SENATE STANDING COMMITTEE ON COMMUNITY AFFAIRS

LEGISLATION COMMITTEE

Inquiry into the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010

SUBMISSION

SUBMISSION NUMBER: **18**

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Department of the Senate
PO Box 6100
Parliament House
Canberra ACT 2600
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Re: Submission to the Senate Community Affairs Legislation Committee Inquiry into National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010

Dear Sir or Madam,

Please find attached a submission for the above inquiry which is based on research conducted in collaboration with Mr Edmund Fitzgerald at the University of Sydney.

Please let know if you require any further information.

Yours faithfully,

Philip Clarke
20 Oct 2010

Submission to the Senate Community Affairs Legislation Committee Inquiry into *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010*

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Summary

Australia currently pays much more for many generic pharmaceuticals (up to twenty times in some instances) than other comparable countries in the OECD.

The proposed price reductions for generics under the Memorandum of Understanding between the Australian Government and Medicines Australia are not of sufficient magnitude to bring prices into line with international prices.

We have estimated that over the next five years the higher prices paid for just one class of drugs, the statins, will amount to around $1.66 Billion dollars, primarily due to the very limited price reduction of only 16% mandated for Atorvastatin and Rosuvastatin after the entry of generic equivalents in 2012.

Additional price cuts over and above those agreed in the MOU for many common generics will be of significant benefit to consumers and taxpayers.

The Australian Government should consider major reforms to ensure that Australian prices for generic pharmaceuticals match those overseas.

Introduction

Earlier this year we published a study in Medical Journal of Australia (Clarke and Fitzgerald 2010) comparing prices of generic Statins (medications for lowering cholesterol) in Australia and England. This study showed that Australia paid much more than England. For example, the wholesale price of Simvastatin 40mg is currently around $31 for a one month supply in Australia, while it is less than $3 in England. The slow downward price reductions of Statins after patent expiry has meant that Australia has spent around $700 million dollars more over the last four years than if we had paid English prices. More importantly, we demonstrated that up to $3.2 billion dollars could be saved over the next 10 years if we were to start paying lower overseas prices now.

Shortly after the publication of this study, the Commonwealth Government announced a Memorandum of Understanding (MOU) with Medicines Australia the peak pharmaceutical industry body (Australian Government and Medicines Australia, 2010). One of the main purposes of this MOU was to establish a framework over the next four years for the pricing of generic drugs when listed on the Pharmaceutical Benefits Scheme (PBS). The purpose of this submission is to evaluate the degree to which the MOU will lower prices and compare this with alternative pricing policies adopted by most other countries for generic therapies.

We will again confine our analysis to Statins, which account for around 16% of PBS funds (Stocks et.al. 2009). Within this class two Statins (Simvastatin and Pravastatin) are already off patent and generic equivalents are expected for the two more commonly prescribed Statins (Rosuvastatin and Atorvastatin) within the life of the MOU[1]. While this submission is confined to a single class of drugs it provides a useful case study which illustrates the high long-term budgetary costs associated with the pricing policies arising from the MOU.

Background

The Pharmaceutical Benefits Scheme (PBS) subsidises around three-quarters of the cost of prescription drugs consumed in Australia. The continuous rise in PBS expenditures, particularly in the late 1990s, has lead to concerns about the long-term sustainability the scheme. For example, based on past trends, the Commonwealth Treasury argued, in its first intergenerational report (Costello 2002), that PBS expenditure was one area of government expenditure most likely to be impacted by an ageing population.

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[1] The patent of Atorvastatin is due to expire in Australia on 18 May 2012 (http://www.freehills.com.au/3200.aspx).
The date of patent expiry for Rosuvastatin is less clear. Mr Leighton Howard a patent attorney who has undertaken research on Rosuvastatin claims “that no equivalent patent protecting the molecule is identified in Australia. However, when considering data exclusivity in major territories, the first marketing authorisation of Rosuvastatin in Australia in May 2006 will preclude the filing for approval of generic equivalents with the TGA until 2011, with likely approval/launch timing of late 2012” (see http://www.genericsweb.com/index.php?object_id=680)

Concerns about rising PBS expenditures provided the underlying motivation for recent changes to aspects of the PBS. The current pharmaceutical pricing agreement under the MOU follows on from the Howard Government's changes to the PBS in 2007 which was divided into two separate formularies: F1 is intended for single-brand patented medications (this currently includes Atorvastatin and Rosuvastatin); and F2 is for medications whose patent has expired and for which generic medications can become available (this includes Simvastatin and Pravastatin).

The recent four year agreement between the Government and Medicines Australia is aimed mainly at reducing the price of generic medications. At heart of the MOU are a series of regulated price reductions:

- 16% when a medicine on the F1 formulary goes off patent and a competitor brand becomes available;
- 2% or 5% in Feb 2011 for medications that are already on the F2 formulary.

Price reductions of generics will then be governed by a formula based on a weighted average of the actual drug prices when they are sold to pharmacies (Australian Government and Medicines Australia, 2010). Under the MOU this price reduction will be determined by a formula based on past price information collected over an 18 month period. However, at the end of the first cycle there will be a minimum price reduction across all F2 drugs of 23%.

International Price comparisons

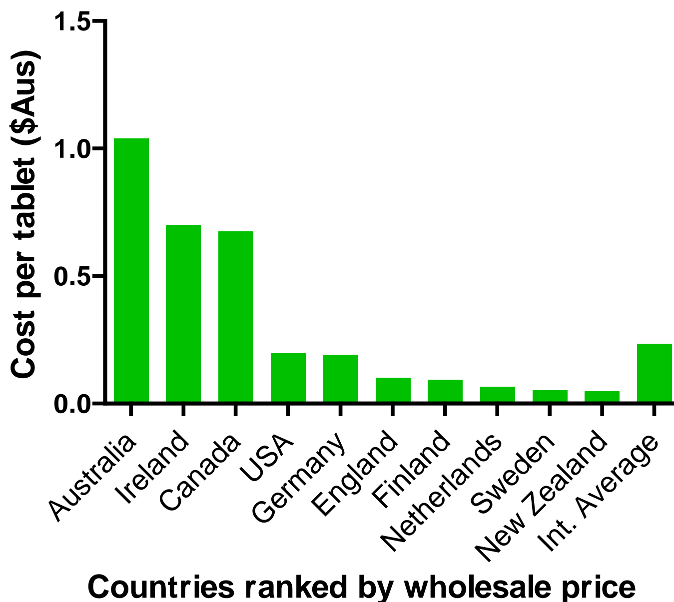
To compare Australian prices with current or recent overseas prices we have compiled information on the wholesale price of Simvastatin (40mg) across ten countries including Australia (see Figure 1). Australia pays the highest price (50% greater than the next highest country) and more than four times greater than the average price against all comparators.

Up until recently two other countries (Ireland and Canada) have also paid well above international average prices for generic Statins, but both have recently implemented much deeper regulatory price cuts than those foreshadowed under the MOU. Ireland reduced the price of generic and off patent drugs by 40% across the board (Gantly 2010). In Canada, many provincial governments have followed the Ontario Government's lead in mandating that generic medicines be sold at no more than 25% of the cost of the brand-name product down from the 50% previously allowed (Dowd 2010).

The lowest international prices have generally been obtained in other countries such as the Netherlands and New Zealand through a tender process in which the company offering the lowest price has a period of exclusivity of supply. When such a process was employed in The Netherlands for common generic therapies they were able to obtain price reductions of over 80% from a single round of tendering which has been estimated to save around 310 million Euros annually (Kanavos 2009).

The United States of America is often regarded as having high prices for patented drugs, but many generic drugs are available at a lower cost than in Australia (Bulfone, 2009).

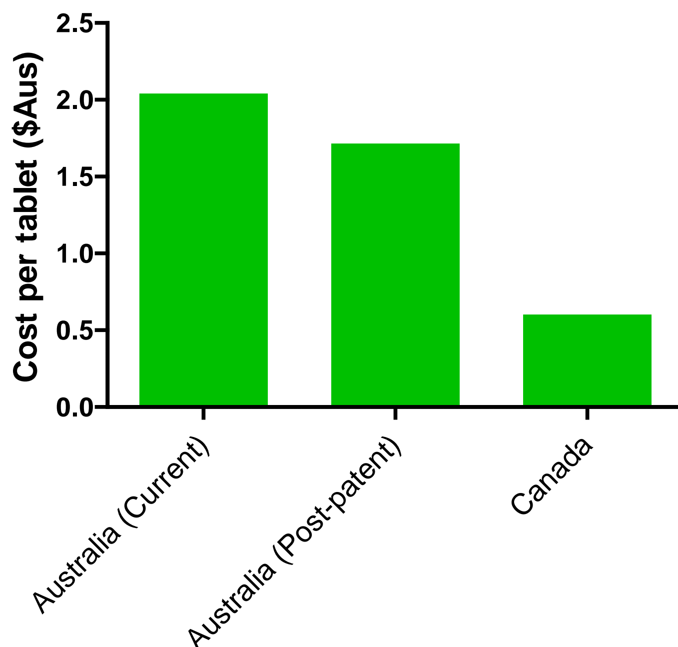
Simvastatin can be purchased from the chains such as Kmart Pharmacy for $US15 for three months supply (Kmart 2010).



Notes:
1.Compartor price converted to Australian $ using average exchange rate over the last 3 years.
2. Selected countries based on information contained in Clarke and Fitzgerald, Letter to the Medical Journal of Australia (forthcoming).

What will happen to the price of those statins that are currently under patent in future? While Atorvastatin is on patent in Australia until 2012, it has already expired in a few countries including Canada. Figure 2 illustrates the current Australian price of Atorvastatin 40mg and the price mandated under the MOU after the entry of generics in 2012. We also show the current price for the same formulation in Ontario that up to eight companies supply in Canada (Ontario Ministry of Health, 2010).

2. Comparison of the wholesale price of Atorvastatin 40mg



Notes:
1.Compartor price converted to Australian $ using average exchange rate over the last 3 years.

The relatively small initial price reduction of 16% agreed under the MOU means that Australia will pay several times more than current Canadian price when Atorvastatin goes off patent in 2012.

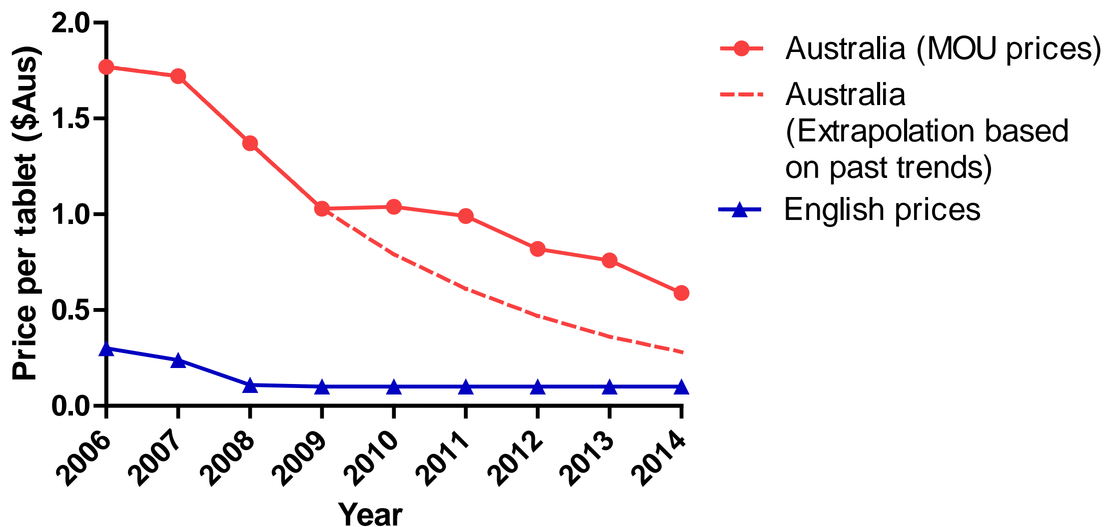
Implications for PBS expenditure

The price reductions specified under the MOU have been estimated by Commonwealth Treasury to save $1296.7 million over the period the agreement (i.e. until June 2014) with an additional $570.9 million in saving projected for 2014-15 (Australian Government, 2010). While the assumptions underpinning these estimates have not been published, the level of savings (or cost) to the budget will depend on the pricing policies that are assumed to apply in the absence of the MOU.

Figure 3 illustrates this issue again using Simvastatin (40mg). The per tablet price of Simvastatin has declined on average by over 20% per year in the two years prior to 2009 due to both regulatory price cuts and the entry of additional generic formulations into the Australian market (Bulfone 2009). While the reductions agreed under the MOU mean savings

relative to the current price (of around $1.00 per tablet) the rate of decline in price has ceased since 2009.

While there are savings from the MOU when measured relative to the current price, the initial price reduction agreed between the Commonwealth Government is very modest when judged either against past trends or international prices. This is illustrated in Figure 2 for Simvastatin 40mg which shows the price reduction of 5% which will apply for 18 months from Feb 2011 (see red line); this is much less than extrapolating past price reductions of around 20% per year (see dotted red line). When the weighted average pricing (WAP) regime comes into force in 2012, the precise price reductions applied will depend on supply prices over the next 18 months, if only the minimum 23% reduction is attained (also illustrated in Figure 2) the price will remain well above past trends over the entire period the MOU is enforce.



Whether the pricing of generics under the MOU represents a saving or cost to the taxpayer/consumers should be judged by measuring against comparable prices for generics overseas. In its submission to this senate enquiry, Medicines Australia recognises that Australia's generic prices are too high compared to international levels and that there is a need to reduce this discrepancy (Medicines Australia 2010).[2] As they note it is important to have "a process that over time is expected to bring generic prices in line with those seen in comparable international jurisdictions." Unfortunately, Figure 2 suggests that this goal is unlikely be achieved during the next five years (as cuts in the order of 75% or more for a drug like Simvastatin would be required).

[2] As Medicines Australia note on page 10 of their submission of 20 August 2010 "The OECD recently reported that Australia continues to pay significantly more for many high volume off-patent or generic [i.e. F2] medicines, a conclusion supported by recent Australian research into commonly used off-patent medicines including those used to treat high cholesterol."

Estimates of total costs from paying higher generic prices

To quantify the cost of Australia maintaining higher prices for generic Statins over the next five years under the MOU, we have estimated the combined cost of all Statin therapies to both the Australian Government (in terms of PBS expenditures) and consumers (from patient contributions). We then compared this figure with the total cost of Statins in Australia if we had used cheaper prices able to be obtained internationally for Statins, that is, the prices to which we compare are the actual prices paid in other countries. For our comparison we used England for the price of Simvastatin and Pravastatin where it has been generic for over 5 years and Ontario (Canada) where Atorvastatin has recently gone off patent and a range of generic versions have become available at discounted prices.

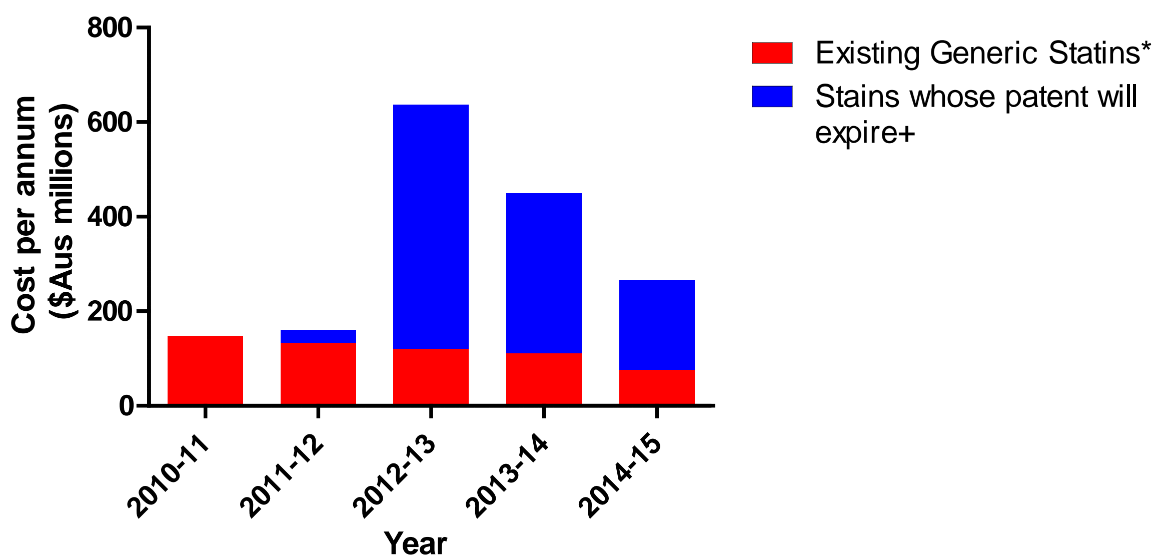
Another assumption which has a material effect on our modelling is that the price of Rosuvastatin will be equivalent to that of Atorvastatin which is likely to occur for two main reasons. Firstly Rosuvastatin is currently in the same therapeutic group as Atorvastatin and so it would appear that reference pricing will apply unless there is a specific exemption granted; and secondly the entry of generic formulations of Rosuvastatin are also likely to become available in Australia from 2012(see footnote 1). We would view the adoption of Ontario as the comparator as producing conservative estimates of the excess cost. While the Ontario policy of paying 25% of the patented price for generics will produce lower prices than those in Australia, Canada is considered to have higher long-term prices than most other countries, notably in the case of Simvastatin in Figure 1.[3]

Regarding the other assumptions underpinning our forecasts we have used past trends in Statin prescription growth and market share to estimate the total cost of statins to Australia. We projected a 3.5% p.a. growth rate in the total number of prescriptions. We set the Statin market share as it is currently; Atorvastatin and Rosuvastatin were set at 50% and 25% respectively and Simvastatin 20%, Pravastatin 5%. For Australia we used the currently available wholesale prices (calculated from the dispensed prices listed in the current Schedule of Pharmaceutical Benefits) and the forecasted prices under the MOU (i.e. 2% or 5% reductions from February 2011 for F2; 16% when generic versions of currently patented Statins become available; 23% reduction for F2 drugs in April 2012; we also assumed a further 20% price reduction for all Statins at the end of 2014 . Figure 2 shows the forecasted losses of the MOU compared to internationally available prices for Statins in England and Canada for each financial year to June 2015.

[3] Interestingly a recent report in Canada by the Fraser Institute (see Skinner and Rovere 2010) argues that Canadian generic prices are much higher than for equivalent drugs in the United States. Their proposed policy response is to introduce "dynamic completion" to Canada by replacing "direct-to-pharmacy reimbursement with direct-to-consumer reimbursement." We have not considered the merits of such a proposal as it would require a new system of the pricing and re-imbursement of drugs in Australia.

In 2010-11 the excess cost of the MOU (i.e. additional costs associated with Australia paying more than comparator counties) is $147 million. In 2011-12 the savings increase slightly as we anticipate that Generic versions of Atorvastatin will be available towards the end of this financial year. In 2012-2013, the first full year where Atorvastatin is off patent, the excess losses are around $636 million which due to modest 16% reduction compared with the 75% reduction already achieved in Canada.

Over the period from July 2010 to June 2015 we estimate that the total excess cost that Australia pays for Statins is around $1.66 billion. Atorvastatin and Rosuvastatin together contribute over $1 billion during this period.



Notes:
* Simvastatin and Pravastatin;
+ Atorvastatin & Rosuvastatin

Conclusions

Australia currently pays much more for many generic pharmaceuticals (up to twenty times in some instances) than other comparable countries in the OECD. The proposed price reductions under the MOU are not of sufficient magnitude to bring prices into line with international prices. These higher prices will mean the pharmaceutical industry will receive a large and ongoing subsidy from the Australian taxpayer and consumers over the duration of the MOU.

We have estimated that over the next five years this subsidy for just one class of drugs, the Statins, will amount to around $1.66 Billion dollars, primarily due to the very limited price reductions of only 16% mandated for Atorvastatin and Rosuvastatin after the entry of generic equivalents in 2012 (compared with the 75% reduction mandated in Canada).

While the main focus of this study is on Statins, a recent Commonwealth Government report on PBS reforms indicated very large price differentials for many other types of generic products (Pricewaterhouse Coopers, 2010). For example, various other commonly prescribed cardiovascular generic drugs like Captopril, Amlodipine, Metformin and Atenolol are around five times more expensive in Australia than in England. Hence our estimates quantify only part of the potential savings from bringing Australian generic prices into line with those currently paid overseas.

It is surprising that the MOU provides no rationale of why the prices of these generic products are maintained well above comparable international levels. For example, Simvastatin 40mg can be currently purchased privately from pharmacies in England (see http://www.chemistdirect.co.uk/) for around $3 per month, below the PBS subsidised price for pensioners (and other Concessional Beneficiaries) of $5.40 and a fraction of the copayment for General Beneficiaries of $33.40. How does maintaining such a high price in Australia relative to almost every other developed country benefit patients?

Policy proposals

If it is the objective of Australian Government and Medicines Australia to ensure "all Australians will continue to have access to a wide range of pharmaceuticals... at the lowest possible prices for consumers" (DOHA, 2010), then changes to the MOU are required.

While the cost of manufacture of generic drugs differs between therapeutic classes, the overseas experience suggests much greater initial price reductions than the agreed 16% under the MOU for many common drugs such as Statins are possible while maintaining a viable generic industry. As we have noted earlier, in Ontario there are several companies supplying Atorvastatin after the mandated 75% price cut. Such a price cut on Atorvastatin (and Rosuvastatin) would bring about large budgetary savings (in excess of $1 billion over the next five years) relative to those agreed in the MOU. These savings could also be used to purchase new health care therapies or technologies.

Secondly, the price reductions for those drugs on F2 of 2% and 5% in Feb 2011 will need to be much greater to bring Australia into line with international prices. One way to achieve this is to mandate greater price reductions for common generic drugs when there are large price discrepancies with other countries (e.g. current wholesale price of Simvastatin in Australia is around five times the average cost overseas).

A limitation of the weighted average pricing mechanism which will apply from 2012 is that it depends entirely on the prices of medicines when supplied to pharmacists in the Australian market. This means there is no direct link to the prices of generic medicines overseas. One way to rectify this is to extend the weighted average pricing (WAP) mechanism to include prices for equivalent therapies in selected overseas countries (e.g. prices can easily be obtained from public data for England, Sweden, New Zealand and at a provincial level in Canada).[4]

Beyond the current MOU there is a need to consider major reforms to the pricing arrangements of generics on the PBS. This is particularly important when so many drugs are coming off patent in the next few years. In this environment there is a need for a system that allows for rapid downward flexibility in prices, as the cost of generic drugs should only reflect the cost of production rather than any return for the intellectual property that is associated with development of new drugs. Governments in other countries have adopted a wide variety of strategies for pricing generic drugs. This ranges from large mandated price cuts (as adopted by many provinces in Canada) to the use of tendering processes (as employed in New Zealand). Countries such as the United States have maintained more market based approaches for the pricing of generics. What is important to note, is that all of these strategies have produced much lower prices for many generics than we pay in Australia. We can learn from this overseas experience when developing a better system for pricing these pharmaceuticals in Australia.

[4] For example, on possible formula would be assign a 50% weight to the existing WAP as outlined under the MOU and then assign 50% weight to an average price from selected countries overseas.

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