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 Siewert asked:

The impact of PBS reform Report to Parliament notes that PBS Reform was originally forecast to save $580 million over the five years 2006-07 to 2010-11. These forecasts were reduced to $103 million. Could the Department please provide the actual savings that were achieved through PBS Reform over this period? If relevant, please provide both net and total savings.

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's Report to Parliament, *The Impact of PBS Reform*, February 2010. This report provides an independent assessment of the savings due to the 2007 PBS Reforms.

For the full year of actual data used in the compilation of the Report, 2008-09, the savings due to PBS Reform (by component, gross and net)[1] were:

Component of 2007 Reforms package	2008-09 Save ($ million)*
2% and 25% mandatory price reductions	330
Price disclosure**	0
Gross save	330
Structural adjustment package	-392
Net save	-61

* totals may not add due to rounding.

** the first round of price disclosure price reductions did not occur until December 2009.

1. Source: *The Impact of PBS Reform*, February 2010, page 91

The PwC report projects net savings to Government for 2009-10 to 2010-11 to be $153 million, resulting in a net save over the 2008-09 to 2010-11 period of $92 million.

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

Question no: 2

OUTCOME 2: Access to Pharmaceutical Services

Topic: Expanded and Accelerated Price Disclosure

Hansard Page: CA

Senator Siewert asked: The first round of price disclosure, as proposed in the legislation, commences on 1 December 2010. The price reduction will not take effect until April 2012. Please provide the rationale for this delay and the justification for the gap between notification of price reduction and the date it takes effect.

Answer:

As price disclosure is based on sales data for a drug, a reasonable period of time is required to base the price changes upon.

The duration of the first price disclosure cycle, commencing on 1 December 2010, is 16 months, including a data collection period of ten months and a six months processing period.

The processing period of six months consists of:

- Six weeks for companies to submit their data. This allows for end of month receipt of data by companies and time to collate and validate their data before submitting. The accuracy of this data is important as it forms the basis of the weighted average percentage calculation;
- Four weeks are required for the weighted average percentage calculations to be performed and independently verified. Companies are advised of any resulting price reductions determined via legislative instrument;
- An eight week period is set aside for any dispute resolution required; and
- A further eight week period is required for the production of the Schedule of Pharmaceutical Benefits so that new prices can be published on the scheduled price reduction day of 1 April 2012.

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

Question no: 3

OUTCOME 2: Access to Pharmaceutical Services

Topic: Expanded and Accelerated Price Disclosure

Written Question on Notice

Senator Siewert asked: Please provide a break-down of the administrative costs associated with implementation of price disclosure arrangements, as follows:

(a) The current staffing levels including APS Levels and SES (if no designated SES, an estimate of the time spent on price disclosure by SES staff) on an annual basis, since the policy commenced

(b) The projected staffing levels for the proposed price disclosure arrangements including APS levels and SES and SES (if no designated SES, an estimate of the time spent on price disclosure by SES staff) on an annual basis, over the Forward Estimates

(c) The projected costs associated with auditing of pharmaceutical manufacturers subject to price disclosure, if relevant

(d) The costs incurred by the Department, to date, of the legal challenges associated with price disclosure, including staffing costs

(e) The proposed budget allocation for legal expenses over the Forward Estimates

(f) The total costs for each (a) and (b), expressed on an annual basis

(g) Any other relevant costs

Answer:

(a) The allocated staffing levels (ASL) and costs for the entire 2007 PBS Reforms package of measures, on an annual basis are provided below. A breakdown of staffing levels for price disclosure only is not available.

Financial year	ASL	Cost
2006/07	6	$665,000
2007/08	12	$1,340,000
2008/09	6	$637,000
2009/10	4	$499,000
	Total cost	$3,140,000

(b) The projected allocated staffing levels (ASL) and costs for the proposed Expanded and Accelerated Price Disclosure arrangements, on an annual basis, over the Forward Estimates are as follows:

Financial year	ASL	Cost
2010/11	4	$318,000
2011/12	2	$178,000
2012/13	1	$80,000
2013/14	1	$80,000
	Total cost	$656,000

(c), (e) and (f) The budget for the implementation of Expanded and Accelerated Price Disclosure is as follows:

Financial year	Cost ($ million)
2010/11	3.6
2011/12	1.4
2012/13	1.2
2013/14	1.2
Total	8.64

It includes, staffing, outsourcing of data collection and analysis, quality assurance, and legal expenses.

(d) Since the commencement of price disclosure in 2007, the Department has received one legal challenge related to the outcome of a Weighted Average Disclosed Price calculation. The costs incurred by the Department in relation to this were approximately $75,000.

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Inquiry into the National Health Amendment (Pharmaceutical Benefits Scheme) Bill
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Question no: 4

OUTCOME 2: Access to Pharmaceutical Services

Topic: Expanded and Accelerated Price Disclosure

Hansard Page: CA

Senator Siewert asked: Has the Department conducted a cost-benefit analysis of price disclosure? If so, please provide this to the Committee. The Committee is especially interested in any cost benefit analysis, or analysis more broadly, which takes into account administrative costs.

Answer:
The Department has not conducted a cost-benefit analysis of Expanded and Accelerated Price Disclosure (EAPD). However, the Bill sets out new PBS pricing arrangements that will provided $1.9 billion in savings this will improve the sustainability of the PBS which will have benefits for patients and taxpayers whilst still providing for the subsidy of new and innovative medicines.

In relation to the administrative costs for manufacturers, the data for EAPD will be the same type and format that is collected under the existing program which commenced in 2007, and is sales data that pharmaceutical companies already collect in the operation of their businesses.

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

Question no: 5

OUTCOME 2: Access to Pharmaceutical Services

Topic: Expanded and Accelerated Price Disclosure

Hansard Page: CA

Senator Siewert asked: What steps will the Department take to:

(a) Prevent collusion in the market as result of price disclosure
(b) To prevent gaming of the 10% margin

To what extent will the information submitted under price disclosure arrangements be audited? Will this be conducted by Government? What are the anticipated costs over the Forward Estimates?

Answer:

Collusion is specifically prohibited under the *Trade Practices Act 1974* for all markets, not just the pharmaceutical industry and the price disclosure program. The ACCC will continue to monitor any collusion across all markets.

Since the commencement of price disclosure in 2007, there has been no evidence of collusion in the market or industry preventing the weighted average percentage difference from reaching above 10 percent.

Product discounting is a business decision made by companies to gain market share. Price disclosure does not discourage competitiveness in the market and still leaves room for further discounting by efficient providers, allowing companies to continue to compete for market share. This is demonstrated by the fact that since price disclosure commenced on 1 August 2007, fifteen drugs have taken or are scheduled to take price disclosure-related price reductions, and all of the drugs that have completed a second round of price disclosure have taken further price reductions.

All data submissions must be accompanied by a Submission Declaration signed by the company's Authorised Representative as nominated to the Department that the information provided in the submission is true, complete and accurate.

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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: 6

OUTCOME 2 Access to Pharmaceutical Services

Topic: Access and affordability

Written question on notice

Senator Siewert asked:
One of the 'pillars' of the National Medicines Policy is 'affordable access' to prescription medicines. What measures will the Government undertake to ensure access and affordability across the entire population? Will the prices of under co-payment medicines be monitored by Government? If so, how will this occur? Furthermore, will safety net measures be altered to reflect the increased costs borne by consumers, particularly those exempt from concessional arrangements?

Answer:
These reforms do not impose any additional costs on consumers; as is acknowledged by the Consumer Health Forum in their submission to the inquiry. In fact some consumers will pay less for their medicines as prices of some medicines fall below the level of the general patient co-payment. An independent study has found that, due to the Further PBS Pricing Reform measures contained in the Bill, on average over 10 years, patients will pay around $3.00 less per general PBS prescription.

Such savings have already been demonstrated on drugs such as Vancomycin and Carvedilol, as shown in the table below.

Drug	**Manner of administration, form and strength**	**Pre-reduction price (1 Feb 2010)**	**Post-reduction price (1 Apr 2010)**	**Patient saving**
Vancomycin	Powder for injection 500 mg	$33.30	$12.19	**$21.11**
	Powder for injection 1g	$33.30	$17.95	**$15.35**
Carvedilol	Tablet 3.125 mg	$18.70	$15.58	**$3.12**

Therefore, there is no need to consider altering safety-net measures to account for additional costs to consumers.

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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: 7

OUTCOME 2: Access to Pharmaceutical Services

Topic: Expanded and Accelerated Price Disclosure

Hansard Page: CA

Senator Siewert asked: Please provide to the Committee, on an annual basis, to date, the savings generated from the products that have been subject to price disclosure.

(a) Please provide a list of the products that have received notification of price disclosure and the date the reduction is due to take effect.

Answer:
The tables below provide an outline of the drugs which have received a price reduction under the current price disclosure. Each table shows how much has been saved on each individual drug since the price reduction took effect. The actual total savings from these price reductions are $15 million to date.

First Round – Price reduction occurred on 1 December 2009

Drug (and manner of administration)	**Weight average percentage reduction**	**Estimated save to date (m)**
Doxorubicin (Solution for I.V. injection or intravesical administration)	63.54%	3.2
Mitozantrone (Injection)	34.42%	0.24
Ondansetron (I.V. injection)	15.37%	0.15

Second Round – Price reduction occurred on 1 April 2010

Drug (and manner of administration)	**Weight average percentage reduction**	**Estimated save to date (m)**
Fluconazole (oral) (Capsule)	55.26%	2.3
Vancomycin (Powder for injection)	71.80%	1.2

Third Round – Price reduction occurred on 1 April 2010

Drug (and manner of administration)	**Weight average percentage reduction**	**Estimated save to date (m)**
Carvedilol (Tablet)	27.29%	6.2

Fourth Round – Price reduction occurred on 1 August 2010

Drug (and manner of administration)	Weight average percentage reduction	Estimated save to date (m)
Cefalotin (Powder for injection)	41.13%	0.138
Doxorubicin (Solution for I.V. injection or intravesical administration)	34.62%	0.079
Meloxicam (Tablet and Capsule)	17.99 %	1.4
Mitozantrone (Injection)	13.33%	0.011
Ondansetron (I.V. injection)	17.61%	0.034

Fifth Round – Price reduction will occur on 1 April 2011

Drug (and manner of administration)	Weight average percentage reduction	Estimated save to date
Alendronic Acid (Tablet)	22.96%	n/a
Cisplatin (I.V. injection)	39.02%	n/a
Fluconazole (Solution of I.V. infusion)	27.52%	n/a
Fluconazole (oral) (Capsule)	38.48%	n/a
Risperidone (Tablet)	17.37%	n/a
Vancomycin (Powder for injection)	12.48%	n/a

Sixth Round – Price reduction will occur on 1 April 2011

Drug (and manner of administration)	Weight average percentage reduction	Estimated save to date
Carvedilol (Tablet)	11.90%	n/a
Gemcitabine (Powder for I.V. infusion)	37.00%	n/a
Irinotecan (I.V. injection)	61.40%	n/a
Paclitacel (Solution concentrate for I.V. infusion)	52.58%	n/a

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HEALTH AND AGEING PORTFOLIO

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

Question no:

OUTCOME 2: Access to Pharmaceutical Services

Topic: Therapeutic Groups

Hansard Page: CA 60

Senator Siewart asked:

Can you remind me of the dates of the last therapeutic groups... the last ones and then more of the history?

Answer:

The therapeutic group policy was first announced in the 1997-1998 Budget and the first four therapeutic groups, set out in Table 1 below, were formed in February 1998.

Table 1: Therapeutic groups formed in 1998

Group & Date	Drugs	Action of Drug
ACE Inhibitors	captopril, cilazapril (since removed – not on PBS), enalapril, fosinopril, lisinopril, perindopril, quinapril, ramipril, trandolapril	Competitive inhibitor of angiotensin I converting enzyme (the enzyme responsible for the conversion of angiotensin I to angiotensin II) - used mainly for heart conditions
Calcium Channel Blockers	amlodipine, felodipine, nifedipine (lercanidipine added since creation)	Prevents calcium from entering cells of the heart and blood vessel walls – uses include lowering blood pressure
H2 Receptor Antagonists	cimetidine, famotidine, nizatidine, ranitidine	Histamine 2 receptor antagonist – inhibits acid secretion (eg: for ulcer treatment)
HMG CoA Reductase inhibitors (Statins)	pravastatin, simvastatin	HMG-CoA reductase inhibitors lower cholesterol levels in the body

In 2007 the then Government introduced a range of PBS Reforms, including amendments to the *National Health Act 1953* (the Act), which provides the statutory basis for the PBS. At the time of these reforms a further two new therapeutic groups, set out in Table 2, were formed and the previously administrative therapeutic group policy was provided for under statute.

Table 2: Therapeutic groups formed in 2007

Group & Date	Drugs	Action of Drug
ATRA	candesartan, eprosartan, irbesartan, olmesartan, telmisartan, valsartan	Angiotensin II receptor antagonist (mainly used to lower blood pressure)
Proton Pump Inhibitors	esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole	Proton Pump inhibitor (decreases gastric acid production).

A seventh therapeutic group was formed in September 2009 following its announcement in the 2009-10 Budget.

Group & Date	Drugs	Action of Drug
Statins-HP	Atorvastatin, rosuvastatin	Higher potency HMG-CoA reductase inhibitors lower cholesterol levels in the body

A further three new therapeutic groups, set out in Table 3 were announced in the 2009-10 Mid Year Economic & Fiscal Outlook.

Table 3: Therapeutic groups formed in 2010

. Group & Date	Drugs	Action of Drug
Venlafaxine	venlafaxine, desvenlafaxine	Anti-depressants (venlafaxine and its PBS listed derivative drug)
Bisphosphonates - osteoporosis	alendronic acid, alendronic acid with calcium, risedronic acid, risedronic acid with colecalciferol, risedronic acid with colecalciferol and calcium – but only oral forms of these drugs are in this group in the circumstances listed on the PBS for treating osteoporosis	These oral bisphosphonates treat problems with bone density
Bisphosphonates - Paget disease	alendronic acid, risedronic acid, tiludronic acid – but only oral forms of these drugs are in this group in the circumstances listed on the PBS for treating Paget disease of bone	These oral bisphosphonates treat Paget disease of bone

These groups were formed with effect of 21 January 2010, with the price changes flowing from the formation of these groups intended to come into effect on 1 April 2010. However, the formation of these three groups was disallowed by the Senate on 11 March 2010. A decision on whether to reform these three groups is a matter for Government.

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Inquiry into the National Health Amendment (Pharmaceutical Benefits Scheme) Bill
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OUTCOME 2: Access to Pharmaceutical Services

Topic: Trade Practices Act

Hansard Page: CA 60

Senator Siewart asked:

Has the Department of Health and Ageing had any advice on whether the mandated price reductions in the MOU and the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010* contradict the *Trade Practices Act 1974*? What checks were done?

Answer:

Statutory price reductions and price disclosure are not new programs. Both were previously introduced in the 2007 PBS Reform legislation.

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.

The provision for a minimum average 23 percent price reduction on 1 April 2012 across the non exempt medicines in F2 that become subject to price disclosure on 1 December 2010 does not mean that each individual drug will be 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 percent 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.

If the average price reduction is greater than 23 percent then there will be no further adjustment to the calculated price reduction for any F2 medicine. In the event that the overall 23 percent price reduction is not initially achieved, prices will be further reduced to achieve the required 23 percent reduction overall.

Prices will not be reduced below the lowest disclosed price, that is, below the lowest price at which brands of a medicine are offered for sale, based on information collected from industry. The price of medicines with average discounting of less than 10 percent will not be affected by price disclosure, in line with current arrangements.