

28 July 2014

Committee Secretary
Senate Standing Committee on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Secretary,

Inquiry into the National Health Amendment (Pharmaceutical Benefits) Bill 2014

Medicines Australia would like to thank the Committee for its invitation to provide a submission to this inquiry.

The amendments contained within this Bill, if passed, will mean that from 1 January 2015:

- The concessional patient co-payment will have an increase of 80 cents;
- The general patient co-payment will have an increase of \$5.00;
- The concessional safety net threshold will increase by two prescriptions each year for four years, to 2018; and
- The general patient safety net threshold will increase by 10 per cent each year for four years, to 2018.

Medicines Australia's submission will reaffirm:

- The proven sustainability of the Pharmaceutical Benefits Scheme (PBS) and the ongoing accrual of savings in the PBS as a result of years of widespread and iterative reforms implemented by successive governments
- The pressure being felt by the industry and therefore that no further reform of the PBS is necessary
- A summary of research on the effect of previous co-payment changes on access to medicines, and potential for shifting healthcare costs
- Medicines Australia's support for the direction of anticipated savings into a Medical Research Future Fund and future investment in the PBS

Recommendations

No further reform of the PBS is necessary

Introduction of co-payment and/or safety net threshold increases should take into account the impact on preventative and chronic health management

Savings must be reinvested into medicines research and the PBS to ensure ongoing access to innovative medicines

Introduction

As the peak body representing the innovative pharmaceutical industry in Australia, Medicines Australia member companies are responsible for the discovery, research, development and commercialisation of up to 86% of medicines by value available through the PBS. Last year, our industry generated around \$4 billion in exports and invested over \$1 billion in medical research in Australia. As recognised within Australia's National Medicines Policy, our members are critical stakeholders in the long term delivery of healthcare and productivity to the community.

The primary mechanism for providing Australian health consumers with access to pharmaceutical products is through the PBS. Since its inception in 1948, it has evolved into a scheme of universal medicine coverage. This role has been captured by the National Medicines Policy, which lists as one of its ongoing objectives timely access to the medicines that Australians need, at a cost individuals and the community can afford.¹

The success of the PBS is reflected in the fact that Australians enjoy one of the longest life expectancies in the world.²

Medicines Australia considers a co-payment system for medicines is appropriate, as it aims to balance: access to treatments, cost to taxpayers and consumers, and community support for national healthcare. Medicines Australia further acknowledges the task faced by the Australian Government to balance the Budget over coming years to ensure that Health portfolio spending remains sustainable over the long term, whilst maintaining pace with comparable jurisdictions and an ageing demographic.

Nonetheless, there is evidence demonstrating that increasing patient contributions by adjusting co-payment rates and safety net thresholds, like any price increase, will likely result in a reduction in consumer utilisation of medicines. Consumers, such as those on concessional benefits, chronic illness management or preventative treatments, may choose to avoid the additional expense by not filling some, or all, of their scripts. Missing medicines and interrupting treatment may lead to adverse patient outcomes and potentially avoidable medical interventions, including hospital admissions. Reducing the appropriate use of medicines can result in significant additional expenditure in other parts of the healthcare system.

Medicines Australia therefore recommends that preventative and chronic illness healthcare policy should be introduced with these potential flow-on effects taken into account.

PBS sustainability and savings

To ensure the PBS remains on a sustainable footing, successive governments have made widespread and iterative reforms to the Pharmaceutical Benefits Scheme's structure and operation, including co-payment rate and safety net threshold increases, as well as pricing reforms affecting manufacturers, wholesalers and pharmacy.

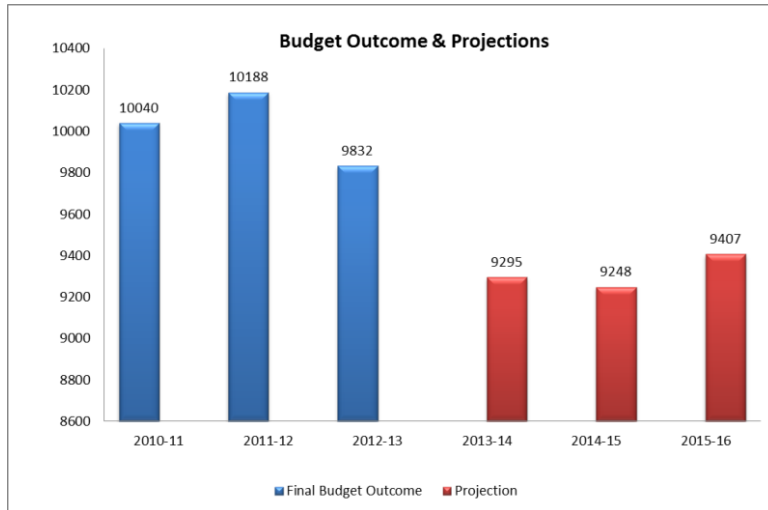
The success of these reforms, particularly the price disclosure reforms initiated by the Howard Coalition Government in 2007 and expanded in 2010 and 2013, is demonstrated by Budget figures on actual and predicted PBS spending (Figure 1). PBS expenditure has

¹ National Medicines Policy, www.health.gov.au

² OECD Health Statistics 2013, <http://dx.doi.org/10.1787/health-data-en>

plateaued since the implementation of the initial reforms and actually fell by 3.5% last financial year.

Figure 1



Source:

Final Budget Outcomes Appendix A:
Expenses by Function and Sub-function
2012/13, 2011/12, 2010/11 &
Budget 2014-15

Furthermore, cumulative savings from the 2007 and 2010 Price Disclosure Reforms are estimated to total \$17.85 billion by 2017-18.³ This figure does not include estimated additional savings of \$835 million from 'Simplified Price Disclosure'⁴ reforms passed by Parliament earlier this year, and applying to PBS medicines subject to price disclosure from 1 October 2014.

The consequences of these reforms have put significant pressure on the pharmaceutical industry, threatening the viability of the industry in Australia. A stable and predictable policy environment is required to re-establish confidence and to encourage future investment in clinical research and manufacturing. The following negative effects on the industry are now apparent:

- Declining exports. While medicines are still our leading industry of manufactured goods, they have declined significantly over the past 12 months. In the year to February 2014, exports were just \$3.444 billion, compared to \$4.281 billion at the same time last year, a decline of roughly 20%.⁵ This decline, after a decade of positive growth year on year, is extremely concerning.
- Declining R&D from clinical trials. The level of clinical trial activity in Australia declined by over 30% between 2007 and 2010, and, despite increases in activity in 2011 and 2012, Australia's share of global investment in clinical trials continues to fall. Given that it is estimated that \$650m is invested in clinical trials and over \$1 billion in overall R&D, this negative trend is of great concern to the industry.⁶

³ Centre for Strategic Economic Studies, The Impact of Further PBS Reforms, May 2013:
<http://medicinesaustralia.com.au/files/2010/01/20130515-rep-The-Impact-of-Further-PBS-Reforms-Final-report-from-CSES.pdf>

⁴ Economic Statement, Simplified Price Disclosure, August 2013

⁵ Australian Bureau of Statistics, International Trade in Goods and Services, Feb 2014:

<http://abs.gov.au/AUSSTATS/abs@.nsf/allprimarymainfeatures/7ACC2D3F5FFB2894CA257CCF001BAB9C?opendocument>

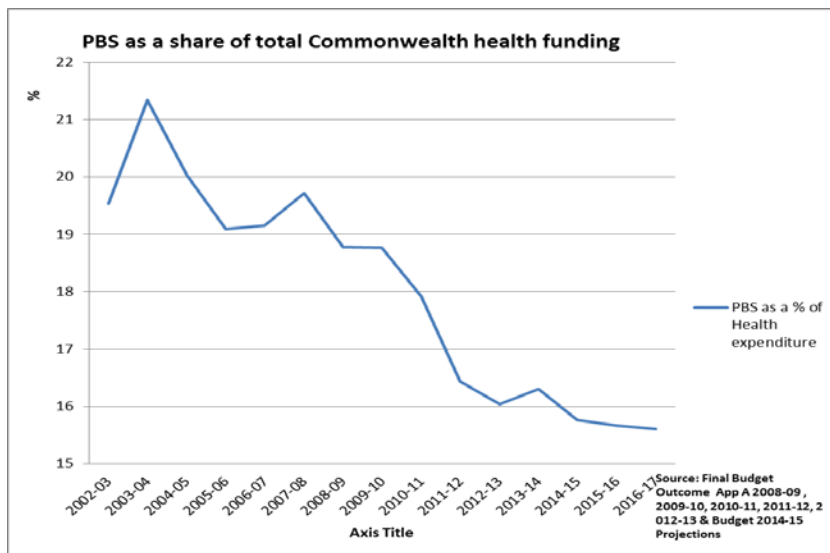
⁶ Therapeutic Goods Administration Half-Yearly Performance reports, Clinical Trials (Medicines). Source:

<http://tga.gov.au/pdf/tga-performance-report-1213.pdf>

- Significant restructuring and job losses in many companies affected by the extent and expansion of the reforms.

In conjunction with rapidly increasing Medicare Benefits Scheme (MBS) expenditure and funding allocations to hospitals, the PBS has fallen as a percentage of total Health spending from a peak of 21% in 2003-04 (prior to the introduction of the initial reforms), to 16% in 2012-13 (see Figure 2). This is expected to continue to decline over the Forward Estimates.

Figure 2



These outcomes indicate that any further structural reforms of the PBS to generate further savings are unwarranted for the foreseeable future, because current measures have placed the PBS on a sustainable path. Medicines Australia therefore encourages measures that will ensure that all savings are reinvested into the PBS to allow continued listing of new and innovative treatments as they become available for patients in Australia.

Research on effect of co-payments on utilisation

Research conducted on a previous one-off co-payment increase in Australia, in 2005, showed that immediately following the co-payment increase to PBS prescriptions, there was a temporary decrease in dispensing volumes in 12 of 17 medicines categories of between 3.2% and 10.9% (lasting some months).⁷ This fall in volumes was identified across a range of treatments, particularly for treatments for asymptomatic conditions such medicines to treat high blood pressure and high cholesterol, as well as those with cheaper over-the-counter options; but also included such medicines as anti-epileptics, anti-Parkinson's treatments, asthma medicines and osteoporosis treatments.

Medicines Australia notes, however, that the 2005 co-payment increase constituted a 24% rise in consumer cost of prescriptions, whereas the current proposed increase constitutes a rise of approximately 13%.

Researchers have also found that the effect of co-payment increases on lower socio-economic consumers is more pronounced. Studies indicate that the decrease in

⁷ *Pharmacoepidemiology and Drug Safety* 2008 Nov;17(11):1091-9, "The impact of co-payment increases on dispensings of government-subsidised medicines in Australia." Hynd A1, Roughead EE, Preen DB, Glover J, Bulsara M, Semmens J.

prescriptions to consumers on social security benefits, such as seniors, was greater than the impact on consumers with no concessional benefits.⁸ These findings were reflected in another study by the same authors in 2009, which found the volume of prescriptions to concessional beneficiaries were between 4% and 5% lower than prescriptions for general beneficiary patients.

Patients may choose to modify or cease their prescribed medicines.⁹ For example, international studies have shown emergency department attendances and hospitalisations increased after decrease in medication utilisation associated with co-payment increase.¹⁰ These findings suggest that increases in patient contributions do impact on concessional patients' access to prescription medicines.¹¹ It seems apparent that higher co-payments are a barrier to seeking care for patients with lower incomes, and remedial measures should be considered when introducing such policies.¹²

The proposed staging of annual increases in safety net thresholds for concessional and general patients will minimise any 'cost shock' for consumers and is less likely to have an effect on medicine access. Additionally, implementation of remedial measures to minimise or to correct any barriers to patients receiving the medicines necessary for maintain good health could also be considered.

Directing Savings to Research Fund and Re-investment in the PBS

Medicines Australia takes this opportunity to reiterate its support for the Government's Budget proposal to direct all savings generated in the Health portfolio into a \$20 billion Medical Research Future Fund.

Such a Fund will stimulate collaboration between Government and a strong existing pharmaceutical research and development sector. Medicines Australia is keen to work with the Government to make this Fund, and the medical and health benefits it will deliver to future generations of Australians, a reality.

It is important that the governance of this fund is strong and directed at driving outcomes for patients from Australian medical research. It should also ensure intellectual property is captured and the fund has a share in this IP, so that commercially successful projects can be reinvested into the fund to the benefit of future generations of Australians. Medicines Australia is willing to contribute the expertise of its members in achieving outcomes-orientated medical research.

Measures that will encourage clinical research and promote access to innovative medicines are critical to the National Medicines Policy and the ongoing viability of the medicines industry in Australia

⁸ Ibid

⁹UWA School of Population Health, ACERH Policy Forum 2009 "The impact of PBS co-payment increases on the use of prescription medicines."

¹⁰ JAMA 2001; 285: 421–429, "Adverse events associated with prescription drug cost-sharing among poor and elderly persons", Tamblin R, Laprise R, Hanley JA, et al.
See also: JAMA 2007; 298: 61–69, "Prescription drug cost sharing: associations with medication and medical utilization and spending and health", Goldman DP, Joyce GF, Zheng Y
"The Effect of Copayments for Prescriptions on Adherence to Prescription Medicines in Publicly Insured Populations; A Systematic Review and Meta-Analysis", Sinnott et al,
<http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0064914>, Published: May 28, 2013

¹¹ *Aust N Z Journal of Public Health*. 2009 Jun;33(3):246-52. "Increased patient co-payments and changes in PBS-subsidised prescription medicines dispensed in Western Australia," Hynd A1, Roughead EE, et al.

¹² *New England Journal of Medicine* 1983, v309. 1426–1435. "Does free care improve adults' health?" Brook R, Ware J, Rogers W, Keeler E, Davies A, et al

Recommendations

Medicines Australia recommends that the Government provide a stable and predictable policy environment for the PBS, and acknowledge that no further reforms are necessary given the negative growth of the PBS and impact of current reforms on exports, R&D and jobs. Ongoing work must be undertaken to ensure Australians continue to have timely access to the latest medicines and maintain the universality of the PBS.

Medicines Australia further recommends that the impact of co-payment changes on general and concessional prescription volumes should be taken into account, and consideration given to promote appropriate continued access to medicines.

For example, monitoring would assist Government in developing complementary health policies, if it becomes evident that certain categories of conditions, or consumers, are experiencing reduced access to medicines.

Finally, Medicines Australia supports re-investment of savings from into the PBS, either through the MRFF or direct investment, to ensure ongoing access to new medicines for Australian patients.

If you or the Committee require any additional information, I would be pleased to assist.

Yours sincerely

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Chief Executive Officer