

17 July 2011

Senator Scott Ryan  
Chairperson  
c/o Committee Secretary  
Senate Finance and Administration References Committee  
PO Box 6100  
Parliament House  
CANBERRA ACT 2600

Dear Senator Ryan,

**Senate Finance and Public Administration References Committee  
inquiry into the Government's administration of the Pharmaceutical  
Benefits Scheme (PBS)**

I am pleased to present Medicines Australia's submission to the Australian Senate Finance and Public Administration References Committee inquiry into the Government's administration of the Pharmaceutical Benefits Scheme

Medicines Australia represents the innovative pharmaceutical industry in Australia. Our 50+ member companies supply more than 80 per cent of the medicines that are available to Australians through the Pharmaceutical Benefits Scheme. Medicines Australia's members also invest more than \$1 billion annually in local research and development, contribute over \$4 billion in high-tech exports to the Australian economy, and employ over 14,000 people.

Medicines Australia opposes the recent decision of the Australian Government to formally and indefinitely defer the listing on the PBS of a number of PBAC recommended medicines. Each of these medicines had undergone rigorous assessment and evaluation by the PBAC, and each had been recommended by the PBAC on the grounds of demonstrated clinical and cost-effectiveness.

Medicines Australia also opposes the recent decision of the Australian Government to deviate from long-standing practice and convention concerning Cabinet approval for the PBS listing of PBAC recommended medicines.

These actions undermine the timely and affordable access of medicines that Australian need. They also risk politicising the Pharmaceutical Benefits Scheme, admired world-wide for its apolitical, evidence-based approach to funding medicines.

As this submission shows, the Government has also acted in a way that undermines business confidence in the Australian market, therefore compromising future access to medicines for patients. A number of Medicines Australia's member companies are reconsidering whether to launch new medicines in Australia due to the business uncertainty that these recent actions have created.

The Australian government's actions come barely months after Medicines Australia had signed a Memorandum of Understanding (MoU) with the Commonwealth of Australia on the management of the Pharmaceutical Benefits Scheme. This MoU delivered a minimum of \$1.9billion in PBS savings to the Australian Government. In return, Medicines Australia had sought, and thought it had achieved, a period of business and policy stability for its members.

Medicines Australia strongly believes that the Australian Government has breached the intent, if not strictly the letter, of this agreement. By deviating from long-standing practices and conventions in the PBS listing process, the Australian Government has significantly changed the business environment for companies in Australia; and has done so without any consultation. It has also done this by restricting Australians' access to medicines.

Amongst other things, the submission calls for the Australian Government to act on the recommendations of the PBAC and immediately list the medicines it has deferred, and for the Australian Government to return to its previous practice of listing medicines recommended to it by the PBAC.

Medicines Australia is happy to make itself available to appear as a witness before the Senate Committee, should it be so invited.

Please do not hesitate to contact me should you require any additional information or clarification of any matter presented in this submission.

Yours sincerely

Dr Brendan Shaw  
Chief Executive

# MEDICINES

*Australia*

Better Health through Research and Innovation

**Submission to the Senate Finance and Public  
Administration Committee Inquiry into:**

**‘The Government’s Administration of  
the Pharmaceutical Benefits Scheme’**

**18 July 2011**

## Executive Summary

The Pharmaceutical Benefits Scheme (PBS) is widely acknowledged to be the hallmark of Australia's health care system<sup>1</sup>. For over 60 years, the PBS has served as the key means of providing Australians with timely and affordable access to the medicines they need. Recent actions by the Australian Government have put such timely access to medicines at risk.

Fundamental to Australians' ongoing access to new medicines is the need to ensure that robust and independent expertise is applied to decisions about the listing of new medicines on the PBS. For this reason, Medicines Australia has long supported the role of the Pharmaceutical Benefits Advisory Committee (PBAC) under the National Health Act 1953 as the independent grouping of experts best placed to recommend which medicines should be subsidised on the PBS. Whilst the industry and the PBAC may occasionally disagree about particular processes, evidentiary requirements and decisions, the PBAC enjoys the respect of Australia's medicines industry.

The PBAC is required by the Act to consider both the effectiveness and cost when making its recommendations for listing. Since 1993, the PBAC has also been required to advise the Minister and the Pharmaceutical Benefits Pricing Authority on a medicine's "value for money" (or relative cost-effectiveness). International comparisons have shown that the PBAC's requirements for clinical data and evaluation rigour are some of the most demanding in the OECD. The robustness of the PBS listing process means that Australia pays some of the lowest prices for innovator medicines in the OECD, spends well below the OECD average on prescription medicines as a proportion of GDP, and has maintained expenditure to between 0.6% and 0.65% of GDP for well over a decade despite a rapidly ageing population.

In February 2011, the Australian Government announced that it would defer the listings of 7 medicines and vaccines on the PBS and the National Immunisation Program. Each of these medicines had undergone rigorous assessment and evaluation by the PBAC, and each had been recommended by the PBAC on the grounds of demonstrated clinical and cost-effectiveness.

At the same time, the Australian Government announced that it would henceforth require that all medicines recommended by the PBAC for listing on the PBS be considered and approved by the Federal Cabinet prior to listing. This is a significant

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<sup>1</sup> Prime Minister the Hon. Julia Gillard, "Indeed, our PBS is very much envied by nations around the world," Hansard, House of Representatives, 1 June 2011 at page 52. Available online at: <http://www.aph.gov.au/hansard/reps/dailys/dr010611.pdf>.

deviation from the long-standing practice of requiring Cabinet approval only for those new medicines with an anticipated budgetary impact of \$10million per annum or more. And it contradicts recommendations from both the Productivity Commission and the Senate Community Affairs References Committee to lift the \$10million “threshold” in the interest of providing more timely access to medicines.

There is widespread disappointment in the community at this refusal to list on the PBS cost-effective medicines. For many it signals an overt politicisation of a long-standing, evidence-based institution and process. It is a very worrying development if Australia, even as a relatively wealthy industrialised country with one of the best fiscal positions of the industrialised world, cannot afford to provide new medicines for sick people.

The actual and potential impact on the Australian community of the Government’s decision should not be understated. Australian consumers have good reasons to be concerned. Not only has the Government decided to ignore PBAC recommendations to list cost-effective medicines, the Government has acted in a way that severely undermines business confidence in the Australian market, therefore compromising future access to medicines.

Medicines Australia has been informed by a number of its member companies that they are reconsidering whether to launch new medicines in Australia. A survey of member companies revealed that a number were seriously considering delaying various new medicines in the areas of cancer, diabetes, cardiovascular, and mental health. Medicines Australia is also aware that the Cabinet deferrals decision *has* made it more difficult for a number of companies to attract clinical trials investment to Australia.

Significantly, the Government’s action comes barely months after Medicines Australia signed, in the presence of the former Prime Minister, a Memorandum of Understanding with the Commonwealth of Australia on the management of the PBS. Through this agreement, Medicines Australia agreed to deliver the Australian Government a series of pricing policy changes and price cuts estimated to deliver a minimum \$1.9billion in savings to the PBS. In return, Medicines Australia sought, and believed it had achieved, a stable and predictable business and policy environment for the Australian medicines industry.

Medicines Australia is very concerned that the commitments made by the Australian Government in the MoU are now seriously in doubt because of the impacts that the Australian Government’s decision to review and potentially defer all new PBS medicines will have on industry, clinicians and ultimately patients. This submission details specifically that:

- a) The deferral of cost-effective medicines is unprecedented and politicises the otherwise rational, evidence-based PBAC process;
- b) The deferrals undermine the first objective of Australia's National Medicines Policy: *timely access to the medicines that Australians need, at a cost individuals and the community can afford*;
- c) By moving away from a rigorous, evidence-based and apolitical PBAC process for determining PBS listing, the Government has introduced significant uncertainty and instability into the market;
- d) A number of member companies have informed Medicines Australia that they are seriously considering delaying or simply not lodging a submission for PBS listing due to the Cabinet's decision to defer listing new medicines;
- e) To the best of Medicines Australia's knowledge, there are no official criteria for determining which PBAC recommended medicines will be deferred by the Government; Medicines Australia believes that Cabinet is not best placed to adjudicate on the clinical need, relative "value-for-money" of individual medicines and whether there are alternative treatments available;
- f) Each of the deferred medicines was recommended based on its relative cost-effectiveness, and the failure to list these medicines will result in health and productivity losses making it highly probable that the long-term cost of the Cabinet's decision will greatly outweigh the short-term financial gain;
- g) No consultations with Medicines Australia or the affected companies were conducted prior to the decision to defer the listing of medicines on the PBS;
- h) Medicines Australia believes that the Government's decision to defer the listing of PBS medicines and change the way Cabinet reviews them is a clear breach of the intent, if not strictly the letter, of the MoU; and
- i) Medicines Australia is concerned about ongoing suggestions that current PBS growth is inappropriately high, and therefore a threat to the long-term sustainability of the PBS.

The decision to require Cabinet to approve all new PBS listings and to defer the listing of medicines is a bad policy decision. Whilst it clearly has an adverse impact on industry, ultimately it is Australians that miss out on access to new medical treatments in the future as a result of the uncertainty created by the Australian Government. As such it should be overturned with a view to respecting fully both the intent and letter of the MoU.

## Recommendations

Medicines Australia urges the Committee to recommend that:

1. Australians' timely and affordable access to medicines as stipulated in the National Medicines Policy continues to be preserved.
2. the Government act on the recommendations of the PBAC and immediately list the medicines it has deferred.

3. the Government return to its previous practice of listing medicines recommended to it by the PBAC, including the Cabinet review processes that were in place prior to February 25 2011.
4. the importance of the MoU in providing a framework to manage the long- term sustainability and efficiency of the PBS be recognised and endorsed; and that the Committee support, by the provision of a stable pricing policy environment, a viable and responsible medicines industry in Australia, consistent with the objectives of the National Medicines Policy
5. the importance of Australian governments of all political persuasions honouring the letter and intent of agreements that they enter into with all sections of the Australian community, not least the business sector, be recognised and supported.

## Introduction

In February 2011, the Australian Government announced that it would defer the listings of seven medicines and vaccines on the Pharmaceutical Benefits Scheme (PBS) and the National Immunisation Program (NIP). Each of these medicines had undergone rigorous assessment and evaluation by the Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert committee established under the *National Health Act 1953* (the Act), and each had been recommended by the PBAC on the grounds of demonstrated clinical and cost-effectiveness.

At the same time, the Australian Government announced that it would henceforth require that all medicines recommended by the PBAC for listing on the PBS be considered and approved by the Federal Cabinet prior to listing. This is a significant deviation from the long-standing practice of requiring Cabinet approval only for those new medicines with an anticipated budgetary impact of \$10million per annum or more.<sup>2</sup> And it contradicts the recent Government-supported Senate Committee recommendation to lift the \$10million “threshold” in the interest of providing more timely access to medicines.<sup>3</sup>

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<sup>2</sup> This long-standing policy and practice has been described in a number of Australian Government documents and publications. A succinct description can be found in the Australian Government Department of Health and Ageing’s report, “Review of Health Technology Assessment in Australia,” December 2009, at p.46:

“Once PBAC has recommended a pharmaceutical for listing on the PBS, the Pharmaceutical Benefits Pricing Authority (PBPA) makes a recommendation on the proposed price for a new PBS item based on advice from PBAC, including consultation with the applicant and other sources. Where the projected net cost is less than \$10million per annum, the Minister notes the advice, and a delegate (of the Minister) approves the inclusion of the product on the PBS. If the projected cost is greater than \$10 million per annum, then approval by the Minister and Cabinet within the context of broader government priorities is required. The Minister (or delegate) then authorises the inclusion of pharmaceuticals in legislative instruments which gives rise to the PBS.”

Available online at:

[http://www.health.gov.au/internet/main/publishing.nsf/Content/00E847C9D69395B9CA25768F007F589A/\\$File/hta-review-report.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/00E847C9D69395B9CA25768F007F589A/$File/hta-review-report.pdf)

<sup>3</sup> See Senate Community Affairs References Committee Inquiry into Consumer Access to Pharmaceutical Benefits Report, November 2010. After considering the relative costs and benefits of adjusting the threshold, the Committee unanimously recommended at p.ix:

“Recommendation 4

- in the interest of Australian patients having timely access to necessary medicines... the threshold for Cabinet consideration of high cost medicines be adjusted, initially to the value the threshold would have had, had it been indexed annually since 2001;
- subsequently, the threshold should be indexed annually; and
- the Department of Health and Ageing examine the most appropriate indicator for indexing the threshold.”

Available online at:

[http://www.aph.gov.au/Senate/committee/clac\\_ctte/consumer\\_access\\_pharm\\_benefits\\_43/report/report.pdf](http://www.aph.gov.au/Senate/committee/clac_ctte/consumer_access_pharm_benefits_43/report/report.pdf)

Significantly, the Committee also noted at page 26, that the Productivity Commission had previously recommended in the “Annual Review of Regulatory Burden on Business: Manufacturing and Distributive Trades 16 September 2008, p.80, that “the Government should consider the merits of increasing the threshold to account for price changes over the past six years and implementing an automatic annual indexation adjustment.”



This action occurred barely months after the signing of a Memorandum of Understanding between Medicines Australia and the Commonwealth of Australia on the management of the PBS. This MoU delivered the taxpayer a minimum of \$1.9billion in savings to the PBS in return for a period of business and policy stability for the Australian pharmaceuticals industry. Medicines Australia believes that the Government has breached the intent, if not strictly the letter, of this MoU through the actions described above and by doing so has put Australians timely access to current and future medicines at risk.

This submission responds to each of the Inquiry Terms of Reference in turn:

***(a) the deferral of listing medicines on the PBS that have been recommended by the Pharmaceutical Benefits Advisory Committee***

The decision to formally and indefinitely ***defer*** a PBS listing of a cost-effective medicine following a positive PBAC recommendation ***is*** unprecedented. It calls into question the Australian Government's commitment to a rational, evidence-based and apolitical process for providing timely and equitable access to affordable medicines to the Australian community. Furthermore, it is politicians, in the form of Federal Cabinet, who are now positioned as the experts who determine which cost-effective medicines are needed, by whom, and by when. The Secretary of the Department of Health and Ageing's acknowledgement that there are no formal criteria against which Cabinet will consider the listing of cost-effective medicines<sup>4</sup> suggests the future access of Australians to medicines is being transformed into a political lottery.

The Australian Government through its actions and statements has explicitly signalled the politicisation of the PBS, a pillar of the National Medicines Policy, and the Australian health system. It has stated that it will continue to defer the listing of some medicines in order to return the Budget to surplus by 2012-2013. To meet this deadline the Government will sacrifice expenditure on medicines which have been rigorously assessed for clinical and cost-effectiveness in favour of funding programs (health or otherwise) for which no such comparable evidence-based assessment or cost-benefit analysis has been undertaken.

Recent statements suggest the Government is prepared to link access to future medicines to Opposition support for its policies in other areas, most notably its proposed changes to the private health insurance rebate scheme. Minister Roxon recently stated:

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Available online at:

[http://www.pc.gov.au/\\_data/assets/pdf\\_file/0003/83028/manufacturing-regulatory-burdens.pdf](http://www.pc.gov.au/_data/assets/pdf_file/0003/83028/manufacturing-regulatory-burdens.pdf).

<sup>4</sup> Senate Community Affairs Legislation Committee, Budget Estimates Hansard, 31 May 2011 at p. 91. Available online at: <http://www.aph.gov.au/hansard/senate/commtee/s83.pdf>; see also, discussion of this topic at Term of Reference (e) in this submission.

"...in the future, listing innovative new drugs like Erbitux and Gilenya will become harder and harder if the Opposition continues to block sensible savings measures. It's time for the Opposition to stand up and act responsibly to recognise that savings that are captured in measures like the private health insurance proposals and the Chronic Disease Dental Scheme are essential if we are to keep Australia's health system and Pharmaceutical Benefits Scheme sustainable."

and

"We need to be able to do that and this is a very important long term question, I think, for the Opposition to have to start behaving responsibly if they want these sorts of innovative drugs to be able to be funded in the future."<sup>5</sup>

There is widespread disappointment in the community at these statements because they represent the over-politicisation of the long-standing, evidence-based process that previously characterised the listing of medicines.<sup>6</sup> It is a very worrying development if Australia cannot afford to provide new, cost-effective medicines for people who need them. It is important to remember that Australia is a relatively wealthy industrialised society, and relative to the rest of the OECD, enjoys one of the strongest fiscal positions of all highly developed nations.

The actual and potential impact on the Australian community of the Government's decision should not be understated. Australian patients have good reasons to be concerned. Not only has the Government decided to ignore PBAC recommendations to list cost-effective medicines, the Government has acted in a way that severely undermines business confidence in the Australian market, therefore compromising future access to medicines.

Medicines Australia has been informed by a number of its member companies that they are reconsidering whether to launch new medicines in Australia. The high upfront investment costs required to bring a medicine to Australia need to be weighed against the uncertainty that the deferrals have generated. Australia is already regarded as a very difficult market to enter with a high regulatory burden (i.e. market entry costs) relative to other OECD countries.<sup>7</sup>

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<sup>5</sup> Minister Roxon press conference, Canberra, 21 June 2011, topics: Pharmaceutical Benefits Scheme Listings, Erbitux, Private Health Insurance, Podiatric Surgeons. Transcript available online: <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/tr-yr11-nr-nrsp210611.htm?OpenDocument&yr=2011&mh=06>.

<sup>6</sup> See for example the campaign by the Consumers Health Forum statement [www.chf.org.au/files/Poster.pdf](http://www.chf.org.au/files/Poster.pdf)

<sup>7</sup> OECD, "Pharmaceutical Pricing Policies in Global Market 2008" at pp. 161-166.

There is an additional price to pay for this beyond Australians' access to medicines. Industry investment in Australian clinical trials and manufacturing continues to decline<sup>8</sup>, and the injection of further uncertainty into the business environment will not help to abate it. Medicines Australia is aware that the Cabinet deferrals decision *has* made it more difficult for a number of companies to attract clinical trials to Australia.

Most significantly, the Government's action comes barely months after Medicines Australia signed, in the presence of the former Prime Minister, a Memorandum of Understanding with the Commonwealth of Australia on the management of the PBS. Through this agreement, Medicines Australia agreed to deliver the Australian Government a series of price cuts estimated to deliver \$1.9billion in savings to the PBS. In return, Medicines Australia sought, and believed it had achieved, a stable and predictable business and policy environment for the Australian medicines industry.

Medicines Australia negotiated the MoU in good faith, has adhered to its terms and intends to adhere to both the letter and the spirit of that agreement through to 2014—an intention that is not evident in the Government's recent actions. There will be some who argue that the Government's recent actions do not explicitly breach the letter of this agreement; this is a moot point, as it breaches the *intent* of the agreement. The actions also came after the Government had locked away \$1.9billion in savings through legislation, largely with the support of Medicines Australia.

#### ***b) Any consequences for patients of such deferrals***

The Australian Government's recent actions undermine the first objective of Australia's National Medicines Policy: *timely access to the medicines that Australians need, at a cost individuals and the community can afford*. Importantly, the actions undermine long-established conventions and processes put in place to achieve this, including the role and authority of the PBAC, an institution the medicines industry respects and supports.

The PBAC is an independent, expert committee established under the *National Health Act 1953* (the Act). Its role is to recommend to the Minister which medicines and vaccines should be subsidised by the Australian Government under the PBS.

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<sup>8</sup> Australian Government, Department of Health and Ageing, Therapeutic Goods Administration, Half-Yearly Performance Report, Clinical Trials (Medicines), July - December 2010. See also, Australian Government, Department of Innovation, Industry, Science and Research, Pharmaceuticals Industry Strategy Group Final Report, 30 January 2009, at p.14.

Available online at:

[http://www.innovation.gov.au/Industry/PharmaceuticalsandHealthTechnologies/PharmaceuticalsIndustryStrategyGroup/Documents/PISG\\_Final\\_Report.pdf](http://www.innovation.gov.au/Industry/PharmaceuticalsandHealthTechnologies/PharmaceuticalsIndustryStrategyGroup/Documents/PISG_Final_Report.pdf).

The PBAC is required by the Act to consider both the effectiveness and cost when making its recommendations. Since 1993, the PBAC has also been required to advise the Minister and the Pharmaceutical Benefits Pricing Authority on a medicine's "value for money" (or relative cost-effectiveness).

Publicly available Guidelines state that "to assess value for money, PBAC considers the clinical place, overall effectiveness, cost and cost-effectiveness of a proposed drug compared with other drugs already listed in the PBS for the same, or similar, indications. Where there is no listed alternative, PBAC considers the clinical place, overall effectiveness, cost and cost-effectiveness of the proposed drug compared with standard medical care".<sup>9</sup>

To receive a recommendation for PBS listing, the Guidelines state that the PBAC must be satisfied that the new medicine or vaccine:

- is needed for the prevention or treatment of significant medical conditions not already covered, or inadequately covered, by drugs in the existing list and is of acceptable cost-effectiveness;
- is more effective or less toxic (or both) than a drug already listed for the same indications and is of acceptable cost-effectiveness;
- is at least as effective and safe as a drug already listed for the same indications and is of similar or better cost-effectiveness.

The vast majority of PBAC recommendations for new PBS listings are made following an evaluation and assessment of clinical data and economic modelling submitted by Medicines Australia member companies. International comparisons have shown that the PBAC's requirements for clinical data and evaluation rigour are some of the most demanding in the OECD<sup>10</sup>. The effect of these demands can be seen in the low number of medicines that receive a positive recommendation for listing at any given PBAC meeting, and the average low prices paid for medicines that are eventually listed when compared with other OECD countries.

Publicly available data indicate that cost-effectiveness submissions lodged during 2010 to the PBAC had less than a 35% chance of receiving a positive recommendation.<sup>11</sup> Many

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<sup>9</sup> Australian Government, Department of Health and Ageing, PBAC Guidelines Section 1.3.3, "General guidelines followed by PBAC." Available online at: <http://www.pbs.gov.au/info/industry/listing/elements/pbac-guidelines>.

<sup>10</sup> Kanavos, et al., "The impact of health technology assessments: an international comparison", Euro Observer, Volume 12, Number 4, Winter 2010 at p.1.

<sup>11</sup> Australian Government, Department of Health and Ageing, PBS Activity Indicators "Supportive Indicator 1." Available online at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-activity-indicators-graphs>.

of those rejected will eventually be recommended following multiple submissions (each attracting cost-recovery fees in excess of \$120,000), albeit with high investment costs for market entry.

It is in no small part due to the PBAC that Australia has historically spent, and continues to spend, significantly less on pharmaceuticals than most OECD countries, both relative to the size of economy and as a proportion of total health system expenditure. To some extent, this is due to the low prices that Australia demands as a condition of listing. A 2008 OECD report into global pharmaceutical pricing policies showed that Australia pays the fourth lowest prices for originator medicines relative to economy-wide prices in the OECD.<sup>12</sup> A more recent analysis published in the academic literature not only confirmed the low prices paid for medicines in Australia relative to 15 other OECD countries, but established that health technology assessment frameworks, such as those used by the PBAC, were a significant factor in driving prices for medicines down.<sup>13</sup>

The relatively low expenditure, however, is also partly due to the tight, restrictions that the PBAC puts on the reimbursable use of the medicines.<sup>14</sup> The PBAC is careful to define precisely which patients are entitled to the medicines, and companies are often financially responsible for any use outside of such restrictions. Such financial responsibility is enforced through contractual arrangement, sometimes called Risk Share Agreements, entered into between the supplying company and the Commonwealth of Australia.<sup>15</sup> This ensures that the taxpayer only pays for those patients for which the PBAC believes will benefit in a cost-effective way.

It is against this background that the impact of the deferrals on patients must be considered. Each of the deferred medicines and vaccines had been rigorously evaluated and assessed by the PBAC for clinical and economic value to the Australian community. Each of them met a demonstrated clinical need, and each was to be priced at a point which was considered "value for money" to the Australian taxpayer (explicitly relative to the opportunity cost of the expenditure). Few, if any other, areas of proposed

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<sup>12</sup> OECD, "Pharmaceutical Pricing Policies in a Global Market 2008" at pp. 161-166.

<sup>13</sup> Kanavos, et al, " 'HTA' has a negative and significant coefficient: countries that explicitly use HTA have on average lower prices by 16.2%, compared with those that do not use HTA." See "Determinants of branded prescription medicine prices in OECD countries," Health Economics Policy & Law, 2011 July, at p.354.

<sup>14</sup> Charles River Associates, A Comparative analysis of the role and impact of Health Technology. 2011 Available online at: <http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=11754> at p. 130.

<sup>15</sup> Australian Government, Department of Health and Ageing, Guidelines for Deeds of Agreement for the Pharmaceutical Benefits Scheme. Available online at <http://www.pbs.gov.au/info/industry/listing/elements/deeds-agreement>

Government expenditure are supported by such rigorous analysis of the costs and benefits.

It is thus no surprise that consumers have expressed dismay at the Australian Government for deferring medicines recommended for listing on the PBS.<sup>16</sup> For example, consumers were mystified as to why Cabinet would disregard a PBAC recommendation to list a new long-acting antipsychotic medicine, Invega Sustenna, to treat poorly controlled schizophrenia, when this would reduce clinic visits for patients and carers by 50%, was demonstrated to be faster-acting, and results in a cost-saving to the health system as a whole (if not more narrowly the PBS).

Likewise, the Government is delaying a PBAC recommendation to list a combination analgesic medicine, Targin, for people whose chronic severe disabling pain is not responding to non-narcotic analgesia. Largely to be used by people with advanced cancer and terminal conditions, this medicine was found by the PBAC to provide the additional benefit of avoiding common and often debilitating opioid-induced side-effects which the PBAC accepted to be currently poorly treated in clinical practice. The PBAC also found that listing this medicine may reduce diversion of opioids onto the black market.<sup>17</sup>

What is more, the Government has so far ignored a PBAC recommendation to list Botox for the treatment of severe primary axillary hyperhidrosis (uncontrolled sweating), claiming that for many people this is a mild condition for which other options are available. This is inconsistent with the PBAC's recommendation, represents a

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<sup>16</sup> Consumers Health Forum media release, "CHF and sixty health consumer organisations tell Cabinet to stay out of Australia's medicines, 24 June 2011. Available online at: <https://www.chf.org.au/pdfs/med/med-PBAC-PBS-Poster.pdf>.

See also, Consumers Health Forum, "Summary of Outcomes: PBS Deferral Decision Forum," 29 April 2011. Available online at: <https://www.chf.org.au/files/PBS-Deferral-Decision-Forum---summary-for-web.pdf>.

<sup>17</sup> "The PBAC noted that the BEACH data analysis indicated that there was a low rate of co-prescribing of laxatives in patients receiving prescriptions for opioids. The PBAC also noted that in general GPs are not commencing laxative treatment until patients require such intervention despite opioid treatment best practice guidelines. Additionally, the PBAC also noted that many people purchase over the counter laxatives for this purpose." *and*

The PBAC considered that it was appropriate to list oxycodone with naloxone on the PBS as the availability of this product is likely to increase prophylactic management of OIC, the cost of the product is similar to oxycodone plus an over-the-counter laxative, the product may prevent constipation and not cause diarrhoea, and it may also reduce diversion.

Australian Government, Department of Health and Ageing, PBS Public Summary Document, Oxycodone hydrochloride with naloxone hydrochloride dihydrate, controlled release tablet, November 2010. Available at <http://www.health.gov.au/internet/main/publishing.nsf/Content/pbac-psd-oxycodone-hydrochloride-nov10>

trivialisation of the suffering of these patients and is misleading about the availability of other treatments.

The Government defended this deferral by claiming that for many people axillary hyperhidrosis is mild; however, it is important to note that the PBAC recommendation restricted the use of Botox only to people with severe cases, for whom daily living is impaired, and who have failed other treatments. In publicly available documents the PBAC acknowledged that:

*"there was significant impact on the quality of life of the patients with hyperhidrosis and that there was a clinical need for botulinum toxin."*

Importantly the PBAC also stated that:

*"no other second line treatments for severe hyperhidrosis of the axillae were available on the PBS, and that currently the only option for patients following failure of aluminium based anti-perspirants was surgery."*<sup>18</sup>

The Government's deferrals have not only placed a clinical burden on patients, but a financial burden as well. It was apparent from the initial deferral announcement that the Australian Government was prepared to transfer the cost of treatment to patients. Amongst the initial deferred medicines were fixed-dose combination formulations of existing medicines to treat COPD, severe asthma and prostate problems. The listing of these medicines would have reduced the out-of-pocket expenses for patients by 50% or more and reduced the threat of non-compliance with treatment. Patients requiring any of the other deferred medicines will have to purchase the medicine privately, a cost that can potentially run into the thousands of dollars.<sup>19</sup>

It would appear that through its actions in deferring the listing of cost-effective medicines on the PBS, the Australian Government is moving towards a two-tiered health system. The Cabinet's decision to defer the listing of new medicines on purely fiscal grounds perpetuates a situation where high-income patients can afford better treatments for things like schizophrenia, chronic pain associated with cancer, debilitating excessive sweating and use of combination products, whereas people on lower incomes have to make do. This appears to go against the Government's long-held objective of equity of

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<sup>18</sup> Australian Government, Department of Health and Ageing, PBS Public Summary Document, Botulinum toxin type A purified neurotoxin complex Botox®, November 2009. Available online at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/pbac-psd-Botulinum-nov09>. See also, Public Summary Document, March 2010, available online at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/pbac-psd-Botulinum-mar10>.

<sup>19</sup> The use of botulinum injections to treat severe hyperhidrosis can cost patients \$2700. Betts, Marianne. "Botox gives Chey-Anne more normal life," *Herald Sun*, 7 July 2011. Available online at: <http://www.heraldsun.com.au/news/botox-gives-chey-anne-more-normal-life/story-e6frf7jo-1226090106900>.

access and avoiding the creation of a two-tier health system where the level of care is determined by one's ability to pay.

The Government may counter this assertion by claiming that only medicines with available alternatives are being deferred. This is categorically incorrect in the case of Botox for severe hyperhidrosis of the axillae as the PBAC has noted. It is also misleading for a number of the other deferred products. As discussed above, the PBAC found that Invega Sustenna provides substantial and meaningful patient and carer-related benefits over existing treatment of schizophrenia, including a more rapid-onset of therapeutic effect. Targin was recommended because clinicians are systematically **not** providing appropriate treatment for opioid-induced side-effects. In the case of Symbicort the available alternative is in effect a doubling of the co-payment.

There is also a long-run clinical and economic risk that the Government assumes if it believes that it can save money through restricting clinical options. Firstly, it is a broadly accepted and understood fact that there is often considerable intra-individual variability in response to medicines. Different people can respond quite differently and variedly to the same medicine, a problem that is a much a challenge to the drug development process as it is to regulatory and reimbursement regimes.<sup>20</sup> It is thus generally preferable for clinicians to have access to a variety of therapeutic options, especially in such difficult to treat areas as mental health and pain where inadequate response or even treatment failure is common. In short, restricting options means restricting health outcomes. Secondly, by deferring the listings of medicines for which the Government believes there to be existing alternatives, it is restricting the market competition which in the long run, due to the design of the PBS market, delivers the taxpayer ongoing savings. In the end it is the consumer and taxpayer who lose out in both cases.

The effect of the Government's decision on deferrals thus goes well beyond restricting access to cost-effective medicines and vaccines for which the PBAC has identified a clinical need. Most importantly, it conflicts with the Australian Government's commitment to a rational, evidence-based and apolitical process for providing timely and equitable access to affordable medicines to the Australian community. For patients, this means that it is now Cabinet, and not independent experts, who will determine which cost-effective medicines are needed by whom and when. Cabinet's capacity to make these

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<sup>20</sup> Eichler, Abadie, Breckenridge, Flamion, Gustafsson et al. "Bridging the efficacy-effectiveness gap: a regulator's perspective on addressing variability of drug response", *Nature Reviews Drug Discovery*. 10, 495-506 (July 2011)



decisions, and the effectiveness and accuracy of this approach, is questionable as evidenced by the fact that two of the initial seven deferrals have since been overturned. Moreover, because Cabinet's decisions in this regard are in-confidence, the industry is left guessing as to the reasons why Cabinet defers the listing of medicines on the PBS, the criteria that are used and the reasons previous deferrals are overturned. This is directly at odds with the intent of the MoU to provide predictability for business and creates enormous uncertainty for companies trying to bring new medicines to Australians into the future.

The risk is that community faith in the PBS and its processes is being undermined by this decision. For example, consumer groups have repeatedly expressed concern that the PBS listing process is now being politicised and linked to other policy objectives unrelated to the PBS, such as returning the Budget to surplus by 2012-13.

*(c) any consequences for the pharmaceutical sector of such deferrals*

As for patients, the impact for the pharmaceutical sector of the Government's deferrals decision extends well beyond the cost to industry of the actual seven deferred listings, as significant as this cost was in itself.

Many of the affected companies incurred significant financial losses as a result of the sudden and unanticipated announcement of the deferrals in February. To meet the Government's own listing requirements, affected companies had purchased and warehoused stock (all of which carry expiry dates), employed people, established post-approval trials and monitoring programs for pharmacovigilance and invested heavily in education programs so that the medicines could be used safely and effectively. Much of this expense could not be recouped and became deadweight loss to the companies (and therefore to the Australian economy) as a result of the deferrals. Apart from the instant financial losses, companies are unsure whether to make further investment, place launch plans on hold or cease investment altogether.

The Government's action has resulted in a significant loss of confidence in the business environment. For legitimate social policy reasons, the Australian Government has positioned itself as an effective monopsonist for pharmaceuticals. The industry is dependent upon the Government, as a sole purchaser, behaving in a consistent and predictable manner in order to ensure that it can invest with confidence in the Australian market. Given the high upfront investment costs required to bring a medicine to Australia, such confidence is highly sensitive to sudden changes in Government purchasing policy and practice. The new Cabinet approach on deferrals, by moving away

from a rigorous, evidence-based and apolitical process for determining PBS listing, has introduced significant uncertainty into the market that is already regarded as difficult with a high regulatory burden relative to other OECD countries. It was this type of uncertainty that the MoU was designed to overcome.

A number of member companies have informed Medicines Australia that they are seriously considering delaying or simply not lodging a submission for PBS listing due to the uncertainty the Government's decision has created. The decision to bring medicines to Australia involves considerable financial commitment on behalf of a company, much of which is upfront. Submissions to the TGA and PBAC attract sizable cost-recovery fees of \$200,000 and \$120,000 respectively regardless of the market-size of the medicine, and which are borne again should a full resubmission be required. (N.B it currently takes 2.2 submissions on average to receive a positive PBAC recommendation). Prior to a PBS listing companies need to purchase and warehouse perishable stock in order to meet the government's own listing requirements and timetable, employ and train staff to support the safe and effective use of the new medicine, and put in place post-marketing programs to monitor such use. All of this can add up to upfront investments totalling many millions of dollars.

The uncertainty in the business environment also seriously hampers local affiliates' ability to compete with those in other countries for investment by head offices in clinical trials and manufacturing – both of which are in decline in Australia.

This collapse in business confidence is not simply the result of the Cabinet's decision to micro-manage the PBS and defer the listing of medicines *per se*. It is the result of the deferrals being announced barely months after Medicines Australia signed a Memorandum of Understanding with the Commonwealth of Australia on the management of the PBS. Through this agreement, Medicines Australia delivered the Australian Government a set of major price reductions estimated to save the Government a minimum of \$1.9billion in savings to the PBS. This was not an easy task, as described in Medicines Australia's submission to the Senate Community Affairs Legislation Committee's Inquiry into the MoU:

"It is important to stress that Medicines Australia did not take the decision to enter into the MoU lightly. The \$1.86billion in savings will hit the industry hard; and as providers of over 86% of the PBS, it is Medicines Australia's members that will bear the overwhelming burden of these savings. Nonetheless, Medicines Australia entered into this agreement to demonstrate that the Australian medicines industry as a responsible fiscal partner in the long-term management of the approximately \$8 billion-a-year Pharmaceuticals Benefit Scheme."<sup>21</sup>

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<sup>21</sup> Medicines Australia, submission to the Australian Senate Community Affairs Legislation Committee "Inquiry into the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010*," 20 August 2010, at p.9.

Against the background of the Global Financial Crisis, the resulting budget deficit and the stated need for the Government to fund a \$8.4billion health reform agenda, Medicines Australia agreed to assist the Australian Government in finding ongoing savings to its PBS expenditure. The Minister for Health and Ageing stated last year in her Second Reading speech in the Parliament when introducing the MoU related legislation:

The negotiations embodied “an historic level of cooperation and collaboration between the government and the pharmaceutical industry, represented by Medicines Australia. Through jointly negotiating these reforms, the government and the industry will help ensure the sustainability of the PBS in years to come.”<sup>22</sup>

In return for such cooperation and collaboration, Medicines Australia sought, and thought it had achieved, a stable and predictable business and policy environment for the Australian pharmaceuticals industry. In light of the deferrals, its member companies are questioning how the MoU will now deliver these objectives. Barely months after the final version of the MoU had been signed, after the Government had secured its savings through legislation with the support of Medicines Australia, the Australian Government changed the rules and removed the stability and predictability achieved only months prior.

***(d) any impacts on the future availability of medicines in the Australian market due to such deferrals***

For the purposes of this submission, Medicines Australia anonymously surveyed 32 of its Class 1 members with a view to quantifying the potential impact of the “deferrals policy” on the future availability of medicines on the PBS.

Specifically the survey asked the following:

1. In light of the recent decision by the Federal Government to defer the listing of new medicines on the PBS, is your company considering delaying submissions to TGA/PBAC for certain new medicines in Australia?

11 member companies responded “Yes”—42.3%

15 member companies responded “No”—57.7%

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Available online at: <http://medicinesaustralia.com.au/files/2010/02/20100802-sub-MoU-Senate-Inquiry-submission-Final.pdf>.

<sup>22</sup> Second Reading, *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010*, Minister for Health and Ageing the Hon Nicola Roxon, 29 September 2010. Available online at: [http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Title%3Anational%20Title%3Ahealth%20Title%3Aamendment%20Database%3Achamber%20Title%3A%22second%20reading%22%3F%20%20Content\\_Phrase%3Abill%3F%20Speaker%3A%3F%20Date%3A01%2F05%2F2010%20%3E%3E%2030%2F11%2F2010%20Speaker\\_Phrase%3A%22roxon.%20nicola.%20mp%22;rec=1;resCount=Default](http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Title%3Anational%20Title%3Ahealth%20Title%3Aamendment%20Database%3Achamber%20Title%3A%22second%20reading%22%3F%20%20Content_Phrase%3Abill%3F%20Speaker%3A%3F%20Date%3A01%2F05%2F2010%20%3E%3E%2030%2F11%2F2010%20Speaker_Phrase%3A%22roxon.%20nicola.%20mp%22;rec=1;resCount=Default).

2. If Yes, Which therapeutic areas were these new medicines likely to target?

Member companies considering delaying submissions indicated that the following therapeutic areas may be affected:

- oncology medicines
- diabetes medicines
- cardiovascular medicines
- respiratory medicines
- mental health medicines

Notably, two companies indicated that regardless of therapeutic group, they would consider delaying medicines indicated for small patient populations.

*(e) the criteria and advice used to determine medicines to be deferred*

To the best of Medicines Australia's knowledge, there are no official criteria for determining which PBAC recommended medicines will be deferred by the Government. This understanding appeared to have been confirmed by the Secretary of the Department of Health and Ageing, Jane Halton, when questioned on the matter during Senate Estimates in May 2011:

**Senator FIERRAVANTI-WELLS:** Let me rephrase the question. Are these the criteria or are there any other criteria used by cabinet?

**Ms Halton:** The answer to that is, are there formal criteria, no; is there an explanation for the ones that were chosen, yes, but in terms of a formal criteria, no.<sup>23</sup>

From various media releases and press statements it is possible to identify some of the motivations for the Government's decision to disregard the PBAC's recommendations. These include:

- The Government's commitment to returning the Budget to surplus by 2012-2013, and the need to save money even when the cost-effectiveness of such an investment has been demonstrated;
- The need for the Government to make hard decisions and weigh-up competing priorities in other areas of health expenditure, even where no such comparable cost and benefits analysis has been conducted in other areas
- The need to prioritise life-saving medicines;

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<sup>23</sup> Senate Community Affairs Legislation Committee, Budget Estimates Hansard, 31 May 2011 at p.91. Available online at: <http://www.aph.gov.au/hansard/senate/commtee/s83.pdf>.

- The claim that there exists an alternative treatment for each of deferred PBAC recommended medicines;
- The need to ensure that PBS growth remains sustainable, despite the fact that PBS growth is at historic lows by any measure and flat relative to GDP (see section (i) below); and
- The need for the Opposition to support other elements of the Government's health reform agenda.

Each of these signals a fundamental revision of the long-standing PBS listing processes and conventions with serious implications for the timely access to medicines that Australians need. The explicit focus on life-saving medicines is particularly perplexing given the prominent and important role that new medicines play in preventative health (cholesterol, hypertension, vaccines, etc) and the management of chronic diseases such as diabetes, heart disease, asthma, COPD, depression and schizophrenia.

It is unclear on whose advice the Cabinet is relying to make its decisions to disregard its independent, expert advisory committee. Medicines Australia has not been formally informed of any process for formulating such advice or of the nature of any such advice.

The experience to date, however, suggests that Cabinet is neither best placed to adjudicate on the clinical need nor relative "value-for-money" of individual medicines. Many in the community and industry welcomed the Government's announcement in June 2011 that it had decided to list a number of medicines recommended at the March 2011 PBAC meeting, but this decision also did nothing to overcome the uncertainty that its earlier decision to defer listings had introduced. The PBS listing process remains a lottery for consumers and industry alike.

#### ***(f) the financial impact on the Commonwealth Budget of deferring the listing of medicines***

Medicines Australia is not privy to the Government's calculation of forward estimates. Medicines Australia's best estimates suggest that the deferrals will save the PBS approximately \$120million over four years.

As each of these medicines was recommended by the PBAC based on its relative cost-effectiveness, the failure to list these medicines will also result in health and productivity losses, if the expenditure that would have otherwise been used to fund them has been diverted to a government program that does not generate the same or greater benefits (health or otherwise) for the cost. In the absence of knowing what has been funded in place of these medicines, it is impossible to judge whether the Government's decision was good economics. Medicines Australia has no reason to believe that such a

comparative economic analysis was undertaken to support the decision. As such it is highly probable that the long-term cost of the Cabinet's decision to defer these medicines will greatly outweigh any short-term financial gain.

***(g) the consultation process prior to a deferral***

Despite the Cabinet's decision to defer the listing of new medicines being a clear breach of the intent of the MoU, no consultations with Medicines Australia or the affected companies were conducted prior to the decision to defer the listing of medicines on the PBS. Given the Government's earlier observation on the current "*historic level of cooperation and collaboration between the government and the pharmaceutical industry, represented by Medicines Australia*" on the management of the PBS, this is yet another major disappointment with the Cabinet's decision.

Medicines Australia was informed of the Government's decision to defer the listing of PBAC recommended medicines less than a day before the public announcement.

***h) compliance with the intent of the Memorandum of Understanding signed with Medicines Australia in May 2010***

Medicines Australia believes that the Government's decision to defer the listing of PBS medicines and change the way Cabinet reviews them is a clear breach of the intent, if not strictly the letter, of the MoU. The objectives and intent are clearly stated in the document itself, most notably in Clauses 3 and 30<sup>24</sup>:

"3. Both parties intend that the MoU will promote the efficiency and sustainability of the PBS and support, by the provision of a stable pricing policy environment, a viable and responsible medicines industry in Australia, consistent with the objectives of National Medicines Policy."

and

"30. This Memorandum of Understanding has been signed to indicate the agreement of Medicines Australia and the Commonwealth of Australia to the matters contained herein to promote the efficiency and sustainability of the PBS and the viability of the medicine industry."

Medicines Australia has explained its reasons for negotiating and signing the MoU to the Senate Community Affairs Legislation Committee. In the interests of historical accuracy and acknowledging that the current inquiry is being heard by a different Senate Committee, it is worthwhile reproducing Medicines Australia's earlier submission at

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<sup>24</sup> Memorandum of Understanding between the Commonwealth of Australia and Medicines Australia at p. 1 and p.6. Available online at: <http://medicinesaustralia.com.au/issues-information/pbs-mou/>.

length for the purposes of understanding Medicines Australia's motivation and expectations:

"On 6 May 2010, a Memorandum of Understanding (MoU) was signed between the Commonwealth of Australia and Medicines Australia. This MoU was the end result of lengthy and difficult discussions between the Commonwealth Government and the pharmaceuticals industry over the months leading up to the 2010 Federal Budget.

At its 2009 Federal Budget and the 2009 Mid-Year Economic and Fiscal Outlook, the Commonwealth Government introduced savings measures to the PBS that took the pharmaceuticals industry by surprise. Medicines Australia steadfastly opposed these measures arguing that such unilateral Government intervention undermined industry confidence in the business environment in Australia, placing ongoing investment at risk; but most importantly, the nature of these measures (the formation of new Therapeutic Groups) threatened the very principles and philosophy of the 2007 PBS Reforms, a position that Medicines Australia has argued at length in previous Senate Committee inquiries.

In the course of discussions around these interventions, Medicines Australia was unambiguously informed that the Australian Government would continue to introduce savings measures into the future, with the aim to generate savings over and above those that could be expected from the 2007 PBS Reforms. Despite independent evidence showing that the 2007 PBS Reforms would deliver up to \$5.8billion in savings to Government over 10 years, the Australian Government continued to maintain that PBS expenditure growth was unsustainable in the short to medium term. The background of the global financial crisis, the resulting Federal Budget deficit, and the need to fund an \$8.5billion health reform program clearly added to the Government's consternation over this.

Faced with such a position, Medicines Australia decided to accept an offer from the Commonwealth Government to enter into discussions about the nature of future savings measures. It is on the public record that such an offer was also put to other stakeholders in the sector.

The discussions between Medicines Australia and the Australian Government (through the Minister for Health and Ageing and the Department of Health and Ageing) resulted in the MoU announced on Budget night, 11 May 2010. A significant provision in the MoU was the delivery of further savings through statutory price reductions and strengthened transparency in the disclosure of prices. These provisions in the agreement are expected to deliver [a minimum of] \$1.86billion in savings to the Government over 5 years, and reduce the cost of many medicines to Australian consumers.

Through the MoU the Commonwealth has also explicitly acknowledged that a stable and predictable pricing environment is important for a viable and responsible medicines industry in Australia. To this end, the Australian government has committed to provide the Australian pharmaceuticals industry with four years of price-related certainty, including a moratorium on the formation of new Therapeutic Groups.

It is important to stress that Medicines Australia did not take the decision to enter into the MoU lightly. The \$1.86billion in savings will hit the industry hard; and as providers of over 86% of the PBS, it is Medicines Australia's

members that will bear the overwhelming burden of these savings. Nonetheless, Medicines Australia entered into this agreement to demonstrate that the Australian medicines industry was a responsible fiscal partner in the long-term management of the approximately \$8 billion-a-year Pharmaceuticals Benefit Scheme. The end result benefits patients and taxpayers, and provides a much needed period of pricing policy stability for industry.”

The Minister for Health and Ageing, during her Second Reading Speech on the MoU-related legislation, acknowledged Medicines Australia’s “cooperation and collaboration”, stating that the MoU helped “*ensure the sustainability of the PBS in years to come.*” She also stressed that the MoU provided “certainty to the pharmaceutical industry in relation to PBS pricing policy.”<sup>25</sup>

It is important to understand that Medicines Australia agreed to the term a “stable pricing environment”, as contained in Clause 3 of the MoU, because it believed that it was a meaningful proxy for a stable and predictable business and policy environment. On the basis of its discussions with the Australian Government, coupled with direct historical experience, Medicines Australia had no reason to believe that the Australian Government during the negotiation period was contemplating any other changes to the policy and conventions underpinning the PBS, its operation or listing processes.

Where the Government had flagged during negotiations other possible policies or mechanisms for achieving further savings over and above those in the MoU, specific clauses were inserted in the MoU to this effect. Thus a close reading of the MoU reveals a number of exemptions and exclusions. These range from a careful delineation of the circumstances in which new Therapeutic Groups would be exempt by the Therapeutic Goods Policy (TGP) moratorium (Clauses 16-19), to the permitted incentives and nature of taxpayer-funded campaigns to promote the use of generic branded medicines (Clauses 20-22). *Notably the MoU also contains an explicit confirmation of the existing principles and market architecture of the PBS (Clause 5).*

**At no point in time during the negotiations did the Government suggest that it may be looking at restricting or delaying patient access to PBAC recommended medicines as a tool for controlling PBS expenditure.**

**On the contrary, many of the provisions in the MoU were negotiated with the clear and unambiguous intention of improving time to access for patients.** These include the introduction of parallel processing for TGA registration and PBS listing, a

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<sup>25</sup> Second Reading, *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010*, Minister for Health and Ageing the Hon Nicola Roxon, 29 September 2010. Available online at: [http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Title%3A%20Title%3Ahealth%20Title%3Aamendment%20Database%3AChamber%20Title%3A%22second%20reading%22%3F%20%20Content\\_Phrase%3A%20Speaker%3A%3F%20Date%3A01%2F05%2F2010%20%3E%3E%2030%2F11%2F2010%20Speaker\\_Phrase%3A%22Roxon.%20Nicola.%20mp%22;rec=1:resCount=Default](http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Title%3A%20Title%3Ahealth%20Title%3Aamendment%20Database%3AChamber%20Title%3A%22second%20reading%22%3F%20%20Content_Phrase%3A%20Speaker%3A%3F%20Date%3A01%2F05%2F2010%20%3E%3E%2030%2F11%2F2010%20Speaker_Phrase%3A%22Roxon.%20Nicola.%20mp%22;rec=1:resCount=Default).



policy improvement that can reduce time to access by 16 weeks or more (Clauses 24-25); a Managed Entry Scheme, which speeds time to access for some safe and effective medicines for which there is a high, unmet clinical need but as yet insufficient information to value fully within the PBAC decision-making context (Clauses 26-27); and explicit provisions signalling the Government's intention to **reduce** the time from a positive PBAC recommendation to actual PBS listing, including a specific "best endeavours" clause for a maximum 6 months time period for those medicines requiring consideration and approval by Cabinet (Clauses 28-29).

Medicines Australia is particularly concerned about how the "best endeavours" clause is being interpreted following the introduction of the new approach on deferrals. Some media reports have suggested that the Government is using this clause to justify delaying the listings of some medicines on the PBS. Medicines recommended by the PBAC in March 2011, for example, would typically have been listed on August 1. The Government has used its new approach on deferrals to delay the listing of some cost-effective medicines by at least one month, meaning that some patients will have to pay for these medicines out of their own pocket or go without.

This was clearly not the intention of the relevant provisions within the MoU. In fact, Clause 29 was a compromise position reached between Medicines Australia and the Australian Government which *assumed* the continuation of existing policy and practice concerning Cabinet approval of medicines for PBS listing. (Medicines Australia had, in fact, attempted to have the \$10million Cabinet threshold, set in 2001, raised to reflect current value<sup>26</sup>). The six months' maximum timing clause in the MoU was envisaged to apply only to those medicines which under the existing arrangements required Cabinet approval. It was never intended, nor anticipated, that it would apply to all PBAC recommendations.

Against such a background, the industry has greeted the Government's new, unanticipated approach on Cabinet approvals with a mixture of anger and disappointment. On the back of long, difficult negotiations on the MoU, the announcement was particularly frustrating. Australia already pays some of the lowest prices in the OECD for innovator medicines, the PBAC already ensures that each and every purchase of a medicine is demonstrated "value-for-money" for the taxpayer in terms of its relative clinical and economic benefits, and the industry had already provided the Government with savings independently estimated to be worth more than \$5billion over ten years through the 2007 PBS Reforms.

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<sup>26</sup> A position unanimously supported by the Senate Community Affairs References Committee in 2010, and recommended by the Productivity Commission in 2008. See above footnote 4.

**Despite all of this, the member companies of Medicines Australia agreed to the MoU because they believed the Australian Government was genuine when it was offering a significant period of business and policy stability in return for the changes to pricing policy that would deliver a minimum of \$1.9billion in additional savings. Unfortunately, the Cabinet changed its approach of approving new PBS medicines without prior consultation.**

*(i) any other matters*

Medicines Australia is concerned about ongoing suggestions that current PBS growth is inappropriately high, and therefore a threat to the long-term sustainability of the PBS. Such assertions are rarely accompanied by any serious analysis or questioning of what an appropriate rate of growth is for pharmaceutical (or health care) expenditure in a highly developed and ageing country such as Australia.

Medicines Australia fully appreciates the need to ensure the long-term sustainability of the PBS. It demonstrated this through its willingness to work with the Government through the framework of a MoU on the management of the PBS. Not only did this deliver the Government a minimum of \$1.9billion in savings, it put in place additional mechanisms to help understand current and future PBS growth. These mechanisms are contained in Clauses 7 and 9 of the MoU<sup>27</sup>, specifically:

“7. Both parties undertake to jointly monitor trends in, and the drivers of [e.g. prescription volume, ageing population, new drugs, drug prices etc], PBS expenditure through the Access to Medicines Working Group (AMWG), which will also develop a framework for this purpose....”; *and*

“9. Medicines Australia undertakes to establish a mechanism for “horizon scanning”. In the context of the MoU, the purpose is to gauge the likely impact on the Pharmaceutical Benefits Advisory Committee (PBAC) and on the expenditure through the PBS, of the drugs in respect of which PBS listing is likely to be sought in the future and to provide information to the Commonwealth...”

The first iterations of a series of rolling reports on PBS Drivers and PBS Horizon Scanning are due to be considered by the Access to Medicines Working Group<sup>28</sup> when it next meets in late August 2011. Medicines Australia continues to operate on the basis that this work will continue despite the “deferrals policy” and its implications for the MoU.

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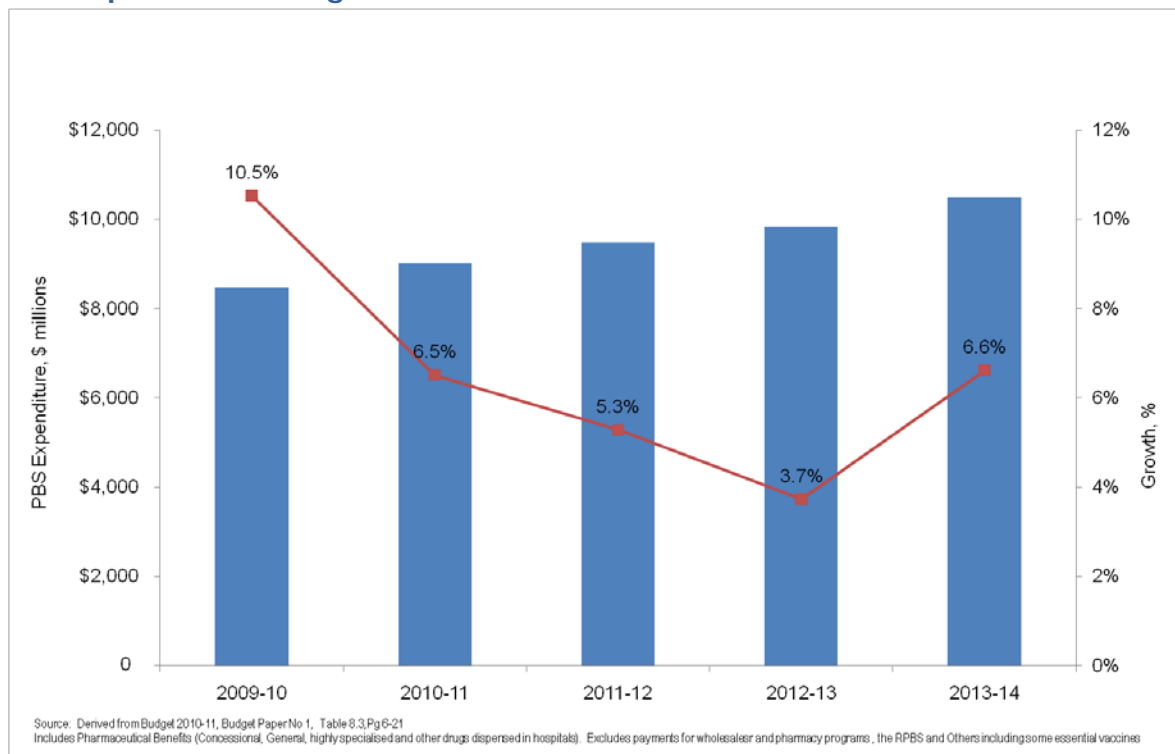
<sup>27</sup> Memorandum of Understanding between the Commonwealth of Australia and Medicines Australia at pages 1 and 2.

<sup>28</sup> The Access to Medicines Working Group (AMWG) was formed by the Department of Health and Ageing and Medicines Australia as part of the 2007 PBS reforms to encourage the Government and the industry to work together and consider access to medicines issues.

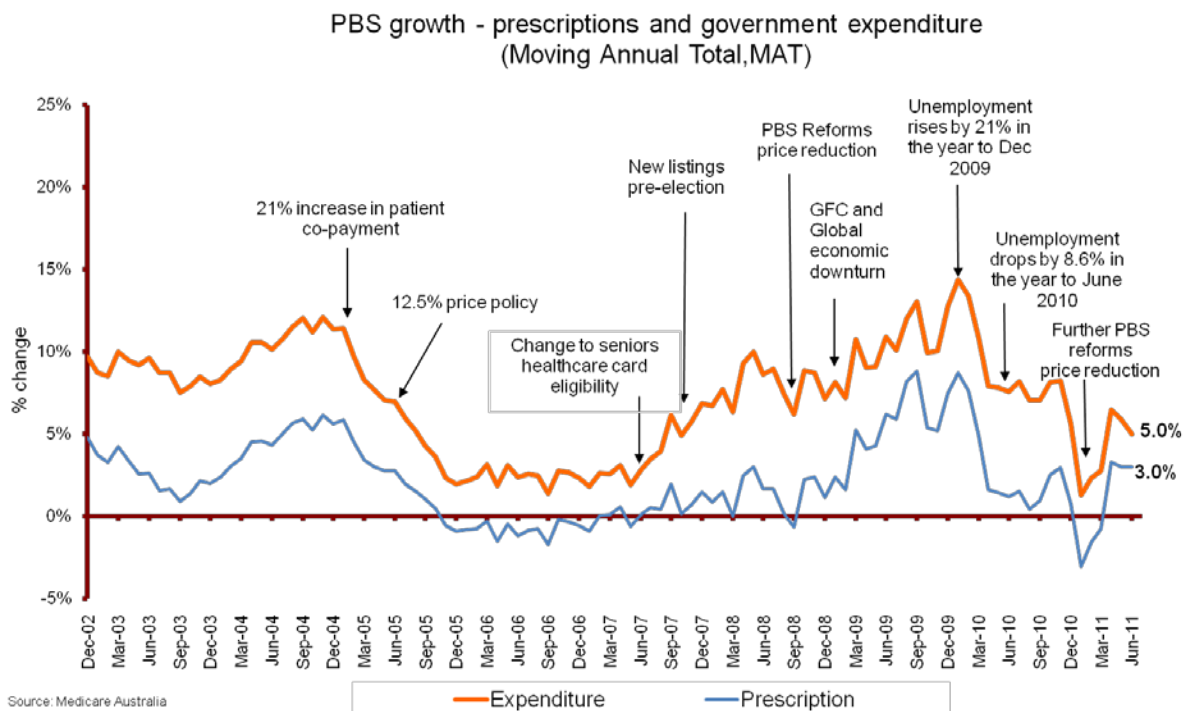
Is the current level of PBS growth unacceptably high? For 2009-2010 expenditure on the PBS grew at 9%. Whilst final data from 2010-2011 are not yet available, Medicines Australia anticipates that the figure is likely to fall from the 2009-10 figure to between 6% and 8%, a view that accords with the Treasury's own projections. Further, although sometimes volatile and uncertain due to data lags, publically available Medicare data show that growth has slowed during 2010-2011 relative to that experienced during 2009-2010.

All indications demonstrate that PBS growth is currently tracking below both the long-term medium (12.2%) and median growth trends (10.2%).

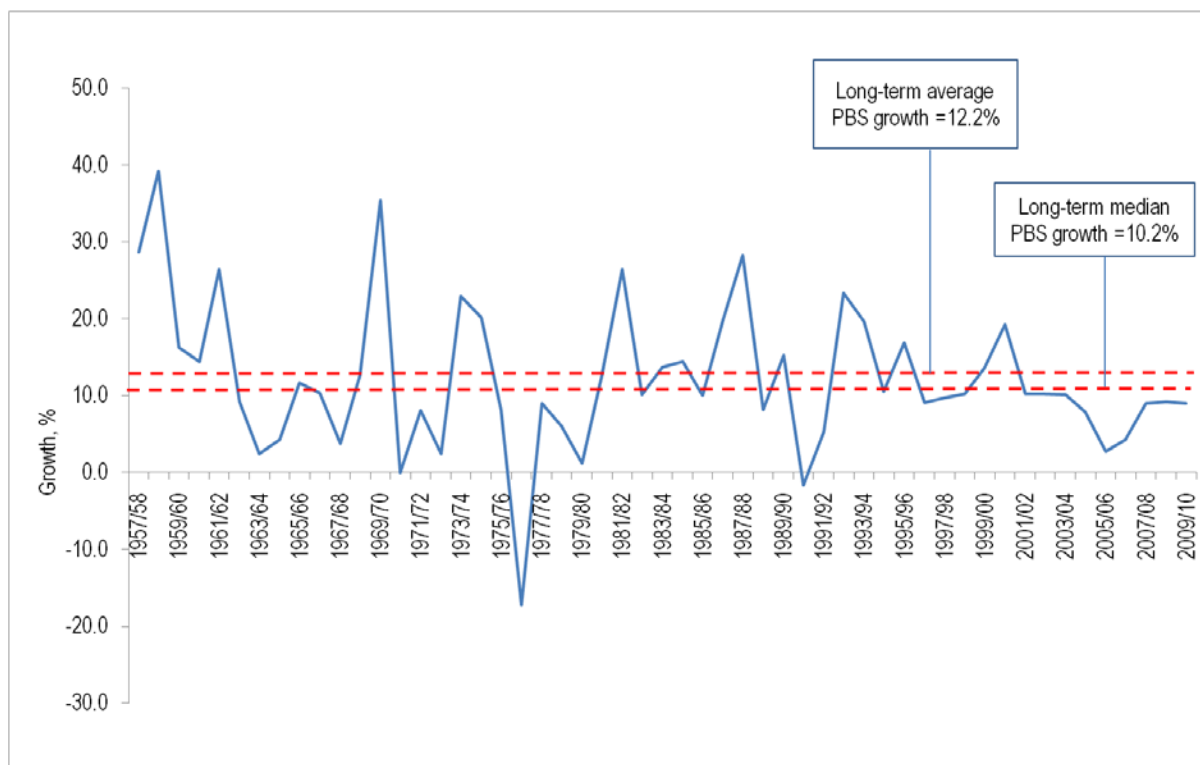
### PBS expenditure and growth



## PBS growth: prescriptions and government expenditure (Moving Annual Total, MAT)



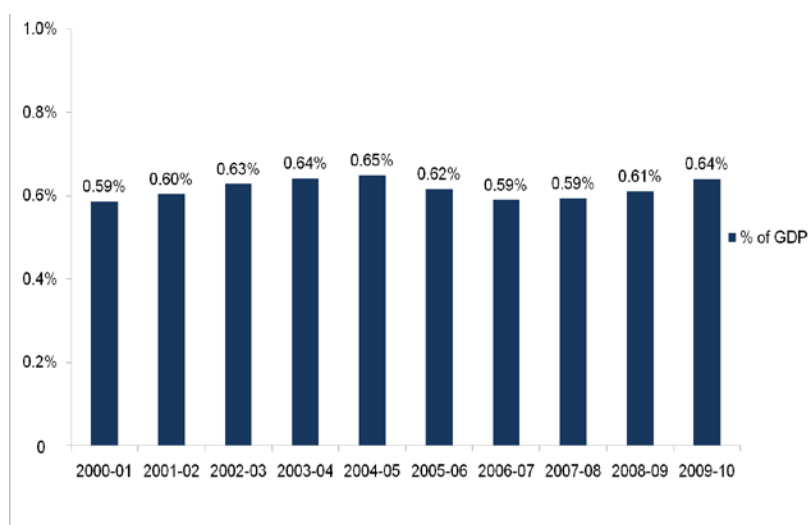
## PBS growth: long-term tracking



Whilst it is true that the PBS is growing faster than the CPI, there are no sound reasons for believing that this is the appropriate metric given the role that medical technology, including pharmaceuticals, play in keeping people well and leading productive lives, and given the fact that Australia is experiencing a rapidly ageing population, which is consuming more health care and living longer for it. To this point it is instructive that all evidence currently points towards “prescription volume” (i.e. consumption), and not prices, as the key driver of expenditure growth on the PBS.

Medicines Australia argues that the most appropriate metric for judging the appropriateness of the level of government health expenditure is in fact GDP. By this measure, pharmaceutical expenditure in Australia has hovered between 0.6% and 0.65% of GDP for over a decade.<sup>29</sup> The Government’s own Intergenerational Report 2010 adopted this approach and projected that the PBS as a proportion of GDP will rise only to 0.7% in the time period to 2020.<sup>30</sup>

#### PBS growth as a percentage of GDP

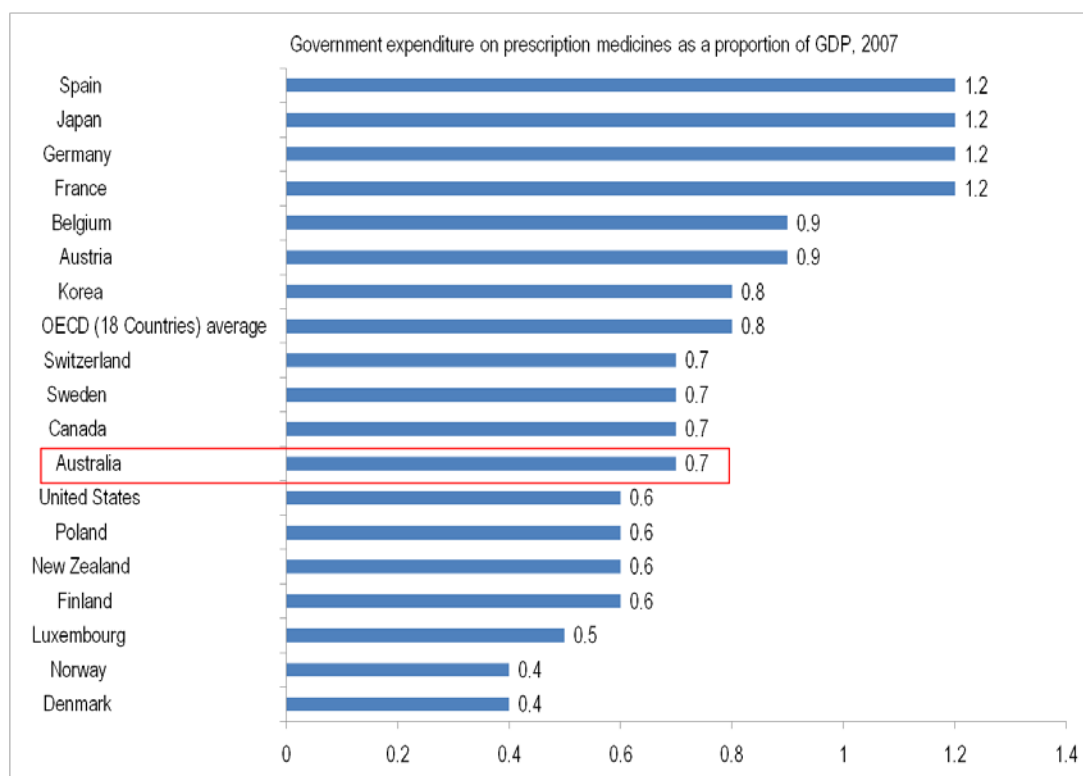


Medicines Australia would also encourage decision-makers to examine how such expenditure compares to other countries in the OECD. The most recent available data show that the Australian Government continues to spend well below the OECD average as a proportion of GDP, as indicated in the chart below.

<sup>29</sup> As can be seen in the chart, the PBS has been stable as a proportion of GDP between 0.6% to 0.7% of GDP in the last 10 years. A minor increase in the last two years is due to the Australian GDP falling in the time period as a direct impact of the GFC.

<sup>30</sup> Australian Government Treasury, “The 2010 Intergenerational Report: Australia to 2050 Future Challenges,” January 2010. Available online at: [http://www.treasury.gov.au/igr/igr2010/report/html/00\\_Preliminaries.asp](http://www.treasury.gov.au/igr/igr2010/report/html/00_Preliminaries.asp)

## International comparison of government expenditure on prescription medicines

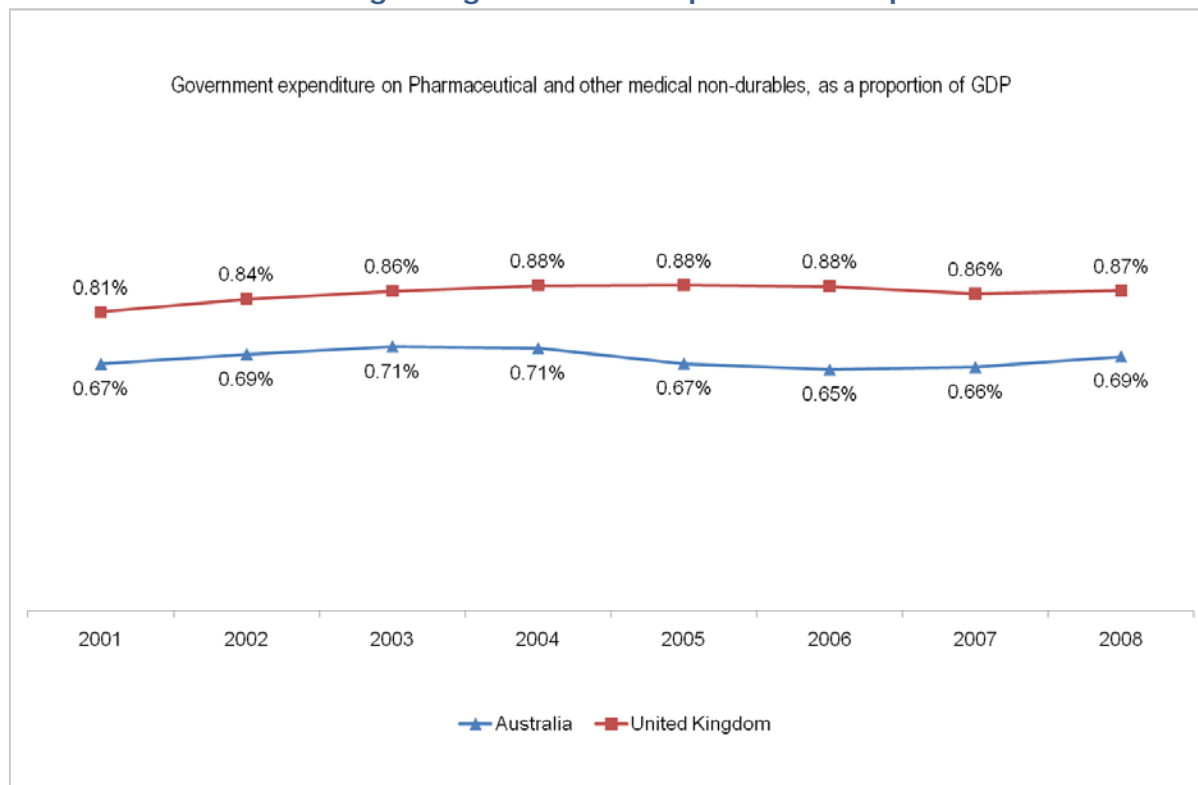


Despite recent claims that Australia could achieve further PBS savings by adopting the pricing policies of the UK, actual evidence that moves beyond naive comparisons of single medicine prices (e.g. off-patent statins) shows that: (1) the UK Government spends more *per capita* on prescription medicines than Australia; and (2) prices in the UK remain on the whole higher than those in Australia.<sup>31</sup>

Taken together, these facts show that claims that current PBS expenditure and growth are unacceptably high are unsubstantiated. Furthermore, these facts suggest that Australia broadly has the appropriate policy settings to ensure that the PBS is sustainable over the long run. The PBAC evaluation process ensures that new medicines are priced at the point for which they can be demonstrated to be “value-for-money” to the Australian taxpayer; and the 2007 PBS Reforms, followed by the 2010 MoU reforms, will ensure that ongoing efficiencies generated through competition in the multi-brand, off-patent market will continue to be delivered through the application of price-disclosure policy.

<sup>31</sup> United Kingdom Department of Health, “The Pharmaceutical Price Regulation Scheme: Tenth Report to Parliament,” December 2009, at p.26. Available online at: <http://www.parliament.uk/deposits/depositedpapers/2009/DEP2009-3123.pdf>.

## Australia and United Kingdom government expenditure on pharmaceuticals



## International comparison of ex-manufacturer pharmaceutical prices<sup>32</sup>

**Table 5: Bilateral comparisons of ex-manufacturer prices**

Country	Price indices					
	2004	2005	2006	2007	2008	2008 indices using five-year* average exchange rate
Australia	–	–	–	94	94	93
Austria	94	96	94	96	111	94
Belgium	90	95	97	101	122	102
Finland	96	101	96	99	119	100
France	84	96	89	92	108	91
Germany	106	108	105	113	142	119
Ireland	99	103	105	112	134	112
Italy	78	84	78	83	101	84
Netherlands	92	95	94	99	115	96
Spain	80	84	85	88	109	91
Sweden	–	0	103	105	116	107
UK	100		100	100	100	100
USA	176	198	188	183	252	212

\* Uses 2008 price information but converted to sterling, for this comparison, using the average exchange rate for the period 2004–08.

<sup>32</sup> Table reproduced from United Kingdom Department of Health, "The Pharmaceutical Price Regulation Scheme: Tenth Report to Parliament," cited at footnote 15, above.

## Conclusion

Medicines Australia is very concerned that the commitments made by the Australian Government in the MoU are now seriously in doubt because of the impacts that the Australian Government's decision to review and potentially defer all new medicines on the PBS will have on industry, clinicians and ultimately the patients who rely on affordable, safe, quality, clinically effective and cost-effective medicines to improve their health outcomes and overall wellbeing.

The Government should revert to the processes that were in place prior to February 2011. The decision to require Cabinet to approve all new PBS listings and to defer the listing of medicines is a bad policy decision for business, patients and Government. It should be overturned immediately.