

Senate Community Affairs References Committee

ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

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

Question no: 1

OUTCOME 2 Access to Pharmaceutical Services

Topic: Impact of Further PBS Reform

Written question on notice

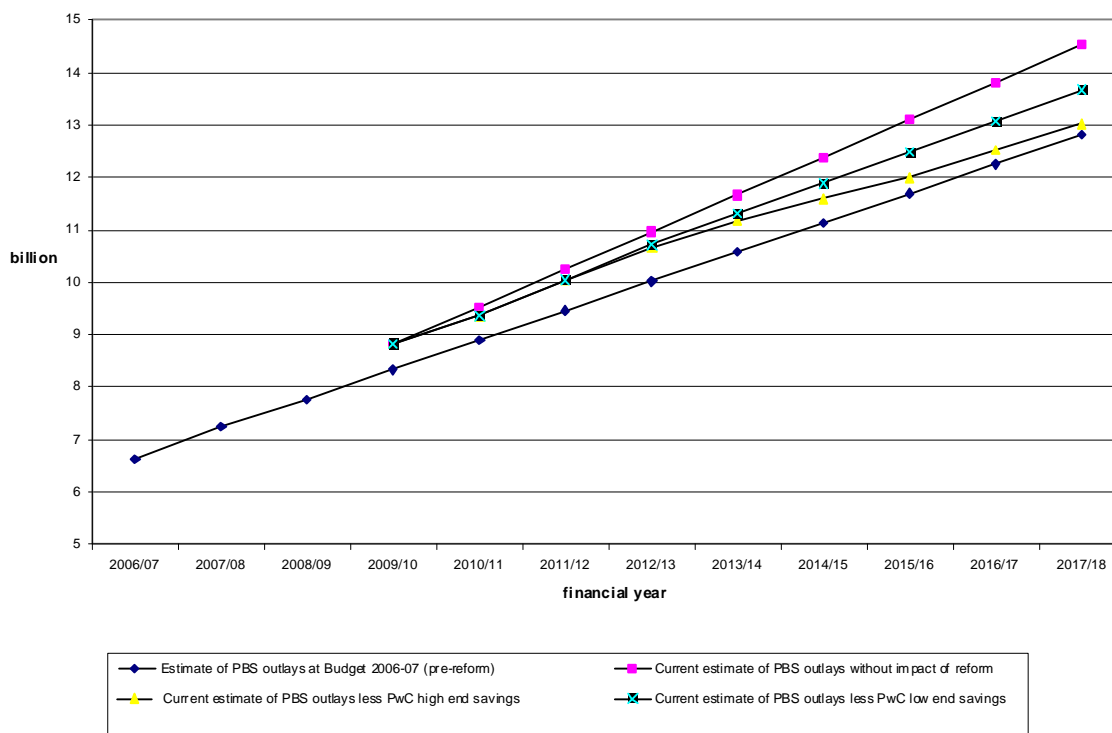
Senator Fierravanti-Wells asked:

Can the DOHA breakdown and document the prospective 2010 to 2015 budget savings from the 2007 PBS reforms that are also now included into the budget forward estimates for the PBS, including a breakdown of the original budget projection of the PBS excluding the impact of the 2007 and the 2010 reforms?

Answer:

While it is acknowledged that the actual savings from the 2007 PBS Reform were higher than initially estimated, this will be more than outweighed by the higher than initially estimated PBS outlays over the same period.

The Department commissioned an independent report by PricewaterhouseCoopers (PwC) into the impacts of the 2007 PBS reforms. This report was used and included in the Minister Report to Parliament on *The Impact of PBS Reform*, February 2010. The following information is taken from that report.



On 1 August 2008, medicines on F2(T) received a 25 per cent statutory price reduction and medicines on F2A received a two percent price reduction. Further, there were additional two percent price reductions on 1 August 2009 and 1 August 2010.

**Estimated savings to Government from the 2 and 25 per cent price reductions (\$ million)**

	2010/11	2011/12	2012/13	2013/14	2014/15
Estimated Savings	416	442	467	492	517

Source: *The Impact of PBS Reform*, page 67

The PwC report presents a range of savings for price disclosure arrangements under the 2007 PBS Reforms. These impacts are heavily dependent on the assumptions used about the levels of discounting occurring in the pharmaceutical supply chain and the likelihood and speed of off-patent molecules gaining generic competition. The low end estimated savings represent conservative assumptions about the levels of discounting occurring, while the high end savings represent more aggressive assumptions about the levels of discounting.

**Estimated savings to Government from price disclosure (\$ million)**

	2010/11	2011/12	2012/13	2013/14	2014/15
Estimated Savings (low end)	38	49	76	157	286
Estimated Savings (high end)	38	62	121	296	578

Source: *The Impact of PBS Reform*, page 67

The 2007 PBS reforms included a structural adjustment package to community pharmacy and wholesalers which significantly offset the savings from the statutory price reductions and price disclosure.

**Estimated cost to Government of the structural adjustment package (\$ million)**

	2010/11	2011/12	2012/13	2013/14	2014/15
Estimated Savings	-302	-284	-291	-299	-307

Source: *The Impact of PBS Reform*, page 68

When the impact of the structural adjustment package is offset against the savings from the statutory price reduction and price disclosure measures the net save to Government is obtained.

**Estimated net savings to Government from 2007 PBS reforms (\$ million)**

	2010/11	2011/12	2012/13	2013/14	2014/15
Estimated Savings (low end)	151	207	251	350	495
Estimated Savings (high end)	151	220	296	488	787

Source: *The Impact of PBS Reform*, page 68

The following chart shows the projection of PBS outlays at Budget 2006-07 not including the effects of the 2007 PBS reforms. It also shows the estimates of PBS outlays including the estimated savings from the 2007 reforms but excluding the estimated savings from the 2010 reforms.

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ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

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

Question no: 2

OUTCOME 2 Access to Pharmaceutical Services

Topic: Impact of PBS reform

Written question on notice

Senator Fierravanti-Wells asked:

What are the projected additional savings from the 2007 PBS reforms and the additional projected savings from the proposed new 2010 PBS reforms?

Answer:

The Department commissioned an independent report by PricewaterhouseCoopers (PwC) into the impacts of the 2007 PBS reforms. This report was used and included in the Minister Report to Parliament on the *Impact of PBS Reform*, February 2010.

The 2007 PBS Reforms were originally estimated to save the Government around \$3 billion over 10 years. After taking into account the impact of the two and 25 per cent statutory price reductions, the estimated impact of price disclosure under a number of assumptions, and the offsetting effect of the structural adjustment package, PwC estimated that the net save to Government over the period 2008/09 to 2017/18 is in the range of \$3.6 billion to \$5.8 billion.

While it is true that the actual savings from the 2007 PBS Reform were higher than initially estimated, this will be more than outweighed by the higher than initially estimated PBS outlays over the same period.

The range in PwC's estimates reflect a heavy dependency on the assumptions used about the levels of discounting occurring in the pharmaceutical supply chain, and the likelihood and speed of off-patent molecules gaining generic competition. The low estimate represents conservative assumptions about the levels of discounting occurring, while the high estimate represents more aggressive assumptions.

The Report notes that long term (10 year) forecasting is difficult and the validity of the assumptions used in modelling will not be known for several years. Therefore the projections of these savings must be viewed with caution.

The Report stated that on current projections (not including any potential impacts from the 2010 Reforms), PBS outlays in 2018 will be in the order of \$13 billion to \$13.7 billion per annum.

The following table shows the projected (four year) impact of the Further PBS Pricing Reforms as announced in the 2010 Budget. The savings from the Further PBS Reforms have

been estimated on the basis of the two and five per cent price reductions to the F2A and F2T formulary medicines on 1 February 2011, and the guaranteed 23 per cent price reduction resulting from the enhanced price disclosure arrangements for all F2 formulary medicines on 1 April 2012.

**Projected savings to Government from the Further PBS Pricing Reforms (\$ million)**

	2009/10	2010/11	2011/12	2012/13	2013/14
Total projected save	-	30.7	191.2	528.4	546.4

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9 November 2010

OUTCOME 2: Access to Pharmaceutical Services

**Topic: Trade Practices Act compliance**

Senator Fierravanti-Wells

Question 3

Can the DOHA confirm that the MoU and Bill comply with the Trade Practices Act (Cth) 1974 and that this has been cleared with the ACCC?

**Answer:**

The *Trade Practices Act 1974* (the TPA) does not apply to conduct of the Department in relation to PBS pricing issues for the purpose of a legislative function and is therefore not relevant to the Memorandum of Understanding between the Commonwealth and Medicines Australia, or to the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010*. The TPA applies to the Commonwealth only in so far as it carries on a business. The PBS is not a government business. Further, the TPA does not bind the government in its legislation making power.

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OUTCOME 2: Access to Pharmaceutical Services

**Topic: Mandated price adjustments and independent review**

Senator Fierravanti-Wells

Question 5.

Good governance requires that Government mandated price adjustments should be subject to independent review, can DOHA advise what independent review the MoU/Bill been subject to?

**Answer:**

PBS prices are not legislated prices for the sale of medicines by manufacturers. They are prices used as the basis for calculating a Government subsidy – ie: the amount payable by the Commonwealth on supply of a PBS medicine.

The price disclosure process provides for an eight week period in which any dispute resolution might be required for a Weighted Average Disclosed Price calculation.

Further, the measures in the Bill are an expansion of the 2007 PBS Reform which were independently reviewed by PriceWaterhouseCoopers in 2010 as reported by the Minister to the Parliament.

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

Question no: 6

OUTCOME 2 Access to Pharmaceutical Services

Topic: Market share information

Written question on notice

Senator Fierravanti-Wells asked:

Why is the full data on market share not being made public?

Answer:

Medicare Australia data on PBS subsidised medicines is available publicly but only at a level that does not raise privacy or commercial-in-confidence concerns. The Medicare Australia data captures all PBS subsidised medicines dispensed at community pharmacies. These are PBS medicines that are priced above the concessional co payment threshold currently \$5.40 and the general co-payment threshold (currently \$33.30).

The Department provides Medicines Australia, GMiA and the Pharmacy Guild, with Medicare Australia data at the level of PBS medicine by form and strength, with respective prescription volumes and Government expenditure.

The Medicare Australia data used by the Department includes a manufacturer code (which is not available to industry for commercial-in-confidence reasons) which goes to Medicare Australia direct from the dispensing software of community pharmacies. Therefore, for PBS subsidised medicines, the Department can allocate volume and cost against each manufacturer supplying PBS subsidised medicines.

The full set of data on PBS prescriptions dispensed to general patients which cost less than the general patient copayment threshold of \$33.30 (under-copayment data) is not available to the Department or any other party. However, the Department does receive a sample of under co-payment PBS data from approximately 200 community pharmacies which is provided by the Pharmacy Guild of Australia. This sample data indicates that under-co-payment PBS prescriptions account for approximately 18 per cent of all PBS prescriptions.

As agreed with the Pharmacy Guild under the Fifth Community Pharmacy Agreement the Bill will allow the collection of the full under-copayment PBS data by Medicare Australia straight from Community Pharmacies dispensing software from April 2012.



ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

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

Question no: xxx

OUTCOME 2 Access to Pharmaceutical Services

Topic: Generic market share and under-copayment data

Hansard Page: CA48

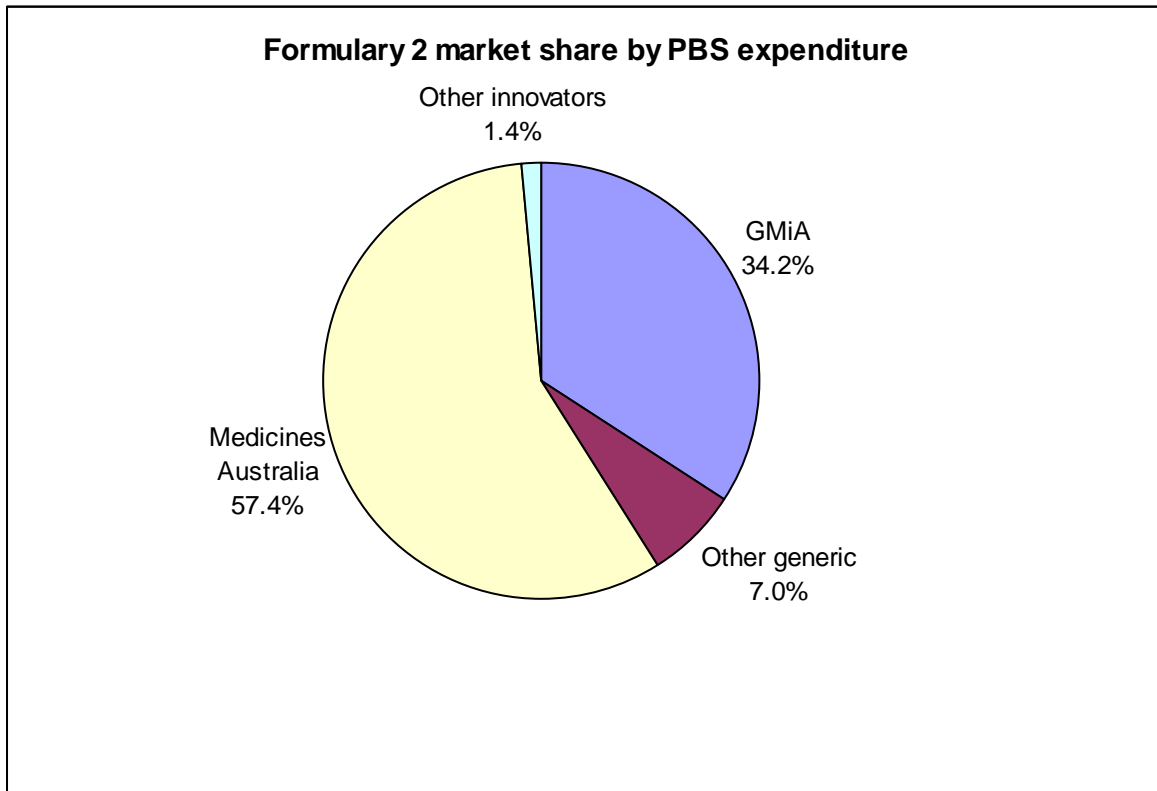
Senator Fierravanti-Wells asked:

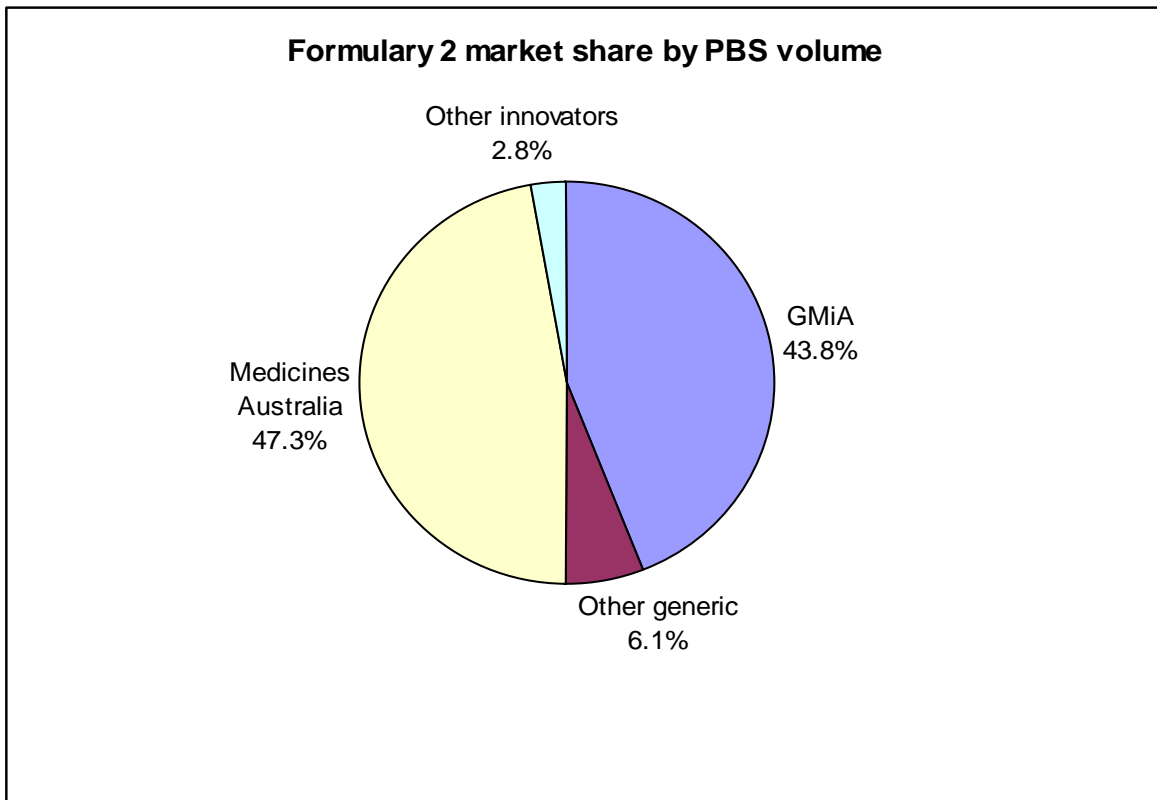
Could we have a chart or table that sets out in a simple way generic market share in both volume and scripts and also showing where the gap is.

Answer:

The following charts show the market share breakdown of the F2 Formulary between Medicines Australia member companies, GMiA member companies, non-GMiA generic manufacturers and non-Medicines Australia innovator manufacturers.

The information in the charts relates to PBS subsidised prescriptions processed by Medicare Australia in 2009/10 for medicines in the F1 and F2 formularies. It does not include under-copayment prescriptions (that is, prescriptions dispensed to general patients where the cost of those medicines is under the general copayment amount (\$33.30 in 2010)).





Other generic companies are defined to be manufacturers that are that are not members of GMiA and that are predominantly manufacturers of generic medicines.

Other innovator companies are defined to be manufacturers that are predominantly manufacturers of innovator medicines and that are not members of Medicines Australia.

Other generic companies are defined to be manufacturers that are not members of GMiA and that are predominantly manufacturers of generic medicines.

Other innovator companies are defined to be manufacturers that are predominantly manufacturers of innovator medicines and that are not members of Medicines Australia.

#### Under-copayment data

Under-copayment prescriptions make up approximately 18 per cent of all prescriptions dispensed in Australia. At present the Department has access to only very limited information on under-copayment prescriptions through a sample survey by the Pharmacy Guild of Australia of community pharmacies. The survey collects information on the volume of all prescriptions (over-copayment, under-copayment and private) being dispensed by these community pharmacies.

The Bill contains provisions that will allow, for the first time, the Department to directly collect under-copayment data through Medicare Australia. This will give the Department a much better picture of dispensing of PBS medicines in Australia.

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ANSWERS TO QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

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

Question no: xxx

OUTCOME 2 Access to Pharmaceutical Services

Topic: \$277 million for patient focused services

Hansard Page: CA58

Senator Fierrvavanti-Wells asked:

Could the Department provide a breakdown of the \$277 million allocated in the Fifth Community Pharmacy Agreement for additional programs to support patient services.

Answer:

The Commonwealth will provide \$277 million for additional programs to support patient services as described on pages 32-33 of the Fifth Community Pharmacy Agreement (Fifth Agreement). The full text of the Fifth Agreement is publicly available on the Department's website (<http://www.health.gov.au/internet/main/publishing.nsf/Content/fifth-community-pharmacy-agreement>). The relevant pages are attached for your convenience.

## 2 Additional Programs to Support Patient Services

It is proposed that the Commonwealth will provide Funds for the Additional Programs to Support Patient Services as described below.

Program name	Program description	Indicative Funds	Program governance
<b>Additional Pharmacy Practice Incentives (PPIs)</b>			
<b>Clinical Interventions by Pharmacists</b>	<p>The purpose of this Program is to identify, resolve and document drug related issues that are identified within community pharmacy. The Program will build on 3<sup>rd</sup> and 4<sup>th</sup> Agreement Research and Development projects to encourage Approved Pharmacists to provide and document clinical interventions arising from their patients' medicine use.</p> <p>The aims of the Program are to:</p> <ul style="list-style-type: none"> <li>• Increase the number of clinical interventions provided and documented and improve communication with patients and prescribers.</li> <li>• Integrate with other services and programs provided by community pharmacies such as Dose Administration Aids, Medicines Use Reviews and Home Medicines Reviews.</li> </ul> <p>Compliance arrangements and an agreed Standard will be put in place to ensure ongoing accountability and quality of the service.</p>	<b>\$97m</b>	<p><b>Program Manager:</b> Guild &amp; Commonwealth</p> <p><b>Program payments made by:</b> Medicare Australia</p>
<b>Support for the Provision of Dose Administration Aids (DAAs)</b>	<p>This Program will assist patients in the community to better manage their medicines, with the objective of avoiding medication misadventure and associated hospitalisation. The Program will provide funding to eligible Approved Pharmacists for meeting performance requirements for providing DAAs under the Program. These requirements will include strict patient eligibility criteria and compliance arrangements. Patient eligibility may be informed by the evaluation of the Dose Administration Aids program conducted under the Fourth Community Pharmacy Agreement.</p>	<b>\$132m</b>	<p><b>Program Manager:</b> Guild &amp; Commonwealth</p> <p><b>Program payments made by:</b> Medicare Australia</p>
<b>Staged supply support allowance</b>	<p>This Program will provide a payment to eligible Approved Pharmacists which meet specified performance requirements in providing dispensed PBS medicines in instalments when requested by the prescriber (excluding the section 100 opioid dependency treatment program). These instalments may be daily, weekly or as directed by the prescriber. This service may be of particular value to patients with a mental illness, drug dependency or who are otherwise unable to manage their medicines safely.</p>	<b>\$35m</b>	<p><b>Program Manager:</b> Guild &amp; Commonwealth</p> <p><b>Program payments made by:</b> Medicare Australia</p>
<b>Funding to support the Accreditation System and roll-out of Additional Programs to Support Patient Services</b>	<p>This Program will support the revision of standards in order to ensure they are focused on clinical and patient issues; and to support Approved Pharmacists to meet the new requirements of the Additional Programs to Support Patient Services.</p>	<b>\$5m</b>	<p><b>Program Manager:</b> Guild &amp; Commonwealth</p>
<b>Other Programs to support patient services</b>			

<b>Supply and PBS Claiming from a Medication Chart in Residential Aged Care Facilities</b>	This will address issues faced in these facilities regarding the supply and PBS claiming of medicines from an available prescription. Introducing supply from a medication chart would streamline supply; claiming and governance issues for Approved Pharmacists ensuring medicines are supplied in accordance with the prescriber's most recent intentions.	<b>\$3m</b>	<b>Program Manager:</b> Commonwealth & Guild
<b>Electronic recording of controlled drugs</b>	This will support the development of a system to collect and report data relating to controlled drugs, to address the problems of forgery, abuse, and doctor shopping.	<b>\$5m</b>	<b>Program Manager:</b> Commonwealth & Guild