COMMUNITY AFFAIRS
LEGISLATION COMMITTEE

INQUIRY INTO:
NATIONAL HEALTH AMENDMENT (PHARMACEUTICAL BENEFITS SCHEME) BILL 2010

SUBMISSION OF THE
DEPARTMENT OF HEALTH AND AGEING
22 OCTOBER 2010

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Terms of Reference

On 30 September 2010, the Senate, on recommendation of the Selection of Bills Committee, referred the provisions of the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 (the Bill) to the Community Affairs Legislation Committee for inquiry and report by 16 November 2010.

1. Overview of the Amendments

The National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 (the Bill) sets out changes to the Pharmaceutical Benefits Scheme (PBS) pricing mechanisms aimed at contributing to the sustainability of the PBS, maintaining access to quality medicines at a lower cost to the taxpayer, cutting red tape, and providing certainty to the pharmaceutical industry (industry) in relation to PBS pricing policy. The further PBS reforms will deliver savings of almost $1.9 billion for the next five years.

The reforms build on the 2007 PBS reform package of pricing policies by preserving the distinction between F1 formulary (for single brand drugs that do not have competitors, usually because the drugs are still under patent) and F2 formulary (for multiple brand medicines subject to competition), and by retaining the concepts of statutory price reductions and price disclosure.

The Bill:

- Accelerates and expands the application of price disclosure to all medicines on the formulary (F2). This means that the Government will be better able to share in the benefits of existing competition between pharmaceutical companies.
- Produces further price reductions:
    - All medicines on F2 will experience a price reduction of two or five per cent on 1 February 2011.
    - The price reduction that occurs when the first new brand of a PBS medicine is listed will increase from the current 12.5 per cent, to 16 per cent as of 1 February 2011.
- Streamlines the way drugs are listed, particularly for supply under section 100 arrangements.
- Addresses gaps in the current PBS prescription data captured by Medicare Australia by enabling the collection of prescription data for medicines whose price is below the general patient co-payment.

There has been consultation with industry on the implementation of the elements of the Bill through a consultative working group which comprises members from each sector of industry.

Under the Bill, consumers will pay no more for their medicines, and some may pay less as prices of some medicines fall below the level of the general patient co-payment. Choice of medicines and brands will continue to be available, unaffected. Nothing in the Bill impinges on the clinical judgment of the treating doctor in prescribing appropriate medicine. Medical practitioners will continue to be able to prescribe medicines that are clinically appropriate.

Due to the recent Federal Election, and the extended caretaker period, the commencement date for price disclosure, originally 1 October 2010, has been delayed to 1 December 2010. However, savings will still be delivered as per schedule by making minor adjustments to the operation of price disclosure such as reducing the 2011 cycle to 10 months.

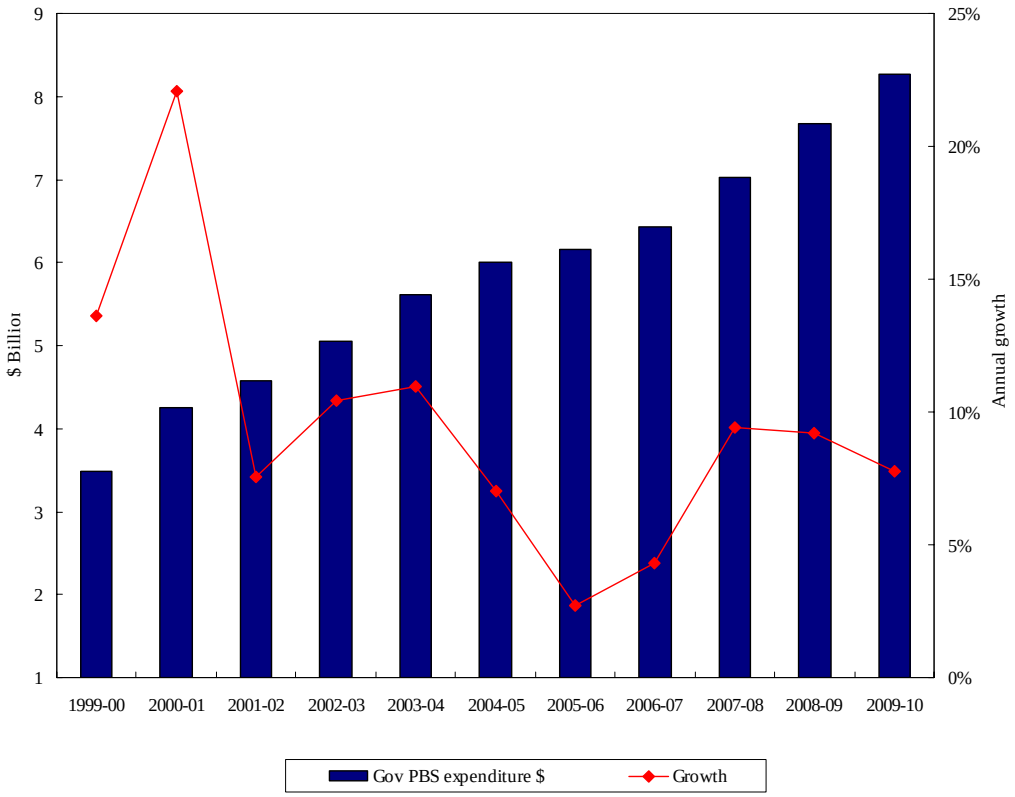
2. Overview of the Pharmaceutical Benefits Scheme

The PBS provides the Australian community with reliable, timely and affordable access to over 760 drugs available in more than 1,900 forms, and marketed as over 3,745 brands. In 2009-10, around 184 million PBS-subsidised prescriptions were dispensed at a cost of over $8.4 billion, representing approximately 15 per cent of the Health and Ageing portfolio budget.[1]

The listing of new drugs on the PBS is based on the recommendation of the Pharmaceutical Benefits Advisory Committee (PBAC) which takes into account the medical conditions for which the medicine was registered for use in Australia and its clinical effectiveness, safety and cost effectiveness compared with existing treatments. Further, before listing on the PBS, the Pharmaceutical Benefits Pricing Authority also considers the price at which a drug could be listed.

As Figure 1 below demonstrates, the cost of the PBS has continued to grow over the past ten years, averaging growth of 9.1 per cent. In 2008-09 the cost of the PBS was 9.2 per cent higher than that in 2007-08, and in 2009-10, the PBS grew a further 9.3 per cent to an annual cost of $8.4 billion.

Figure 1: Government PBS expenditure growth: 1999-2000 to 2009-10



Source: Department of Health and Ageing, Expenditure and prescriptions 12 months to 30 June 2009.

[1] Department of Health and Ageing *2008/09 Annual Report*

This continued growth has been acknowledged by the 2010 Intergenerational Report (IGR), *Australia to 2050: Future Challenges* which forecasts that spending on the PBS will increase in real terms from $443 per capita in 2012-13 to $534 per capita in 2022-23. Expenditure on the PBS will remain a steady proportion of total GDP in the medium term, 0.7 per cent to 2019-20.

PBS growth is mainly driven by growing demand and the listing of new higher cost medicines. The continuing trend of clinicians to prescribe newer, more expensive medicines is illustrated by the fact that the PBS prescription volume was 183.9 million scripts in 2009-10, an increase of 1.1 per cent on 2008-09. At the same time, the cost to the government of the PBS increased by 9.3 per cent.

Current projections for PBS expenditure are for continued steady growth beyond the forward estimates period. The February 2010 *Impact of PBS Reform* report to Parliament estimated that on current projections, PBS outlays in 2018 would be in the order of $13 billion to $13.7 billion.

Due to this continuing growth in the cost of the PBS, successive governments have sought to find efficiencies in the pricing of those PBS medicines which are subject to competition from a number of suppliers in order to ensure the sustainability of the PBS in the future.

Finding efficiencies in PBS pricing also allows for continued investment in new, innovative drugs. For example, some major new PBS listings during 2008 and 2009 (that is, drugs with an additional expenditure estimated to exceed $10 million per annum in any of the first four years of listing) are set out in Table 1.

Table 1: Recent major new listings on the PBS

Medicine	To treat	Projected Cost to Government during first four years after listing
Varenicline	Smoking cessation	$76.3 million
Cinacalecet	Secondary hyperparathyroidism	$165.9 million
Natalizumab	Relapsing-remitting multiple sclerosis	$358.3 million
Adalimumab	Crohn disease	$131.8 million
Clopidogrel	Acute coronary syndrome	$74.7 million
Posaconazole	Prophylaxis and treatment of invasive fungal infections	$39.1 million
Sunitinib	Renal cell carcinoma	$131.0 million
Bevacizumab	Colorectal cancer	$314.0 million
Lenalidomide	Multiple myeloma	$104.0 million
Total		**$1,395.1 million**

This increased investment in new drugs not only provides the Australian community with affordable access to medicines that deliver improved health outcomes, but it also continues to demonstrate support for the Australian pharmaceutical industry. Maintaining a responsible and viable medicines industry is one of the four objectives of the National Medicine's Policy.

However, this level of investment in new therapies can only be sustained if measures are also undertaken to optimise the efficiency of the PBS for drugs where multiple suppliers compete in the marketplace.

The measures proposed in the Bill are in line with other efficiency initiatives that have been implemented over the past thirteen years to help ensure the long term sustainability of the PBS. Major initiatives implemented in that time include:

- formation of therapeutic groups and introduction of the therapeutic groups pricing policy (1997);
- increased focus on pricing medicines in specified groups by reference to the weighted average monthly treatment cost methodology;
- administrative 12.5 per cent price reduction policy - applied when the first new brand of an already PBS listed medicine is listed on the PBS (2005); and
- the PBS pricing reform measures (2007).

2007 PBS Pricing Reform

The reform of the Pharmaceutical Benefits Scheme (PBS) announced in 2006 resulted in the restructuring of the PBS Schedule into separate formularies on 1 August 2007. The goal of this restructuring was to recognise the different market circumstances within which single brand and multiple brand medicines are sold, and to enable more effective targeting of savings measures while ensuring continued patient access to medicines.

The two formularies are:

- Formulary 1 (F1), for single brand drugs that do not have competitors (usually because the drugs are still under patent); and
- Formulary 2 (F2), for multiple brand drugs subject to competition, either because they have competing brands or fall within a 'therapeutic group' of drugs that are considered interchangeable at the patient level (within these groups, in the vast majority of cases, patients can move from one drug in the group to another without any clinical or financial impact). Up to 1 January 2011, the F2 formulary is further split into F2A and F2T on the basis of the level of competition and discounting to pharmacies.

A drug on F1 moves to F2 when a second brand of the drug is listed on the PBS that is bioequivalent or biosimilar to the existing brand.

Under the 2007 PBS reform, a series of price reductions were mandated by the *National Health Act 1953*:

- a 12.5 per cent price reduction for a medicine when the first new brand of a competitor for that medicine is listed on the PBS (typically on patent expiry);
- a 25 per cent price reduction for medicines on F2T from 1 August 2008; and
- three annual two per cent price reductions for medicines on F2A from 1 August 2008.

Price disclosure recognises that there is significant discounting of the off patent medicines in Australia. Pharmaceutical companies give discounts to pharmacists to get them to stock their items over their competitors' items. Price disclosure takes a share of these discounts for the taxpayer and the patients. Under this policy, the price the government pays for PBS medicines will move closer to the actual price at which those medicines are supplied to the market.

Under the 2007 PBS pricing reforms, any new brand listed on or after 1 August 2007 is subject to mandatory price disclosure requirements if it is bioequivalent to an existing brand unless the medicine is on F2T. The manufacturers of new brands are required to provide information about the price at which they sell their brand/s to the market. The Government then adjusts PBS prices to the weighted average market price being paid for these medicines. By reducing the Government price to the average and not the lowest, price disclosure leaves room for further discounting by efficient providers. In this way it follows the market rather than setting it.

These arrangements have the dual benefits of basing price reductions on market dynamics, as well as returning to taxpayers the difference between PBS prices and the prices at which suppliers actually sell.

The objective of the 2007 PBS pricing reforms was to ensure that payments for medicines are made at the best available price, without interfering with the clinical relationship between prescribers and patients. Throughout the implementation of pricing reforms introduced since 1997, prescribers have been able to continue prescribing whichever medicines are most appropriate for their patients.

It is those same objectives that underpin this further PBS pricing reform, which represents only an extension, not a change, to existing policy.

3. The Need for Further PBS Pricing Reform

Report on the Impact of 2007 PBS Pricing Reforms

The Report, *The Impact of PBS Reform,* was presented to the Parliament on 9 February 2010.

Impact to July 2009

The Report estimated that the overall impact on patients from the PBS reform has been limited. The combined impact of the 25 per cent and the first two per cent price reductions and changed mark-ups and dispensing fees, have resulted in some PBS items decreasing in price, and others increasing:

- 398 PBS items decreased in cost to general patients – the average decrease was $1.92;
- 688 PBS items increased in cost to general patients – the average increase was $0.64;
- 1,122 PBS items did not change in price to general patients; and
- the average price change across the PBS was a decrease of $0.15.

The total estimated savings in PBS outlays from statutory price reductions in 2008-09 was $274 million ($263 million from F2T and $11 million from F2A). This is based on prescription volumes and assumes all else remains equal.

The structural adjustment package provided $343.3 million to pharmacy (to July 2009):

- $145.5 million through the PBS Online incentive (40c per on line script);
- $102.4 million in premium free dispensing incentives ($1.50 per script indexed);
- $73.4 million as a result of the changes to dispensing fees and mark-ups;
- $22 million was paid to wholesalers to support the Community Service Obligation (CSO).

Long term impacts of reform

It was originally anticipated that the 2007 PBS reform package would save $3 billion for the period 2008-09 to 2017-18. However, independent estimates put the savings to government in a range of $3.6 to $5.8 billion, with price disclosure contributing from $2.2 to $4.4 billion. Consumers are anticipated to pay from $0.6 to $0.8 billion less in co-payments.

While the 2007 PBS reforms are anticipated to provide more savings than originally estimated, these will be more than outweighed by higher than expected growth in PBS costs. The February 2010 *Impact of PBS Reform* Report to Government stated that on current projections, PBS outlays in 2018 will be in the order of $13 billion to $13.7 billion.

This is acknowledged to place the health budget under increasing pressure over time. As a result, the report concludes that a 'responsible Government must keep such a large and growing program under constant review'.

4. The National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010

The National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 (the Bill) proposes to achieve a more efficient and sustainable PBS, better value for money for Australian taxpayers, and policy stability for the pharmaceutical sector. The Bill will both expand and bring forward the changes made under the 2007 PBS pricing reforms.

The proposed pricing measures are consistent with and build upon the architecture of the 2007 PBS reform package of pricing policies, which were designed to recognise the significant competitive pricing that already exists in the market for many PBS subsidised medicines. The objective of both 2007 and 2010 reforms reflect that Australian taxpayers should benefit from that competition and the lower prices that result.

The Bill also embodies cooperation and collaboration between the government and the pharmaceutical industry represented by Medicines Australia. This is consistent with the National Medicines Policy objectives for government and industry to be partners in ensuring value for money.

Elements of the Bill

The key elements of the Bill are:

Schedule 1 – Increasing the 12.5 per cent price reduction to 16 per cent
Schedule 2 – One-off two per cent and five per cent price reductions
Schedule 3 – Bringing forward the merging of Part A and Part T of F2
Schedule 4 – Expanded and accelerated price disclosure
Schedule 5 – Collection of under co-payment data
Schedule 6 – Special arrangements

The pricing reform elements of the Bill (Schedule 1 to 4) form an interconnected package that will assist the sustainability of the PBS in the future and assist in funding of other health priorities and new innovative medicines.

Pricing Arrangements under the Bill – Schedules 1 to 4

Schedule 1 – Increasing the 12.5 per cent price reduction to 16 per cent

The price reduction that occurs when the first new brand of a PBS medicine is listed will increase from the current 12.5 per cent to 16 per cent as of 1 February 2011. Medicines that have already taken a 12.5 per cent price reduction will not be required to take the balance of the 16 per cent price reduction.

Schedule 2 – One-off two per cent and five per cent price reductions

All medicines on the F2 formulary will experience a price reduction of two or five per cent on 1 February 2011. The level of price reduction for each medicine reflects the level of discounting the medicine has been experiencing in the market. Medicines that were on F2A as of 11 October 2010 will take a two per cent reduction and medicines on F2T a five per cent reduction. The reductions will not apply to exempt items under section 84AH of the Act.

On 1 February 2011, a two per cent price reduction will be applied to all non-exempt medicines containing drugs listed on the F2A formulary as at 11 October 2010. This is in addition to the two per cent price reduction which occurred on 1 August 2010.

Having the relevant date for formulary allocation as 11 October 2010 provides certainty on the formulary allocation three and a half months in advance of the reduction day, facilitating notice and correspondence between the Department and affected companies in accordance with previously applied timeframes for similar statutory price reductions.

All advice provided by the Department on these statutory price reductions will note that the final application of price reductions will be subject to passage of the legislation.

Where a 12.5 per cent new brand price reduction has been applied to an F2A drug on 1 December 2010, the February 2011 two per cent statutory price reduction would not apply. This is consistent with existing policy.

Also on 1 February 2011, a five per cent price reduction will be applied to all non-exempt medicines containing drugs listed on F2T as at 11 October 2010. Single-brand on-patent drugs listed on F2T that are subject to staged 25 per cent price reductions will have this five per cent price reduction applied as if the full 25 per cent price reduction has already been applied. The Bill will also apply the remaining staged statutory price reductions even if these drugs experience a mandatory price disclosure price reduction.

Schedule 3 – Merging of Part A and Part T of F2

The F2 formulary was established in 2007 and was separated into F2A (containing drugs subject to low levels of competition) and F2T (high levels of competition). The placement of drugs in each Part was a temporary measure based on market factors relevant at that time.

The proposed amendments will bring forward the date for the merging of the F2 formulary from 1 January 2011 to 1 December 2010.

Schedule 4 – Price disclosure

Under the 2007 PBS pricing reforms pharmaceutical suppliers were required to advise the Department of the price at which PBS medicines are sold into pharmacies, but only as part of

listing in the F2A formulary a new brand of the existing PBS item (drugs in the F2T have not yet been subject to price disclosure). All other manufacturers of brands of that PBS item can supply price information on a voluntary basis.

Under this Bill the application of price disclosure will be accelerated and expanded to include all drugs in the F2 formulary, and the disclosure of pricing information will be mandatory for all non-exempt pharmaceutical items containing drugs listed on the F2 formulary as at 1 December 2010. This will increase the number of drugs subject to price disclosure from 40 drugs[2] reported at Budget [3] to approximately 220 drugs [4].

The first disclosure reporting period for these brands will be a period of ten months from 1 December 2010 to 30 September 2011. A further period of six months is allowed for data analysis and notification.

The total period for a price disclosure cycle will be condensed from two years to 18 months. This will comprise a data collection period of 12 months and a combined data analysis and notification period of six months.

The Bill provides that for the main cycle commencing on 1 December 2010 only, an overall price reduction of at least 23 per cent is to be achieved across all the medicines in that cycle. It does not mean that each individual drug will subject to a 23 percent price reduction. What is guaranteed is that across all of the F2 medicines in that cycle there will be an on average 23 per cent price reduction. In practice this means that some medicines will take a smaller price reduction (possibly zero) and some will take a larger price reduction. These price reductions will occur on 1 April 2012.

If the average price reduction is greater than 23 per cent then there will be no further adjustment to the calculated price reduction for any F2 medicine. In the event that the overall 23 per cent price reduction is not initially achieved, prices will be further reduced to achieve the required 23 per cent reduction overall. Prices will not be reduced below the lowest disclosed price, that is, below the lowest price at which a brand of medicine is offered for sale, based on information collected from industry. The price of medicines with average discounting of less than 10 per cent will not be affected by price disclosure, in line with current arrangements.
Price disclosure price reductions will be independently validated, with calculations and quality assurance undertaken by a third party (or parties) commissioned by the Department.

In recognition of some of the learnings developed from the introduction of price disclosure in 2007, which resulted in a three months delay, the administrative burden on industry from the expanded price disclosure arrangements will be limited by the format and type of data required being the same as the original price disclosure arrangements.

The Department has established a price disclosure working group with all sectors of the industry (Generic Medicines Industry Association (GMiA), Medicines Australia, National Pharmacy Services Association (representing pharmacy wholesalers) and AusBiotech to discuss any administrative issues that may arise from the new arrangements. Site visits to individual companies were also undertaken by departmental officers to understand their reporting systems for price disclosure.

Whilst the proposed processes and administration of the extended and expanded price disclosure arrangements were based on the existing processes preferred by industry as part of

[2] Across 162 brands
[3] 45 drugs across 196 brands as of 1 October 2010
[4] Across over 1,600 brands

the 2007 reforms, feedback recently provided by the industry has resulted in some revisions as to how often data is provided for the purpose of calculating the weighted average disclosed price. This industry feedback is reflected in the regulations.

Price Disclosure to date

The new proposals in relation to price disclosure will build on the results of the application of price disclosure arrangements to date. The first four completed rounds of price disclosure have seen a number of drugs take a price reduction ranging from 13 per cent to 72 per cent. The resulting percentage price reductions from the first six rounds of price disclosure are provided below.

Table 2: The first six rounds of price disclosure

First Round – Price reduction on 1 December 2009

Drug	Weight average percentage reduction	Manner of Administration
Doxorubicin	63.54%	Solution for I.V injection or intravesical administration
Mitozantrone	34.42%	Injection
Ondansetron	15.37%	I.V injection

Second Round – Price reduction on 1 April 2010

Drug	Weight average percentage reduction	Manner of Administration
Fluconazole (oral)	55.26%	Capsule
Vancomycin	71.80%	Powder for Injection

Third Round – Price reduction on 1 April 2010

Drug	Weight average percentage reduction	Manner of Administration
Carvedilol	27.29%	Tablet

Fourth Round – Price reduction on 1 August 2010

Drug	Weight average percentage reduction	Manner of Administration
Cefalotin	41.13%	Powder for injection
Doxorubicin	34.62%	Doxorubicin hydrochloride
Meloxicam	17.99%	Tablet
		Capsule
Mitozantrone	13.33%	Injection
Ondansetron	17.61%	I.V. Injection

Fifth Round – Price reduction on 1 April 2011

Drug	Weighted Average Percentage Reduction	Manner of Administration
Alendronic Acid	22.96%	Tablet
Cisplatin	39.02%	I.V. Injection
Fluconazole	27.52%	Solution for I.V. Infusion
Fluconazole	38.48%	Capsule
Risperidone	17.37%	Tablet
Vancomycin	12.48%	Powder for Injection

Sixth Round – Price reduction on 1 April 2011

Drug	Weighted Average Percentage Discount	Manner of Administration
Carvedilol	11.90%	Tablet
Gemcitabine	37.00%	Powder for I.V. Infusion
Irinotecan	61.40%	I.V. Injection
Paclitaxel	52.58%	Solution concentrate for I.V. Infusion

Overall, the current price disclosure arrangements have resulted in some significant price reductions for those drugs that are subject to discounting in the supply chain.

International Comparison of Pharmaceutical Prices

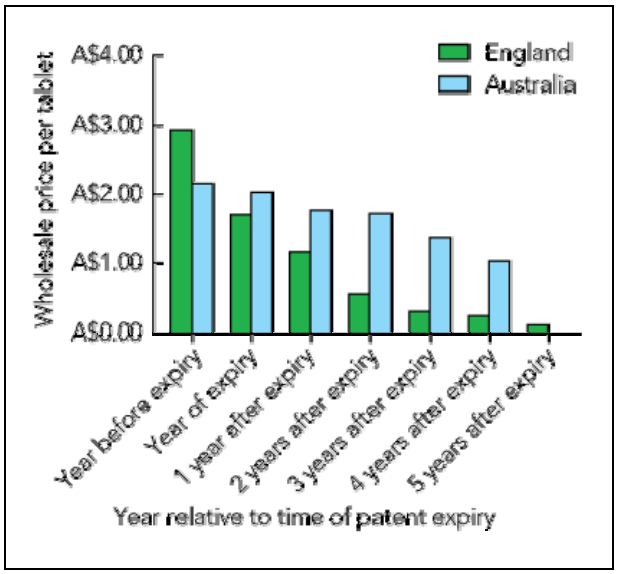
There is strong evidence that Australia continues to pay more for generic medicines than other countries.

Comparing Australian prices for common multiple brand drugs with those paid in other countries, such as the United Kingdom (UK), clearly illustrates that the Australian Government has been paying more for these drugs. For some commonly prescribed drugs that cost the PBS hundreds of millions of dollars per annum, the Australian price can be four times or more than that paid in the UK.[5]

[5] Clarke, P. and Fitzgerald, E. *Expiry of patent and protection on statins: effects on pharmaceutical expenditure in Australia* in The Medical Journal of Australia 7 June 2010

The high prices at which these drugs are reimbursed on the PBS has allowed a market to develop in which many suppliers of multiple brand drugs provide them to pharmacy at heavily discounted rates without benefit to taxpayers.

Table 3: Price of 40 mg simvastatin in Australia compared with England by year relative to patent expiry*



Source: Clarke, P. and Fitzgerald, E. *Expiry of patent and protection on statins: effects on pharmaceutical expenditure in Australia* in The Medical Journal of Australia 7 June 2010. *Price data for Australia were unavailable for 5 years after expiry.

It should be noted that prices in different markets reflect a large range of factors, from market size to distribution networks. There are also differences in product forms, strengths, and pack sizes that are available in different markets.

Projected savings from further pricing reforms

The projected savings generated from the combined package of further pricing reform are estimated to be some $1.9 billion over five years. Savings over the forward estimate period are provided in the table below.

Table 4: Savings from Schedule 1 to 4 in the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010

	2010-11 ($m)	2011-12 ($m)	2012-13 ($m)	2013-14 ($m)
Department of Veterans' Affairs	-2.0	-10.9	-29.0	-29.9
Department of Health and Ageing	-28.7	-180.2	-499.4	-517.2
Total	-30.7	-191.2	-528.4	-546.4

Source: Budget Paper No. 2 2010/11

Potential Impact of delay

Price disclosure is the significant savings measure under the Bill. The level of savings to be achieved through this package assumes the mandatory price disclosure cycle commencing on 1 December 2010 with the resulting price reductions occurring in April 2012.

This commencement date is later than the original date of 1 October 2010 announced in the 2010-11 Budget, but savings will still be delivered as per schedule by making minor adjustments to the operation of price disclosure such as reducing the first data collection period for the main cycle to 10 months.

This is data that companies already collect as part of their business operations, and whilst data is collected from 1 December, the first lot of data submissions does not have to occur until mid 2011.

Other arrangements under the Bill – Schedules 5 and 6

Schedule 5 – Collection of under co-payment data

The Bill contains provisions that will address gaps in the current PBS prescription data captured by Medicare Australia. Currently, community and hospital pharmacies supplying PBS medicines only provide data for PBS prescriptions for which the Commonwealth pays a subsidy. The changes being introduced will result in all data being captured.

The general patient co-payment is currently $33.30 and the concessional patient co-payment is $5.40. Where the price the Commonwealth pays (the Commonwealth price) is greater than the co-payment, the Commonwealth pays the difference. Where the Commonwealth price is less than, or equal to, the co-payment, the Commonwealth makes no payment. It is these under co-payment drugs for which the approved suppliers will now be required to provide information.

It has been proposed that the collection of this data will be through a modification of the community pharmacy software, resulting in no additional workload for the community pharmacy. Further, there will be no change to current processes relating to the Prescription Record Form, PBS Safety Net or PBS claiming.

No price information will be transmitted to Medicare Australia but all other information currently provided on subsidised prescriptions will be transmitted.

The collection of this data, together with all other PBS prescription data, will give the Pharmaceutical Benefits Advisory Committee (PBAC), the Department and other agencies a more complete picture and better understanding of PBS medicine prescribing, dispensing and usage. This change was agreed in the Fifth Community Pharmacy Agreement signed on 3 May 2010.

Any use or disclosure by the Commonwealth of under co-payment data will be in accordance with the *Privacy Act 1988* and the secrecy provisions of the *National Health Act 1953*. It is intended that the Privacy Commissioner's guidelines will be widened to include this new under co-payment information.

Schedule 6 – Special arrangements

Section 100 of the *National Health Act 1953* (s100) applies to certain specialised medicines with specific supply arrangements, including chemotherapy and HIV-AIDS medicines. The amendments will make clear how general PBS provisions apply to drugs supplied under those arrangements. The power to make special arrangements under s100 will also be clarified.

For example, measures introduced as part of the 2007 PBS reform apply to 'brands of pharmaceutical items' under Pt VII of the *National Health Act 1953*. However the current listings arrangements for section 100 medicines are unclear. The amendments will provide a clearer method for listing s100 drugs, resulting in s100 medicines coming within the concepts of a 'pharmaceutical benefit', a 'pharmaceutical item' and a 'listed drug'. The provisions of the Act will then apply to s100 medicines in a same way to all other PBS medicines.

The Bill will also confirm that s100 arrangements can be made to supply pharmaceutical benefits to persons receiving 'treatment', thereby modifying the existing expression 'medical treatment'. This will mean that medicines used in dental and optometrical treatment are clearly included.

Further changes will ensure that s100 arrangements can be made to supply pharmaceutical benefits where they can be more conveniently or efficiently supplied under the arrangement. As a result of these changes, pharmaceutical benefits may be supplied at a more efficient cost to the Commonwealth.

The Bill will not alter the PBAC's role in relation to the listing of drugs – that is, drugs may not be made generally available on the PBS, or available for supply only under a s100 arrangement, without a PBAC recommendation.

5. The Memorandum of Understanding

A Memorandum of Understanding (MoU) between the Commonwealth and Medicines Australia was originally signed on 6 May 2010 and was re-signed on 28 September 2010 to reflect the change in start date for price disclosure arrangements.

As the peak body of the innovator pharmaceutical industry, Medicines Australia is actively involved in the research, development, manufacture, supply and export of prescription medicines. Medicines Australia represents almost 60 per cent of the F2 formulary.

The MoU provides for a period of stable pricing policy for all suppliers (generic and innovator) in the market for the next four years. The further reforms to PBS pricing outlined in the MoU propose to expand and bring forward existing PBS pricing policy in operation since 2007.

Importantly, although the MoU was entered into with Medicines Australia, the further reforms proposed in the Bill do not provide a price or market advantage to either the generic sector or innovator companies when they are competing to sell the same off-patent medicines at the same approved price to pharmacists.

Other elements of the Memorandum of Understanding

The MoU outlines the savings measures for further PBS pricing reform contained in the Bill. As mentioned earlier, the savings measures recognise that competitive pricing already exists for medicines in the F2 formulary, and that the Australian taxpayer should be benefiting from that competition, in terms of lower prices, better choices and access to innovative treatments as they become available.

In addition to the further pricing reform measures, the MoU also contains other commitments which will provide stability and policy predictability for the pharmaceutical industry for the next four years, cut red tape, and ensure that new medicines can be listed on the PBS as quickly as possible.

The MoU includes an undertaking not to introduce any new policies that generate price-related savings over the four-year period, providing pricing certainty to the industry. This includes a commitment not to form any new Therapeutic Groups (a price saving measure in which a number of similar acting drugs are priced at the cost of the cheapest one in that group) during the life of the agreement. An exception acknowledged in the MoU is where the Commonwealth believes that a manufacturer is seeking to list a minor variation of one of its already listed drugs, and where the PBAC forms a view that the new drug offers no meaningful clinical advantage over the existing drug.

Under the MoU, as of 1 January 2011, industry will be able to 'parallel process' their submissions to the Therapeutic Goods Administration and the PBAC with PBS listing potentially available as soon as the TGA approval is received.

The MoU also supports a Managed Entry Scheme for submissions to the PBAC. From 1 January 2011, the Commonwealth will introduce a mechanism in certain circumstances for the PBAC to recommend PBS coverage at a price justified by the existing evidence, pending submission of more detailed evidence of cost-effectiveness to support listing of a drug at a higher price.

The Department and Medicines Australia will also undertake to jointly monitor trends in, and the drivers of, PBS expenditure through the Access to Medicines Working Group. Medicines Australia has also undertaken to establish a mechanism for 'horizon scanning' by 1 January 2011, with the purpose of gauging the likely impact on the work of the PBAC and on expenditure through the PBS, of drugs in respect of which PBS listing likely to be sought in the future.

Finally, under the MOU the Government will use its best endeavors to improve the timetable for medicines recommended for listing on the PBS, in particular aiming to have Cabinet consideration of a drug within six months of a price being negotiated.

6. Consultation

In developing the measures contained in the Bill, extensive consultations were held with the Australian pharmaceutical manufacturing industry and the Pharmacy Guild of Australia.

There are two major representative bodies for Australian pharmaceutical manufacturers: Medicines Australia which represents innovator manufacturers; and Generic Medicines Industry Association (GMiA) which represent the major generic manufacturers. The Department approached both Medicines Australia and GMiA in November 2009 to seek their views on possible future reforms to the PBS.

Medicines Australia represents over 50 member companies that account for around 85 per cent of the total cost of PBS medicines, and nearly 60 per cent of the value of F2 (generally off-patent) medicines annually. GMiA represents five generic manufacturers that account for 34 per cent of the value of F2 medicines.

As part of consultations for the development of further PBS reforms, both Medicines Australia and GMiA were asked to provide proposals for consideration. Discussions with Medicines Australia proved to be very fruitful and the matters being agreed with Medicines Australia were ultimately given expression in a MoU which was signed on 6 May 2010.

Since the Budget announcement of these measures the Department has continued to engage on the implementation of the program with GMiA, Medicines Australia and wholesalers via the Price Disclosure Working Group. Further information is provided on this under 'Ongoing Consultation'.

Consultation with GMiA

The issue of consultation with GMiA has been publicly raised. GMiA had a number of opportunities to discuss options for reform to the PBS, including with senior officials of the Department of Health and Ageing since November 2009 and prior to the Budget:

- 18 November 2009 - Meeting between First Assistant Secretary of the Pharmaceutical Benefits Division and GMiA;
- 21 January 2010 - Meeting between First Assistant Secretary of the Pharmaceutical Benefits Division and GMiA;
- 4 February 2010 - Senior Departmental meeting (including the Deputy Secretary) with GMiA;
- 16 March 2010 - Meeting between the Minister for Health and Ageing and GMiA;
- 30 March 2010 - Senior Departmental meeting (including the Deputy Secretary) with GMiA; and
- 22 April 2010 - Meeting between the Minister's Office and Alphapharm.

GMiA had a good hearing and the Department has valued the exchange of views. GMiA's views about price disclosure were made clear in these discussions.

However, GMiA's key ongoing proposal over this period was that patients should be made to pay some $5 more for off-patent medicines made by originator companies, compared to the same drugs made by generics companies - and for which the PBS reimbursement is the same. This proposal would have resulted in concessional patients paying nearly twice as much as they do currently ($5.40) for some off-patent medicines. This proposal could not be supported.

GMiA was not shown the proposals being put forward by Medicines Australia, and neither were GMiA's proposals discussed with Medicines Australia. As requested by both industry parties, discussions were treated as confidential by the Department.

The Department offered GMiA a briefing on the MoU within two business days of the MoU being signed, on the afternoon before announcements were made in the Budget context, but this offer was declined.

Outlook for generic medicines

The intention of the measures in the Bill is to allow companies to continue to compete for market share for their products as prices under price disclosure are reduced to the weighted average price rather than the lowest price.

Claims have been made that PBS pricing reforms result in a disproportionate impact on drugs subject to brand competition, being generic medicines in the F2 formulary. The reforms in fact address the particular characteristics of the competitive market for multiple branded medicines, namely the discounting to pharmacies for drugs in the F2 formulary. In doing so the reforms allow competition to play a real part in pricing for PBS medicines, allowing taxpayers to benefit from discounting practices in the market.

And in expanding the scope of these existing 2007 PBS pricing reform policies, the Government has made a commitment to provide for pricing policy stability for all sectors of the industry (generic and innovator) over the next four years.

The generic medicines industry will benefit from significant growth in the market for generics medicines in Australia. The Bill does not prevent the generics industry from competing for a growing share of PBS prescriptions. In 2008-09, market share of generic manufacturers had a share of 33.8 per cent of PBS scripts, compared with 27 per cent in 2005-06. The PBS is continuing to grow, with annual growth rates expected between six and 10 per cent. The share of off-patent drugs (including generics) within the pharmaceutical sector is also growing.

There will be increasing opportunities for generic manufacturers in Australia as the proportion of medicines that are not under patent is rising, and is predicted to increase further over the next few years.[6]

There are 19 medicines estimated to come off patent in the next 12 years that cost the PBS $2.3 billion in 2008/09, including high volume drugs such as atorvastatin and olanzapine, which are both due to come off patent in 2012. Overall these 19 medicines represent almost 30 per cent of total PBS expenditure. These patent expiries will provide the off-patent sector with significantly increased opportunities to expand their business.

Further support for the generics sector will be provided through the National Prescribing Service being funded to undertake a consumer awareness campaign aimed at increasing consumers' understanding of the safety and efficacy of generic medicines, and increase their confidence to choose generic when popular brand medicines may cost them more. Increasing consumers' awareness of, and confidence in, generic medicines as an equal choice benefits consumers and will also contribute to the viability of the generic medicines industry.

Analysis of the last awareness campaign showed a five per cent increase in consumer confidence as a result of the campaign.

Fifth Community Pharmacy Agreement

On 3 May 2010, the Commonwealth Government and the Pharmacy Guild of Australia jointly signed the Fifth Community Pharmacy Agreement. The Fifth Agreement provides $15.4 billion (over 2010-11 to 2014-15) in remuneration for around 5,000 community pharmacies for dispensing of PBS medicines, the provision of pharmacy programs and services, and the Community Services Obligation (CSO) arrangements with pharmaceutical wholesalers. The Agreement will result in a gross saving of $1 billion across 2010-11 to 2014-15 (excluding implementation costs).

Through the Fifth Agreement, community pharmacy will receive $277 million in transitional funding. This transitional funding is being provided to community pharmacy in recognition of the impact of further PBS reform on their income. The Agreement offsets some of this lost income by providing funding for additional patient focused-professional pharmacy programs such as the staged supply of PBS medicines, the provision of dose administration aids, medicine-related clinical interventions and supporting the use of prescribing from medication charts in residential aged care facilities.

[6] Beecroft, G. *Generic Drug Policy in Australia: a community pharmacy perspective* in Australia and New Zealand Health Policy June 2007

Eligible pharmaceutical wholesalers will benefit from continuation of the higher level of CSO funding initiated by the 2007 PBS reform structural adjustment package. The CSO is continued under the Fifth Community Pharmacy Agreement and will provide eligible wholesalers almost $950 million over the life of the Agreement, to ensure all Australians can access any PBS medicine regardless of where they live at no extra cost. This compares to total CSO funding of approximately $660 million under the Fourth Agreement.

The Department will provide sufficient notice of which medicines are affected by the further PBS reforms under price disclosure arrangements. This allows time for wholesalers and community pharmacies to manage stock levels. It is also noted that price disclosure reductions have taken place four times, demonstrating that wholesalers and community pharmacies have effectively managed stock levels resulting in no stock shortages taking place.

The Fifth Agreement is consistent with the Bill. In particular, the development of the under co-payment measure was a key aspect of the Fifth Agreement negotiations. Through the Fifth Agreement, the Pharmacy Guild has provided its support for the collection of under co-payment data.

Ongoing Consultation

An on-going consultative process has been put in place to discuss various aspects of reform. The Price Disclosure Working Group, with representatives from the Department, GMiA, Medicines Australia, AusBiotech and the National Pharmaceutical Services Association has already held discussions on two occasions, on 18 June and 20 July 2010, with the Department maintaining on-going communications with relevant stakeholders on price disclosure implementation.

Wholesalers, represented by the National Pharmaceutical Services Association, have been involved in the Price Disclosure Working Group, which has discussed issues regarding the extended price disclosure arrangements.

Industry has raised concerns about the potential complexity of the further reform measures, leading to further administrative burden on industry. In particular, the requirement of companies to provide data to the Department for the purposes of price disclosure calculations has been raised.

The processes underpinning price disclosure are based on the input of industry in implementing the 2007 reforms. The data required by the Department is generally collected by companies as part of their day to day business operations. There should not, therefore, be any significant issues with providing this data for the purpose of price disclosure calculations.

Industry has indicated a concern about the variability of savings under the further price disclosure arrangements, whereby different drugs are subject to different percentage price reductions. Criticism from industry has characterised the price disclosure arrangements as ‘arbitrary’. In fact, this variability is a feature of price disclosure, which responds to market conditions. As a result, those drugs subject to higher levels of discounting will receive higher price reductions and those drugs subject to lower levels of discounting will receive lower or possibly no price reductions.

7. Access to Pharmaceuticals

The reforms embodied in the Bill will preserve the essential features of the PBS. Under the new pricing arrangements, medical practitioners will continue to be able to prescribe PBS medicines that are clinically appropriate. The robust process for listing new medicines on the PBS will continue, with only medicines recommended by the PBAC being considered for listing by the Government.

The Bill supports the aims of the PBS in providing affordable access to a wide range of medicines. Patients will not be disadvantaged by the provisions of the Bill. Patients will pay no more for their medicines, and some might pay less. Neither will they be disadvantaged in terms of quality or availability of medicines. This is consistent with the goals of the National Medicines Policy.

Patients

There will be no extra costs for patients. The measures in the Bill will enable the Australian community to have ongoing access to essential and new medicines that manage chronic and life-threatening conditions at an affordable price for consumers.

The Report to the Parliament on the 2007 reforms estimated that consumers would benefit from those reforms through direct reductions in prices for some prescriptions by $600 to $800 million over the ten years to 2018. The additional direct savings to consumers from the new measures under this Bill has been independently estimated to double this previous estimate, and to save general patients on average almost $3.00 per prescription over this ten year period. With current price disclosure producing savings of between 13 and 72 per cent, some general patients will see significant price cuts for their medicines.

Prescribers

There will be no impact on prescribers' ability to prescribe clinically appropriate PBS medicines under the measures proposed in this Bill.

Supporting the National Medicines Policy

Australia's National Medicines Policy (NMP) provides the overarching framework for the operation of the PBS. The NMP is an established framework based on partnerships, which was launched in December 1999. Governments (Commonwealth, States and Territories), health educators, health practitioners and other healthcare providers and suppliers, the medicines industry, healthcare consumers, and the media work together to promote the objectives of the policy.

The central objectives of the NMP are:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

The NMP recognises that the partners in the policy should take responsibility for achieving value for money, and that a fair distribution of costs and savings between the partners should be achieved.

The NMP also supports industry in providing medicines in a timely fashion at reasonable cost. The NMP supports a stable and conducive business environment for the medicines industry. These goals are reflected in the Memorandum of Understanding with Medicines Australia.

8. Conclusion

The need for further PBS pricing reform has been demonstrated by the continued growth of PBS expenditure. The 2010 Intergenerational Report states that there will be strong growth in total health spending, and price comparisons between some Australian and international off-patent medicines show that Australia is paying higher prices.

Innovation in F1 drugs continues to be a valued aspect of the PBS. The savings estimated to be generated from the proposed amendments will enable ongoing support for the pharmaceutical industry, through the listing of new drugs on the PBS, and provide the Australian community with affordable access to new medicines that deliver improved health outcomes.

Patients will continue to benefit from ongoing access to new medicines as well as reduced prices of some medicines as a result of the new proposals for reform. Clinicians will also continue to prescribe the clinically appropriate medicine.

The measures in the Bill were subject to extensive consultation with industry. In recognising the importance of providing a stable pricing policy, the resulting Memorandum of Understanding supports the goal of maintaining a viable industry. Medicines Australia acknowledged the benefits that the agreement would provide in ensuring price stability.