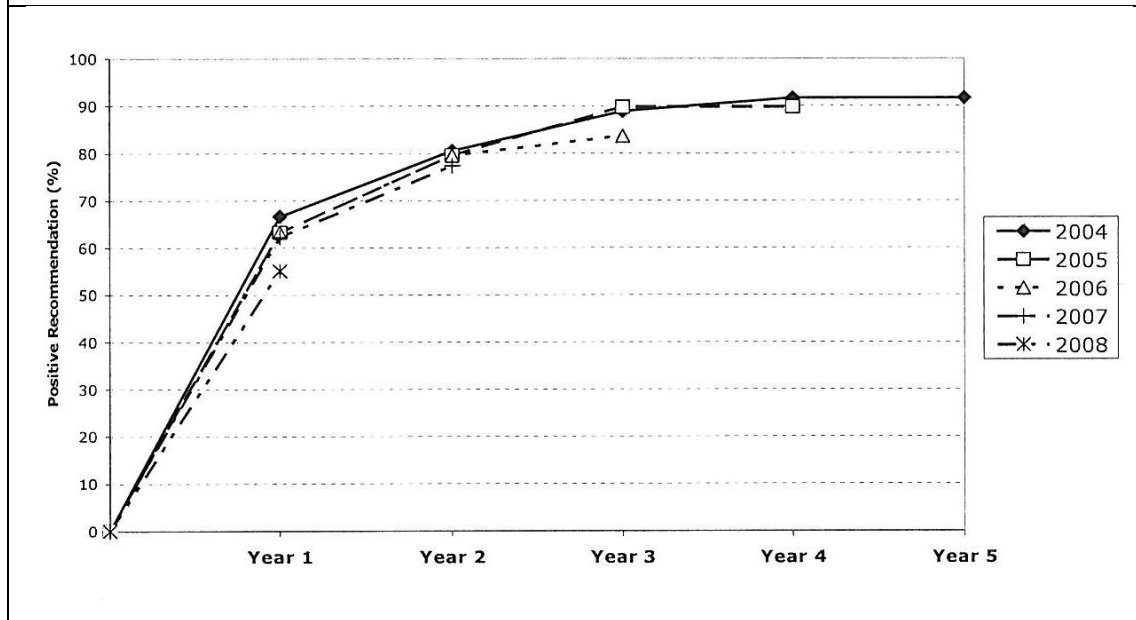
Medicines Australia maintains that there are no longer compelling reasons for not allowing the evaluation processes for both TGA registration and PBS listing to be de-linked and allowed to operate in parallel. This process is currently permitted in a number of other jurisdictions, including Canada and Sweden.

As the TGA and PBS listing evaluations have a fundamentally different frame of reference, there are no a priori reasons for the demand that they take place sequentially. The only limiting step is the requirement that a medicine be first registered for use in Australia before the Government can list it on the PBS. This does not, however prevent the PBAC from considering its claims for relative clinical and cost-effectiveness and providing the Minister with a recommendation which can be acted upon following approval by the TGA.

This is acknowledged by both industry and government. In the past, the principal objection put forward by the Department of Health and Ageing has been the risk of wasting significant public resources on evaluating a PBS submission for an indication that is outside the use that is finally approved by the TGA – rare as this occurrence is in practice.

In 2010, PBS cost-recovery will be introduced to cover the cost of the PBS listing process. **This means that the risk outlined above will be fully borne by the industry alone.** When deciding to lodge a submission for PBS listing, the company will now have to weigh-up the potential risk of a TGA indication change in the knowledge that such a change will lead to the need to re-submit a revised submission at a future date at a cost to the company of more than \$120,000. This will provide a significant deterrent to any company which has doubts about the strength of the evidence provided to both the TGA and PBAC.

Figure 2 Cumulative PBAC Recommendation Percentage for Initial Major Submissions by Calendar Year 2004-2008



By permitting the registration and reimbursement evaluation process to be de-linked, a new medicine might be listed on the PBS and available to Australian patients within 7 months of seeking registration with the TGA. Currently, very few medicines become available in less than 3 years.

In addition to the de-linking of the TGA and PBS evaluation processes, there are a number of other areas that the AMWG will continue to work on. Medicines Australia believes that there are still significant efficiency gains to be achieved in the PBS listing process itself.

Figure 2 indicates that whilst 55% of all medicines receive a positive PBAC recommendation within 1 year of the lodgement of the initial submission, it takes another 3 years to achieve 90% approval¹⁷. There are important gains to be made by finding solutions earlier for those 35% of medicines that take longer than a year to negotiate a PBS listing, not the least to those patients who need them.

Medicines Australia Recommends that the Government:

- **Implement the AMWG initiatives in the near future to realise efficiencies in the PBS listing process and decrease the time taken to list new innovative medicines on the PBS.**

¹⁷ Figure 1 Cumulative PBAC recommendation percentage for initial major submissions by calendar year, 2004-2008, *PBAC Outcome Indicators 2008*, P12.

Cabinet Threshold

The requirement that Cabinet approve the listing of any medicine costing more than \$10 million per annum can additionally add more than 12 months to the time it takes for some medicines to be available to the Australian public. During this period, Australians are denied access to life-saving drugs. Such delays mean longer periods of debilitating illness for patients, time off work, increased use of other health services and, in some cases, such delays can literally be life threatening.

The \$10 million threshold at which Cabinet approval is required was established in 2001 and has remained at this level ever since. It has not been adjusted to reflect changes in the economy or even indexed to inflation.

By failing to adjust the threshold to accommodate economy-wide price changes over time the listing of an increasing number of new medicines is likely to be delayed in the future.

This was recently recognised by the Productivity Commission, when in its *2008 Annual Review of Regulatory Burden on Business: Manufacturing and Distributive Trades*, it commented that:

“The Government should consider the merits of increasing the threshold to account for price changes over the past six years and implementing an automatic annual indexation adjustment.”¹⁸

Medicines Australia has been provided with data by the Department of Health and Ageing that show that even a small rise in the value of threshold would significantly reduce delays to the listing process for many medicines. For example, these data show that doubling the threshold to \$20 million would have reduced the number of medicines requiring Cabinet consideration from 2002-03 to 2007-08 by 54%.

Figure 3: Number of Cabinet submissions if the threshold was increased

| Threshold | 2002-03 | 2003-04 | 2004-05 | 2005-06 | 2006-07 | 2007-08 | Total | Percentage Reduction |
|------------------------|----------------|----------------|----------------|----------------|----------------|----------------|--------------|-----------------------------|
| \$10m (current) | 2 | 5 | 3 | 5 | 13 | 11 | 39 | 0% |
| \$15m | 2 | 3 | 2 | 4 | 8 | 4 | 23 | 41% |
| \$20m | 1 | 3 | 2 | 4 | 6 | 2 | 18 | 54% |
| \$50m | 0 | 3 | 0 | 0 | 2 | 1 | 6 | 85% |

Source: Department of Health and Ageing

In addition to improving patient access to new medicines, relieving Cabinet time pressures and removing a regulatory burden for some medicines that companies are

¹⁸ Productivity Commission (2008) *Annual Review of Regulatory Burden: Manufacturing and Distributive Trades* p80.

seeking to have listed, Medicines Australia does believe that increasing the threshold will not cost the Government any additional money. For example, Medicines Australia is not aware of any medicines in the \$10 million to \$20 million cost range where Cabinet has rejected listing a medicine on the PBS. It is therefore unlikely that increasing the threshold to \$20 million would lead to increased Government spending.

Medicines Australia Recommends that the Government:

- **Increase the threshold at which Cabinet approval is required for the listing of a medicine on the PBS from the current \$10million to \$35million, and index future adjustments to reflect economy-wide prices**

Unintended Consequences of Legislation

Patient Premiums

The PBS Reform legislation contains provisions, opposed by Medicines Australia, which restrict the ability of a sponsor to adjust “premiums” on some medicines. Specifically, the legislation prevents sponsors from adjusting premiums on the same day as a statutory price reduction takes effect (whether due to mandatory or price disclosure price reductions). The legislation also ensures that the existing patient premium is reduced by a factor proportionate to the price reduction.

At the time, the reason for including such provisions in the legislation was to ensure that sponsors did not increase patient premiums to compensate for the lower reimbursed price. The intention was thus to protect consumers from higher out of pocket costs.

The provisions however also prevent sponsors from removing or lowering patient premiums on the same day. One way that companies seek to counteract a price reduction in a competitive market is to position their medicine in such a way to increase volume of sales. When a patient premium is a barrier to this, companies will seek to remove or lower it. The legislation introduced regulatory barriers and time delays preventing sponsors from doing this with the consequence being that patients could bear higher out-of-pocket costs where they otherwise would not. Such regulatory barriers can also constrain competition in the generics market, thereby potentially leading to higher prices in the generics market.

Medicines Australia recommends that the measures implemented as part of PBS reform restricting changes to patient premiums be removed as it results in higher than intended prices to patients for their chosen brand of medicine.

Medicines Australia Recommends that the Government:

- **work with industry to review the restrictions on removing or lowering patient premiums at the same time as a legislated price reduction so companies can pass on lower prices to patients.**

Exemptions to legislated price Reductions

The PBS reforms contained provisions to ensure that small numbers of vulnerable patients in a unique sub-population, such as children and the elderly, continue to have access to necessary medicines. This provision is noted in Section 84AH of the National Health Act 1953 (Appendix B) and ensures that low volume single branded medicines continue to be available to these unique sub-populations.

Currently, there are 45 medicines for the treatment of specific unique sub-populations that are exempt from statutory F2 price reductions.

Industry was of the understanding prior to implementation of the PBS reforms that multiple strengths of a single brand formulation could be exempt from statutory price reductions. Certainly industry believed this is the intent of the provision. However, during implementation, a review of the exemption criteria and list was undertaken by the Department of Health and Ageing, resulting in some strengths of a medicine treating the same unique sub-population being deemed not to comply with the exemption criteria.

As a result of the Department of Health and Ageing's review multiple strengths of two medicines were forced to take the prescribed mandatory price reductions even though they did not have any other brands listed on the PBS. Consequently, two companies elected to delist one strength of the affected medicines from the PBS in order to keep exemption status for that medicine.

Six molecules were affected by the review of the criteria for exempt medicines. Consequently, the following medicines were delisted from the PBS:

- *Cyclosporin 250mg in 5 ml – used as an immunosuppressant for organ transplant treatment; and*
- *Baclofen 10mg in 5 ml – for the treatment of muscle spasticity where oral treatment is ineffective.*

The unintended consequence of this policy was decreased patient choice, and the inability for a doctor to appropriately prescribe a dose that is suitable for the patient.

The current exemption arrangements are inconsistent with the intent of the original exemption measure. In fact, it has reduced access to appropriate strengths of medicines for patients in these sub-populations.

The current criterion disregards quality use of medicine principles particularly concerning the individual administration of appropriate strengths of medicines. Indeed, the current exemption arrangements work to increase the risk of an adverse outcome, as many patients are now forced to purchase a strength of medicine that may be inappropriate for their condition.

They also force many patients to pay full price for the appropriate strength of medicine on the private prescription market.

Medicines Australia urges that the exemption measures be reviewed and altered to allow multiple strengths of a single branded medicine identified for treatment of a unique

sub-population to be exempt from price reductions. Otherwise, unique sub-populations, such as children and the elderly, will potentially miss out on treatment options they require.

Medicines Australia Recommends that the Government:

- **work with industry to review the s84AH exemption arrangements to permit the listing of multiple strengths of a single branded medicine formulations to ensure continued access of these medicines to treat small unique sub-populations (as originally intended).**

Patients have Benefited from PBS Reform Overall

Key beneficiaries of the PBS reform include Australian patients and there are a number of reasons for this.

Firstly, the PBS reforms will enable future Australian governments to continue subsidising new innovative medicines on the PBS whilst further bolstering an already highly efficient and financially sustainable scheme. This means that Australians will have affordable access to the range of new therapies being developed by the pharmaceutical industry now and in the future.

Whether Australians ultimately benefit from PBS reform in this way depends in part on whether system improvements to listing new medicines are implemented and the extent to which future Australian governments are prepared to fund new medicines, even though PBS reform has made this financially sustainable in its own right.

Secondly, patients will also benefit from PBS reforms through lower medicine prices. CSES estimates that the direct savings to patients will be \$420 million over 10 years (2008-09 to 2017-18).

As more PBS listed medicines patents expire in the future, patients will benefit from the price reductions that result from multi-brand competition. IMS data indicates that \$120 billion worth of medicines will lose patent protection and be subject to brand competition within the next 5 years. PBS reform will allow these significant savings to be fully realised by patients and the taxpayer over the coming years.

Despite concerns expressed at the time PBS reform was introduced, patients have not seen an increase in patient premiums charged by pharmaceutical companies over and above the PBS patient co-payment. However, as noted above, patients have been disadvantaged by the inability of a company to remove or lower a patient premium at the time of a mandatory or price disclosure price reduction.

In addition, Medicines Australia is aware that patients in some patient sub groups have missed out on receiving subsidised access to multiple strengths of some medicines due to the Government's interpretation of Section 84AH.

Companies, many of which are sole suppliers for some of these medicines have been forced to de-list some strengths of special formulations to ensure those products do not undergo PBS price cuts.

PBS reform is delivering a more competitive generics market

One of the policy objectives of PBS reform was to provide for a more competitive generics market to facilitate more competitive generic pricing in Australia. The Government has noted that the price of Australia's generic medicines has been too high by international standards¹⁹ and Australian taxpayers, through the PBS, were paying too much for older generic medicines.

The PBS reform package introduced price disclosure to the PBS to lower the price paid by government for off-patent medicines on the PBS and it was industry's understanding that it would require 3-4 years to fully effect the price disclosure arrangements. This provided a transition phase (2008 - 2011) allowing sponsors to adapt to the new model.

The first three rounds of price disclosure price reductions have been calculated and is estimated to save government \$102 million from 2009-10 to 2012-13 through the government adjusting the PBS reimbursed price to reflect the 'actual market price'. Importantly, these measures did not impede the critical market principles of competitive neutrality: all manufacturers were equally affected.

We have also seen evidence of increased competition in the 'generics' market with the percentage of medicines dispensed at the benchmark price increasing steadily since the late 1990s. However, PBS reforms seem to be enhancing this trend, with 'premium free' prescriptions increasing from 68% of the total generics market prior to PBS reform (2007-08) to 74% post PBS reform implementation (2008-09) (Figure 3).

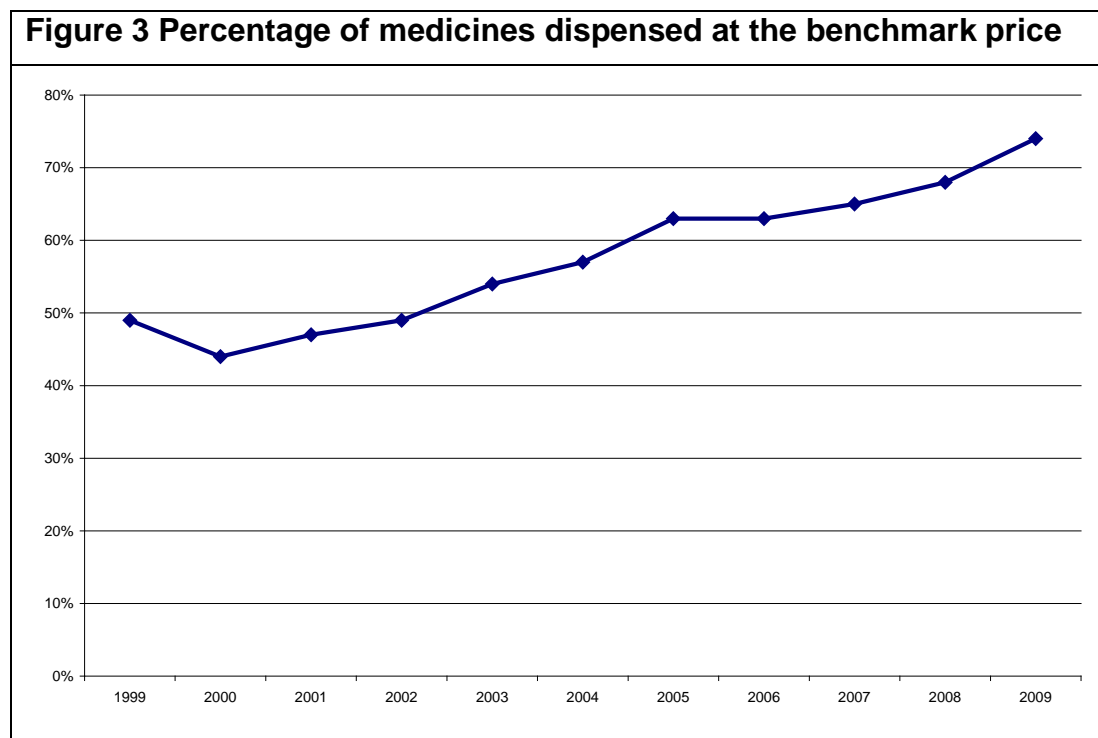
There is also a belief that the generic companies' share of the off-patent medicine market is small. However, the figure usually quoted is the generic market share of the total PBS, which in 2007-08 was 17.6% by expenditure and 34.7% by volume. However, as the generic medicines industry can only compete in the off-patent medicine market (or the F2 formulary on the PBS), it is more appropriate to review market share of the generic medicines industry in this market only. In 2007-08, the generic companies' market share of F2 medicines by value was over 41% and over 48% of prescription volume.

Although the PBS reform package did not include specific incentives to encourage the augmentation of generic's market share, trends indicate that the percentage of medicines dispensed at the benchmark price has been steadily increasing for a number of years.

The forthcoming expiration of numerous patents, and the increase in the number of generic companies which these expirations will continue to facilitate, provides ample scope for the expansion of the generic's market share. Given these trends, and the

¹⁹ Pharmaceutical Benefits Pricing Authority. *Annual Report for the Year ended 30 June 2008*, p17, <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-pricing-pbparpt.htm>, [Accessed 16 November 2009]

importance of preserving competitive neutrality in the Australian off-patent market, it is not desirable or appropriate for any additional policy measures that work to generate greater market share for generic manufacturers.



Medicines Australia Recommends that the Government:

- **should not introduce any additional policy measures to direct market share for generics companies in the off patent market so that a competitive off-patent market is maintained.**

Conclusion

The PBS reform will bolster an already sustainable and efficient PBS, delivering savings to Government of \$6 billion dollars from 2008-09 to 2017-18. (double the \$3 billion the Government estimated in 2006).

Patients will benefit from lower medicine prices and continued listing of new innovative medicines as a result of PBS reform.

However, patient access to new and innovative medicines is contingent on the Government ensuring that PBS reform measures such as the price disclosure arrangements are administered efficiently and accurately.

The PBS reforms must work to preserve business certainty and predictability if the Australian innovative pharmaceutical industry is to continue listing new and innovative

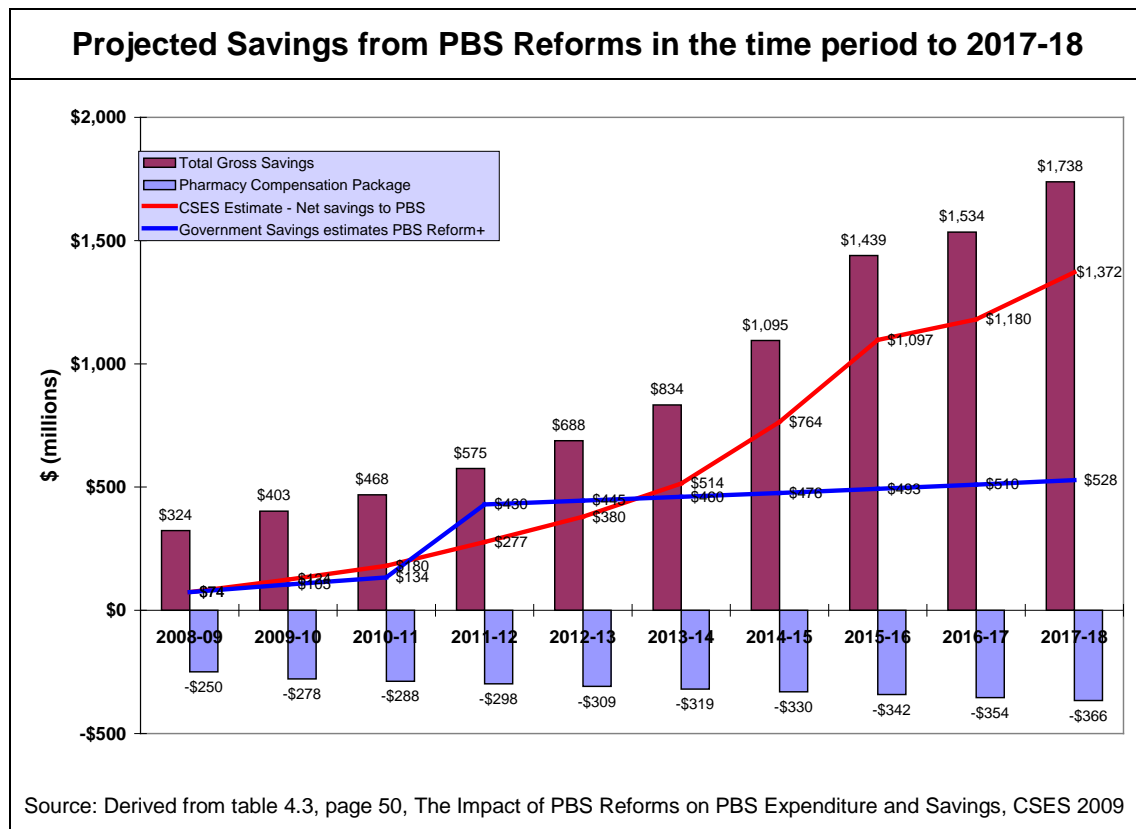
medicines in the future. The abandonment of the TGP policy would go a long way to providing this necessary certainty

Government needs to continue to work with the innovative industry to ensure that the PBS listing process is robust, transparent and efficient as this will allow for the timely access to new innovative medicines for all Australians.

Appendix A – The Impact of PBS Reforms on PBS Expenditure and Savings – Centre for Strategic Economic Studies, Victoria University – Summary

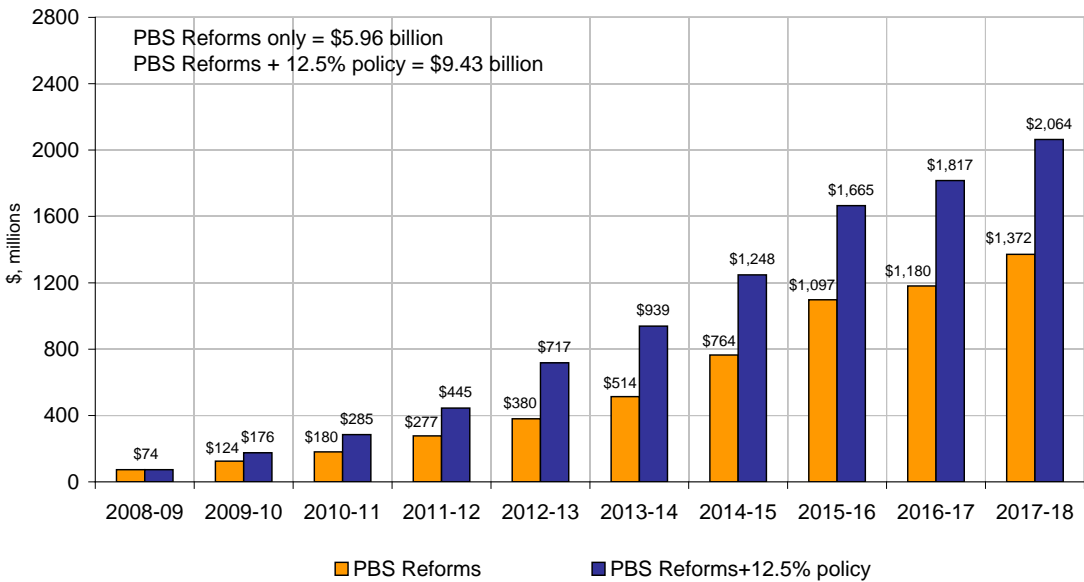
In March 2009 Medicines Australia commissioned the Victoria University Centre for Strategic Economic Studies (CSES) to analyse the impact of PBS reform measures since their implementation. CSES was asked to analyse the trends in overall PBS expenditure and to report on how reforms have affected stakeholders, namely, Government, pharmacists, wholesalers, manufactures and patients. The commissioned report was to also include modelling of the potential impact of the PBS price disclosure mechanism

When the introduction of the PBS reforms was announced in 2006, the then Government estimated that these reforms would save the Government \$3 billion over 10 years. However, the CSES report projects that these original estimates were conservative and that in fact, PBS reforms is projected to save the Australian Government nearly \$6 billion in the 10 years from 2008-09 to 2017-18 - \$3 billion of which is projected to come from price disclosure price reductions.



Furthermore, the CSES report projects that when savings facilitated by PBS reforms are combined with those facilitated by the 12.5% policy, the overall savings to Government over the 10 years from 2008-09 to 2017-18 will amount to \$9.4 billion.

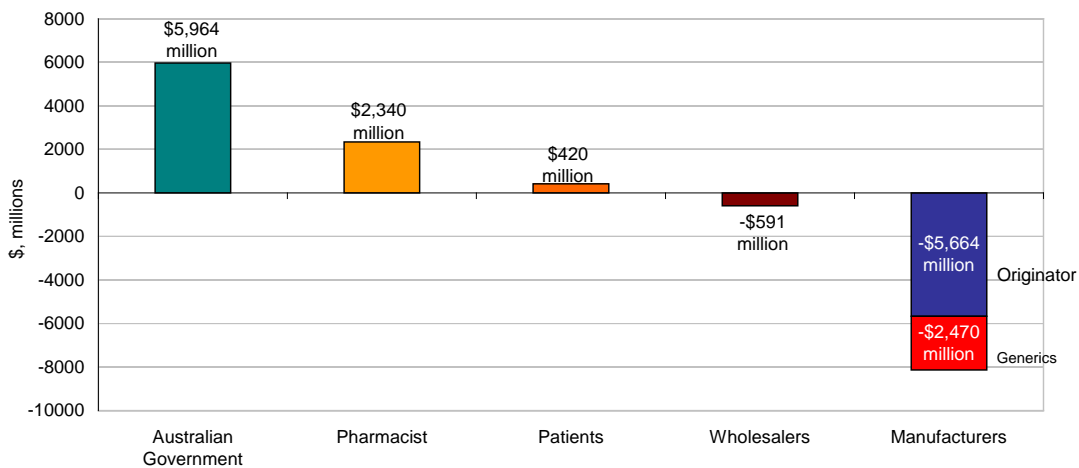
Net savings to Australian Government in the time period to 2017-18



Source: Derived from table 4.3, page 50, The Impact of PBS Reforms on PBS Expenditure and Savings, CSES 2009

The CSES report estimates that originator pharmaceutical companies are providing the bulk of savings from PBS reforms. Originator Companies are projected to provide \$5.7 billion worth of savings, generics companies \$2.4 billion and wholesalers \$591 million.

Impact of PBS Reforms on Stakeholders in the time period from 2008-09 to 2017-18



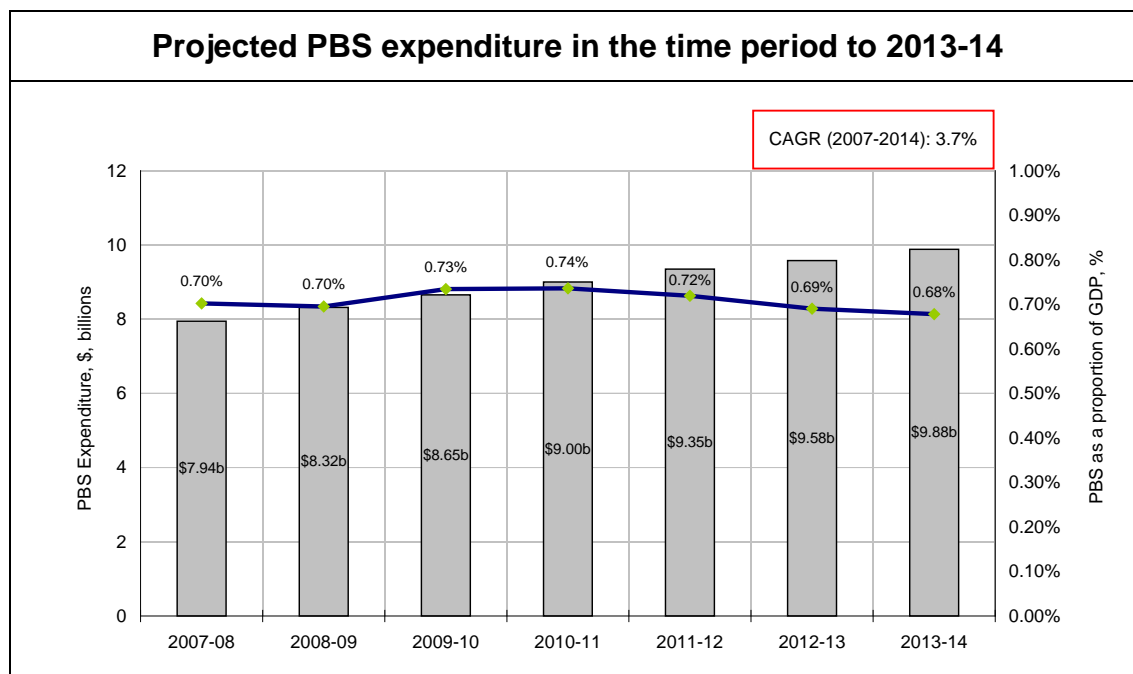
Source: Derived from table 4.3, page 50, The Impact of PBS Reforms on PBS Expenditure and Savings, CSES 2009

Based on the CSES report's projections it is clear there is no justification for the Government to target originator companies for more savings in the PBS. Originator companies have already absorbed huge losses in revenue in a bid to guarantee the future sustainability of the PBS and their ability to absorb further losses is limited. Indeed, any further cost savings measures that target originator companies will work to severely undermine the long-term sustainability of the innovative pharmaceutical industry in Australia.

PBS Sustainability

The CSES report projects that the combined impact of PBS reforms and the on-going 12.5% mandatory price cuts indicates that the sustainability of the PBS in the medium-term is not open to question.

CSES estimates that the PBS expenditure will remain between 0.6 – 0.7 percent of GDP in the time period to 2013-14 and anticipates its growth at a compounded annual rate of just over 3% per annum.



The fact PBS reforms did not deliver substantial savings in the first years following implementation was to be expected given the way the reform package was structured. CSES modelling shows that in the first years before the full impact of price reductions in the generic market were realised, the pharmacy structural adjustment package works to offset the savings obtained from manufacturers.

A copy of the CSES report can be found at:
<http://www.medicinesaustralia.com.au/pages/images/The-impact-of-PBS-reforms-on-PBS-expenditure-and%20savings.pdf>

Appendix B – Section 84AH of the National Health Act 1953²⁰

84AH Exempt items

The Minister may, by legislative instrument, determine that a pharmaceutical item (the **relevant item**) is an **exempt item** if:

- (a) there is only one listed brand of the relevant item; and
- (b) there are no listed brands of other pharmaceutical items that are bioequivalent or biosimilar to the listed brand of the relevant item; and
- (c) the relevant item and at least one listed brand of another pharmaceutical item have the same drug; and
- (d) the Minister is satisfied, having regard to advice (if any) given to the Minister by the Pharmaceutical Benefits Advisory Committee (whether before or after the commencement of this section), that:
 - (i) the listed drug in the relevant item represents suitable therapy for a particular patient population; and
 - (ii) the relevant item is suitable for use by a particular subgroup of that population because of either or both of the form and manner of administration of the drug in the item; and
 - (iii) no other pharmaceutical item that has that drug is suitable for use by that subgroup because of either or both of the form and manner of administration of the drug in that other item.

²⁰ P164 National Health Act 1953, Act No.95 of 1953 as amended 1 January 2009