20 October 2010

Attention: Ms Naomi Bleeser, Committee Secretary
Senator Claire Moore
Chairperson
Senate Community Affairs Legislation Committee
Parliament House
CANBERRA ACT 2600

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

Dear Senator Moore

Medicines Australia welcomes the re-referral of the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010* to the Committee following the Bill's re-introduction on 29 September 2010.

The purpose of this letter is to update the Committee on developments affecting the Bill since the previous Inquiry and to confirm Medicines Australia's position in support of the Bill as outlined in its submission to the Committee dated 20 August 2010 (Attachment 1).

Developments resulting in a revised Memorandum of Understanding and amendments to the Bill

As highlighted in its previous submission, Medicines Australia reached an agreement with the Commonwealth that was enshrined in a Memorandum of Understanding (MoU) dated 6 May 2010 and announced with the Federal Budget on 11 May 2010. The MoU, which was extensively and carefully negotiated by both parties, aims to provide for a more efficient Pharmaceutical Benefits Scheme (PBS) for all Australians by enhancing certainty for industry, implementing regulatory reforms and delivering almost $1.9 billion in savings to the PBS over five years. The savings measures contained in the MoU cannot, however, take effect until the Bill giving effect to the measures is secured through the Parliament.

During the last sittings of the 42nd Parliament, the Australian Government introduced a Bill that would have given effect to the savings measures in the MoU; the Bill was referred to the Committee but was not passed before the Parliament was prorogued on 17 July 2010. It was re-referred to the Committee on 30 September.

As a result of the timing of the 2010 Federal Election outcomes, certain start dates for the implementation of the savings-related measures contained in the MoU, which were reflected in the original Bill, were no longer feasible. Medicines Australia and the Australian Government agreed to amend the MoU in this light, and a revised MoU was signed by both parties on 28 September 2010. The Bill before the Committee, introduced on 29 September 2010, accordingly reflects the changes contained in the revised MoU. A copy of the revised MoU is at Attachment 2.

For the Committee's reference, the following changes are contained in the revised MoU:

- the expanded and accelerated price disclosure program is to commence on 1 December 2010 instead of 1 October 2010;
- 10 months of data will be collected for the first round only (1 December 2010 to 30 September 2011, for effect on 1 April 2012), reverting to a 12 month data collection cycle thereafter;
- the date for the statutory price reductions for F2A and F2T medicines remains unchanged, however the reference date for the 1 February 2011 mandatory price cuts in F2A and F2T has been amended from 30 September 2010 to 11 October 2010 (ie. seven working days later).

No other changes have been made to the original MoU or Bill.

In the context of the revised MoU, Medicines Australia agreed to a reduction in the period of time for the special round of price disclosure from 12 months (under the original MoU and Bill) to 10 months, but noted in a letter to Minister Roxon that the special round must commence no later than 1 December 2010. Medicines Australia advised that delaying the commencement beyond 1 December 2010 would create significant uncertainty in both the size of the likely price cuts and the medicines likely to be included in the calculation, which would undermine the objective of this measure.

Importance of the savings measures as provided for under the Bill

In its previous submission, Medicines Australia outlined the role that the MoU would play in fostering a more efficient and sustainable PBS, better value for money for Australian taxpayers, and policy stability for the pharmaceutical sector. The submission particularly highlighted how, through statutory price cuts and expanded price disclosure, considerable savings will flow to consumers, taxpayers and the Australian Government through a more competitive generics market.

Data show that the Australian Government pays 20 per cent less than the OECD average for new, patented medicines but that the prices it pays for older, off-patent medicines (the off-patent F2 market) are high by international standards. In theory, because they are different brands of the same medicine, competition between brands should set the price paid for by the consumer and ultimately, the taxpayer. The Bill promotes competition and downward pricing pressure by ensuring that, as is the case with most other government volume purchaser agreements, the Australian Government is provided with clear and transparent information about the real market prices for these medicines.

Medicines Australia acknowledges that the savings measures contained in the revised MoU and Bill clearly target the off-patent F2 market. However, the savings measures principles have already been encapsulated in the price disclosure reforms initiated by the Howard Government in 2007 and passed in 2008. The strength of these reforms is underlined by the effect they are already having in aligning the price paid by the Australian Government with the price paid in the actual marketplace for some of the off-patent F2 medicines. For example, early data referred to in the previous submission show that the efficient price paid by the Australian Government for a number of medicines has already fallen by as much as 70 per cent.

However, the reforms apply only to a small subset of the total number of these medicines, which has prevented cost savings from being fully realised by the Australian Government, with consequent impacts on Australian consumers and taxpayers.

This means that the Australian Government is currently unable to access the information it needs to be a fully informed purchaser – with the result that it does not have adequate information to decide whether to take advantage of any competition-driven discounting in the supply chain that is occurring in the market. As the Minister for Health and Ageing, Minister Roxon, noted in the Second Reading Speech of 29 September 2010:

> Price disclosure allows market forces to play a part in PBS pricing. Competition between pharmaceutical companies to gain market share for their products can result in significant discounting to pharmacies. The actual price of a brand of medicine may be much less than the Government PBS subsidy price.....price disclosure ensures that over time Government prices reflect more closely actual market prices. This is a fairer deal for taxpayers.
>
> Under price disclosure arrangements, suppliers are required to advise Government of the price at which PBS medicines are sold into pharmacies. The information is used as the basis for possibly adjusting the price for all brands of a medicine to the average weighted price. Consumers will pay no more for their medicines, and some may pay less.

This echoes the Second Reading Speech of the then Minister for Health, the Hon Tony Abbott MP, on the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007 which contained price disclosure reforms for F2 medicines. In that speech on 24 May 2007, the then Minister said:

> Price disclosure will introduce transparency to the pricing arrangements for PBS medicines. It will retain the benefits that flow from market competition, whilst enabling taxpayers to capture some of those benefits..... Access to medicines will continue to be through community pharmacies but with much greater transparency about the level of pharmacy remuneration, resulting in better prices being paid by government.

The expanded application of the price disclosure regime to all off-patent F2 medicines is in keeping with the principles of the 2007 reforms, and can only be expected to further promote the sustainability of the PBS.

When coupled with the mandatory price reductions set down in the Bill, the price savings measures contained in the Bill will reduce the price taxpayers pay for older, off-patent medicines. These include commonly used medicines to treat heart disease, high blood pressure, asthma, depression, high cholesterol and rheumatoid arthritis. As Minister Roxon said during the second reading debate on 18 October 2010:

> The direct savings to consumers from these new measures is independently estimated to save general patients on average close to $3 per prescription. As Medicines Australia averred in its earlier submission, the almost $1.9 billion of savings that are estimated to result from the Bill over a five-year period are possible because of the widened scope of the price disclosure program and also the industry's guarantee to the Australian Government that the market-based competition will provide a minimum weighted average price reduction of 23 per cent for all medicines involved in the price disclosure round commencing 1 December 2010.

Medicines Australia members employ over 14,000 people and export more than $4.1 billion in pharmaceutical products per annum. They invest more than $1 billion in research and development per annum to help ensure Australians can access new, innovative medicines at affordable prices. Because Medicines Australia's members are the providers of more than 86 per cent of medicines on the PBS and around 60 per cent of the off-patent market by value based on cost to Government, Medicines Australia is well-positioned to assess the Bill. Supporting facts about the industry, for the reference of the Committee, are attached with this letter (Attachment 3).

Medicines Australia commends the Bill and the commitment embodied in it to progress genuine savings within the health system. There are significant benefits that will flow to Australian consumers, taxpayers, industry and the Australian Government under the Bill. Importantly, the reforms are not cost-free to industry, but the industry is prepared to invest in the reforms so that Australian consumers and taxpayers and in turn the Australian Government, can be assured that they are paying appropriate prices for medicines.

Realising the benefits contained in the Bill depends upon its successful passage in 2010. I look forward to discussing these benefits further with the Committee at the hearings scheduled for 9 November 2010.

Dr Brendan Shaw
Chief Executive

Attachments

1. Medicines Australia submission to the Senate Community Affairs Legislation Committee dated 20 August 2010
2. Revised signed MoU dated 28 September 2009
3. Supporting facts about the pharmaceutical industry

ATTACHMENT 1

MEDICINES Australia
Better Health through Research and Innovation

Submission to the Australia Senate

Community Affairs Legislation Committee

Inquiry into

National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010

20 August 2010

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Executive Summary

Medicines Australia represents the research-based pharmaceutical industry in Australia. Our member companies supply the majority of medicines on the Pharmaceutical Benefits Scheme.

In the lead-up to the 2010 Federal Budget the Government invited the industry to discuss a range of potential savings measures.

As a result of those discussions, Medicines Australia reached an agreement with the Commonwealth which was enshrined in a Memorandum of Understanding (MoU). The MoU was signed on 6 May 2010 and announced with the Federal Budget on 11 May 2010.

The *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010* enables changes in legislated pricing arrangements for medicines listed on the PBS that are part of a broader package enshrined in the MoU. The Government estimates these legislative changes will deliver Australian taxpayers $1.86 billion in savings over a five-year period.

These savings will flow from a combination of statutory price cuts and an expansion of the price disclosure mechanism which is already in place for medicines in the off-patent market, and which will reduce the price of medicines once they become subject to generic competition. The elegance of price disclosure policy is that it uses companies' own decisions to extract savings, thus minimising direct Government intervention in the marketplace.

The first round of mandatory price disclosure, from which these savings will flow, is scheduled for 1 October 2010, subject to the passage of this legislation.

The MoU delivers further benefits to Australian consumers, through cheaper medicines and process improvements to the PBS. The MoU also delivers pricing certainty to industry, through an agreement that the Government will make no further price-related savings from the PBS for a four-year period. (n.b. While the term of the MoU is four years, the legislative changes will deliver $1.86 billion in savings over five years.)

There are five compelling reasons why the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 should be supported:

1. **The MoU benefits consumers by meeting the first objective of Australia's National Medicines Policy (NMP), namely *timely access to the medicines that Australians need, at a cost individuals and the community can afford*.**
2. **The MoU is fully consistent with the fourth objective of Australia's National Medicines Policy, namely *maintaining a responsible and viable medicines industry*.**
3. **The Bill and the MoU are fully consistent with the principles and architecture of the 2007 PBS Reforms.**
4. **The Bill delivers the highest level of pricing transparency in the medicines marketplace.**
5. **The MoU has been negotiated on behalf of, and agreed to, by the vast majority of affected parties.**

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Recommendations

1. The Parliament acknowledges that this Bill gives legislative effect to a number of the provisions contained within the MoU recently signed by the Australian Government and Medicines Australia. The MoU is a broader package of reforms designed to ensure the sustainability of the PBS and was effective from the date it was signed, 6 May 2010.

2. The Parliament passes the *National Health Amendment (Pharmaceutical Benefits) Bill 2010* before 1 October 2010.

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Introduction

Medicines Australia welcomes the opportunity to present its position to the Senate Community Affairs Legislation Committee's inquiry into the *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010* ('the Bill'). Medicines Australia represents the innovative medicines industry in Australia. Our member companies supply the majority of prescription pharmaceuticals to the Pharmaceutical Benefits Scheme, and are engaged in the research, development, manufacture, supply and export of prescription medicines.

The Bill gives effect to parts of a Memorandum of Understanding (MoU) between the Commonwealth of Australia and Medicines Australia, signed on 6 May 2010, and announced on Budget night 2010The Bill enables changes in legislated pricing arrangements for medicines listed on the Pharmaceutical Benefits Scheme (PBS). The Government estimates that these legislative changes will deliver Australian taxpayers $1.86billion in savings over a 5 year period. The MoU will also provide significant benefits to consumers, both in terms of savings on existing medicines and faster access to new medicines.

As an integral part of the Government's 2010/11 PBS Budget announcement, the MoU provides the Australian pharmaceuticals industry with a 4 year period of pricing policy stability. In addition, there are policy improvements to the PBS listing process that will directly benefit Australian consumers through faster access to safe and effective medicines. The Commonwealth Government has explicitly acknowledged that a stable and predictable pricing environment is important for a viable and responsible medicines industry in Australia. Importantly, this includes a four-year moratorium on the formation of new Therapeutic Groups, an existing savings tool that has caused significant concern to the pharmaceuticals industry in the past.

The Bill enables changes that will deliver Australian taxpayers $1.86b in savings over a 5 year period and will result in significant benefits for consumers, both in terms of savings on existing medicines and improved access to new medicines.

Although it imposes a substantial financial impost on its members, Medicines Australia asks the Committee to recommend the passage of this legislation.

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There are five major reasons to support the legislation, summarised as follows:

1. **The MoU benefits consumers by meeting the first objective of Australia's National Medicines Policy (NMP), namely *timely access to the medicines that Australians need, at a cost individuals and the community can afford*.** Access to medicines will become more "timely", because the MoU provides for policy improvements in the PBS listing process that will reduce the time it currently takes for many safe and effective medicines to become available to the public. Medicines will also become more affordable for both individuals and the community. The MoU provides taxpayers with an estimated $1.86 billion in savings to the PBS over five years. It also saves patients money by making many commonly used medicines, including those used to treat high blood pressure, high cholesterol, asthma, depression and gastric problems, significantly cheaper to buy at the pharmacist.

2. **The MoU is consistent with the fourth objective of Australia's National Medicines Policy, namely *maintaining a responsible and viable medicines industry*.** Through the MoU, the Commonwealth has explicitly acknowledged that "a stable pricing environment" is important for a viable and responsible medicines industry in Australia. As such the MoU provides industry with 4 years of pricing policy predictability, including a moratorium on the formation of new Therapeutic Groups.

The changes were agreed to by the majority of affected parties; they are consistent with National Medicines Policy and 2007 PBS Reforms and deliver the highest level of pricing transparency to the medicines marketplace.

3. **The Bill and the MoU are fully consistent with the principles and architecture of the 2007 PBS Reforms. *Those reforms sought to promote the efficiency and sust*ainability of the PBS by creating transparency in and taking advantage of multi-brand competition in th**e off-patent market (F2), whilst continuing to use rigorous cost-effectiveness analysis to secure value-for money prices for new medicines entering the F1 formulary.

4. **The Bill delivers the highest level of pricing transparency in the medicines marketplace.** Strengthened price disclosure arrangements for full transparency in the off-patent marketplace created through the Bill will deliver significant and on-going savings to taxpayers and Australian consumers and minimise further, direct government intervention into the price setting arrangements of industry. As such, any incurred price cuts will solely reflect the commercial decisions that the companies themselves take as they seek to be competitive in the market place.

5. **The MoU has been negotiated on behalf of, and agreed to, by the vast majority of affected parties** through the auspices of the industry association representing companies that provide the majority of the PBS market.

If the Bill is not passed before 1 October 2010, savings to Government from price cuts expected from the introduction of mandatory price disclosure will be delayed.

This submission will provide a brief description of the MoU to give context to the main focus of the inquiry and the reasons that the industry sought to negotiate and enter into an agreement with the Commonwealth of Australia, followed by the rationale for supporting the passage of the *National Health Amendment (PBS) Bill 2010*.

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The Memorandum of Understanding

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. [1] 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.

Medicines Australia has steadfastly opposed unilateral Government intervention for PBS savings measures...so accepted an offer from the Government to discuss future savings...an offer which was also put to others

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[2].

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 $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.

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[1] Commonwealth of Australia (2010)The Impact of PBS Reform Report to Parliament on the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007*

[2] Budget Estimates, Senate Community Affairs Legislation Committee, Mr D. Learmonth, Department of Health and Ageing (Hansard, 2 June 2010, CA106,

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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 National Health Amendment (PBS) Bill 2010

The National Health Amendment (PBS) Bill will give effect to the savings measures contained within the MoU. The $1.86billion in savings is to be achieved through the following policy measures requiring legislative amendment:

- From February 2011, the price reduction incurred when a medicine moves from F1 to F2 following the introduction of the first generic competitor will increase from 12.5% to 16%.
- On February 2011, a 2% price reduction to all medicines listed on F2A as at September 30, 2010 will be applied.
- On February 2011, a 5% price reduction to all medicines listed on F2T as at September 30, 2010 will be applied.
- From October 1, 2010 strengthened price disclosure arrangements will apply. Most importantly this means price disclosure will be extended to all brands of all medicines in the competitive multi-brand F2 market.

The price disclosure round, commencing on 1 October 2010 and concluding on April 2012, will provide a weighted average price reduction of 23% or higher. Should this not be achieved, additional price cuts will be applied to affected medicines according to an agreed formula to meet the 23% target.

Each of these measures must be introduced through legislation, and the Bill under consideration seeks to do this.

The savings measures in the MoU to which the Bill refers clearly target the off-patent F2 market. There are good reasons for this, as evidence shows a) taxpayers and consumers continue to pay high prices by international standards and b) for some of these, the Government is paying higher than the true and actual market price.

The savings measures in the MoU to which the Bill refers clearly target the off-patent F2 market. There are good reasons for this, as evidence shows a) taxpayers and consumers continue to pay high prices by international standards and b) for some of these, the Government is paying higher than the true and actual market price.

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The OECD[3] recently reported that Australia continues to pay significantly more for many high volume off-patent or generic [i.e. F2] medicines, a conclusion supported by recent Australian research into commonly used off-patent medicines including those used to treat high cholesterol.[4] The strengthened price disclosure arrangements are designed to align the price paid by the Australian government with that paid in the actual marketplace, a process that over time is expected to bring generic prices in line with those seen in comparable international jurisdictions.

By contrast, prices for single-branded innovative F1 medicines are some of the lowest in the developed world and there is little scope to reduce prices further without damaging the market. The OECD reported that Australian prices for originator medicines are 81% of the OECD average, and Australia pays the fourth lowest prices for these medicines relative to economy wide-prices in the OECD.[5] All evidence suggests that this is due to the rigorous cost-effectiveness analysis that new medicines are subject to when a PBS listing is sought. The efficient price paid by Government for F1 medicines is that which can be demonstrated by the clinical trial evidence to be "value-for-money".

[3] OECD, Pharmaceutical pricing policies in a global market, OECD Health Policy Studies, 2008. pp161-166.
[4] Clarke, Philip M & Fitzgerald, Edmund M. Expiry of patent protection on statins: Effects on pharmaceutical expenditure in Australia. The Medical Journal of Australia. Vol 192. 2010.
[5] OECD, Pharmaceutical pricing policies in a global market, OECD Health Policy Studies, 2008. pp161-166.

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The provisions within the MoU, which are given effect by the Bill, benefit consumers by meeting the first objective of the National Medicines Policy: *timely access to affordable medicines*

The MoU provisions were negotiated within the framework of Australia's National Medicines Policy (NMP), as stated in Clause 3 of the agreement:

> *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 the National Medicines Policy.*

In line with Objective 1 of the NMP "timely access to affordable medicines", the changes in pricing policy reduce the cost of medicines to both the community and individuals, and the associated PBS listing process policy improvements are designed to enhance "the timely access to medicines that Australian need".

The savings measures contained with the MoU are estimated to generate $1.86billion to the taxpayer alone, reducing the costs of medicines to the community. Importantly, however, individual consumers are also set to benefit.

...it is anticipated that the price Australian consumers pay for a number of medicines used to treat common conditions like high cholesterol, hypertension and gastric reflux may fall by as much as 50%.

The MoU will ensure that many common medicines will become cheaper to purchase, often dramatically so. This is because the price disclosure policy, in combination with the mandatory price-cuts for medicines on F2A and F2T, will drive the dispensed price of many medicines below the general co-payment level of $33.30. Due to the way that price disclosure works, it is difficult to quantify the total savings from the MoU that will accrue to Australian consumers; nevertheless it is anticipated that the price the consumer pays for a number of medicines used to treat common conditions like high cholesterol, hypertension and gastric reflux may fall by as much as 50%.

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Table 1

Common Medicines That Will Fall Below the Co-Payment

The high volume, common medicines shown will become cheaper for the Australian consumers as early as February 2011 simply due to the effects of mandatory price cuts of 2% and 5% respectively in F2A and F2T formularies. Importantly this does not factor in the expected price cuts that will be generated through price disclosure which are expected to reduce the price of many medicines to consumers by a further 50%.

	High volume drugs	Use	Number of scripts dispensed in 2008
1	**Carvedilol**	To treat hypertension and certain cardiovascular diseases	3,249,745
2	**Meloxicam**	To treat rheumatoid arthritis, osteoarthritis	2,065,671
3	**Ramipril**	To treat hypertension and certain cardiovascular diseases	2,584,471
4	**Esomeprazole Magnesium Trihydrate**	To treat hyperacidity and gastroesophageal reflux disease (GERD)	2,762,918
5	**Omeprazole**	To treat hyperacidity and gastroesophageal reflux disease (GERD)	3,618,747
6	**Simvastatin**	To reduce Cholesterol	2,645,374
7	**Perindopril**	To treat hypertension and certain cardiovascular diseases	2,479,304
8	**Salbutamol Sulfate**	To treat asthma, bronchitis, emphysema, and other lung diseases	2,099,063
9	**Sertraline Hydrochloride**	To treat depression	20,275
10	**Risperidone**	To treat schizophrenia or bipolar disorder	18,189

Source: Prescription and expenditure to 30 June 2009, Department of Health and Ageing 2009.

Note: a total of over 20 million prescriptions for these medicines were dispensed to Australian consumers in 2008-09

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The MoU also contains policy improvements to the PBS listing process that will directly benefit Australian consumers. These include permitting the TGA and PBAC evaluation processes to be conducted in parallel, thus significantly reducing the time that it takes for some innovative medicines to become available to the Australian public. The MoU also introduces a managed entry scheme for some effective and safe medicines for which there is a high, unmet clinical need but as yet insufficient information to value fully within the PBAC decision-making context. As a tool for managing "uncertainty", this will also potentially lead to Australian consumers getting access to important medicines earlier than might otherwise have occurred, as well as provide an opportunity for the government, health professionals, and companies to better understand how such medicines should be most effectively used in actual clinical practice.

Importantly, the MoU also includes a commitment from the Government to improve the "timely access to medicines that Australians need" by setting a "best-endeavours" 6 month time limit on those PBAC recommended medicines requiring Cabinet approval. Whilst Medicine Australia welcomes this, it is one of a number of measures in the MoU which the industry believes does not go far enough. What Medicines Australia seeks is to reset the current $10 million threshold for medicines requiring Cabinet consideration so that it reflects the "real" level of that established in 2001. This would further reduce delays in the listing of many life-saving medicines. As such, Medicines Australia continues to recommend that the Cabinet threshold be raised to $20 million and indexed to inflation.

Following the signing of the MOU in May 2010 Medicines Australia has been actively working with member companies and the DoHA to ensure the measures contained in the MOU are implemented as effectively as possible. This process was commenced to minimise any disruption to all stakeholders with the implementation of the PBS listing process efficiencies.

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The provisions within the MoU and given effect by the Bill are consistent with the fourth objective of the National Medicines Policy: *maintaining a responsible and viable medicines industry*

The Commonwealth's commitment to provide the industry with four years of price-related certainty, including a moratorium on the formation of new Therapeutic Groups, helps to "maintain a viable and responsible medicines industry", or objective 4 of the National Medicines Policy.

Medicines Australia has long argued - including in various submissions to Australian Senate Committee inquires - that a predictable and stable business environment is essential for ensuring ongoing investment in Australia by the pharmaceuticals industry. The drug development process is high-cost, lengthy, and characterised by an unusual high level of risk relative to other industries. The latest peer-reviewed published research suggests that it costs over $US1 billion and 15 years to bring the average medicine to market. As this research and development pipeline is funded almost exclusively by returns on existing medicines, it is not surprising that company decisions about bringing new medicines to Australia, as well as ongoing investment in clinical trial research and manufacturing, are directly affected by business confidence in the regulatory and pricing environment.

Medicines Australia has long argued that a predictable and stable business environment is essential for ensuring ongoing investment in Australia by the pharmaceuticals industry

The MoU goes some way to providing such confidence. In the context of the savings measures, the Commonwealth has explicitly acknowledged that "a stable pricing environment" is important for a viable and responsible medicines industry in Australia. As such the Commonwealth has undertaken "not to implement new policy to generate price-related savings from the PBS during the period of agreement" and "not to form any new Therapeutic Groups during the period of the MoU" (with tightly defined exceptions).

The effect of such confidence in the business environment was rapid, if not unsurprising to Medicines Australia. Days after the official announcement of the signing of the MoU, one of Medicines Australia's member companies Eli Lilly Australia announced that it would be contributing over $50 million to a $250 million biotech venture capital fund located in Queensland. The Queensland government, also a partner in this venture, announced that this was the first part of a plan to see a $20 billion biotech industry employing 16,000 people in the Queensland by 2025.

Eli Lilly welcomed the pricing certainty arising from the Medicines Australia MoU and noted: "Such certainty helps foster exactly this type of investment."

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The Bill and MoU provisions are fully consistent with the architecture and principles of the 2007 PBS reforms

In order to bolster the long term sustainability and efficiency of the PBS, the previous Coalition Government introduced a series of microeconomic reforms to the scheme designed to take advantage of market place competition amongst off-patent medicines. Taking effect in 2007, these reforms split the PBS into two distinct formularies and markets: F1 and F2.

F1 is the market for single brand medicines (i.e. typically patented, originator medicines without competition) where efficient price setting and cost control is achieved through rigorous cost-effectiveness evaluation and initial prices are set by reference to *different* medicines used to treat the same conditions. The efficient price paid by Government for these medicines is that which can be demonstrated by the clinical trial evidence to be "value-for-money".

F2 is the "off-patent" market for multiple brands of the *same* medicine where, in theory, competition between *brands* for market share sets the price paid for by the taxpayer. Before PBS Reform, the Government simply reimbursed pharmacists for the full listed price of a medicine, regardless of whatever discounting was occurring in the supply chain. PBS Reform introduced the ***price disclosure policy***, the objective of which is to make transparent the prices for which companies are selling medicines to pharmacists and wholesalers. The Government can then take advantage of any competition-driven discounting in the supply chain by adjusting the price it reimburses the pharmacist to the price for which manufacturers are selling individual medicines to the market. The elegance of price disclosure policy is that it uses companies' own decisions to extract savings, thus minimising direct Government intervention in the marketplace.

PBS Reform introduced the price disclosure policy, the objective of which is to make transparent the prices for which companies are selling medicines to pharmacists and wholesalers. The Government can then take advantage of any competition-driven discounting in the supply chain

Since its introduction, the price disclosure policy has already seen the efficient price paid by Government for a number of medicines in F2 fall by up to 70%.[6]

The MoU is fully consistent with the principles and architecture of the 2007 PBS Reform, which is explicitly reaffirmed in Clause 5 of the agreement. The MoU provides, nonetheless, a number of policy adjustments which taken together provide the government with the confidence that competition in the off-patent market will deliver savings to the taxpayer over and above what had previously been estimated. These policy changes, especially to existing price disclosure arrangements, permit the Government to "bank" $1.86 billion in savings over a 5 year period. This is possible because (1) the widened scope of the price disclosure policy enables the Government to take advantage of discounting in the market for all F2 medicines (previously this has only applied to a much smaller number); and (2) the industry has offered a guarantee that the market based competition will provide a minimum weighted average price reduction of 23% for all medicines involved in the price disclosure round commencing 1 October 2010.

It is also important to note that the MoU strengthens the administration of the price disclosure policy, providing confidence to industry that any price reductions incurred will reflect accurately, the prices for which these medicines are actually being sold. The MoU provides for a

[6] Commonwealth of Australia 2010, *The Impact of PBS reform – Report to Parliament on the National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007*, Pg 37, Table 3.

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third party administration of the price disclosure calculations, along with independent verification of both the methods and calculations. The Commonwealth has also committed to working cooperatively with industry to finalise a dispute resolution process in time for the commencement of the new arrangements. Price disclosure delivers savings to taxpayers and consumers while minimising government intervention in the medicines market.

The savings measures in the MoU were designed to maximise savings to the Australian taxpayer and consumer whilst providing policy and pricing predictability to the Australian pharmaceuticals industry. It is for this reason that over 75% of the savings, by Medicines Australia's own calculations, are to be achieved through enhanced price disclosure arrangements rather than simply wielding the blunt tool of across-the-board price cuts.

The elegance of price disclosure policy is that it uses companies' own decisions to extract savings, thus minimising direct Government intervention in the marketplace

The 2007 PBS Reforms introduced price disclosure to take advantage of discounting by companies competing for market-share. Table 2 (below) provides a simplified example of how the price disclosure policy works.

The MoU simply extends this price disclosure mechanism to **all medicines in F2**. It is important to stress that this system is designed to ensure that the Government does not pay a higher price than that in the marketplace. As such, any incurred price cuts due to this measure are determined by commercial decisions taken by companies themselves.

Table 2

How Price Disclosure works in the medicines marketplace: An example.

Medicine A is listed on the PBS for $100.00 per prescription. This is the price (plus additional dispensing and mark-up fees) that the Government reimburses the pharmacist every time a consumer purchases Medicine A from a pharmacist.

Multiple brands from a variety of manufacturers of Medicines A exist as its patent has expired. Medicine A is therefore listed on the F2 formulary. The various manufacturers sell Medicine A to pharmacists (often through a wholesaler) and must compete to sell their brand. This competition is facilitated by manufacturers selling their brand to pharmacists at discounted prices to gain market share.

If the average discount offered to pharmacists for Medicine A is 25%; then the pharmacist purchases Medicine A for an average price of $75.00.

Without price disclosure, the Government will continue to reimburse the pharmacist $100.00 for a medicine which was purchased for $75.00. Under these circumstances, the taxpayer forgoes any benefit derived from competition in the market.

With price disclosure, the Government will adjust the price that it reimburses the pharmacist for Medicine A so that it reflects the average price for which Medicine A is actually sold by the manufacturer over a 12 month period. The PBS price of Medicine A will thus be reduced from $100.00 to $75.00, a 25% saving to the taxpayer.

Since the introduction of the price disclosure policy in 2007, the price Government pays for some medicines has been reduced by up to 70%.

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Medicines Australia represents the vast majority of the Australian pharmaceuticals industry and the majority of savings are derived from Medicines Australia members

The Memorandum of Understanding is between the Commonwealth of Australia and Medicines Australia. The provisions within the MoU affect all sponsors with medicines listed on the PBS of which Medicines Australia members are a significant majority, both in terms of number of affected companies and the value and volume of prescribed PBS medicines.

Medicines Australia has a membership of over 50 companies, 41 of which supply medicines to the PBS. These include both research-based and non-research-based prescription medicines companies, employing over 14,000 people throughout Australia (This contrasts to the membership of the Generics Medicines Industry Association, which currently comprises just 5 companies[7] with 5000 employees[8] (See Figures 13 and 14 below)) Between them, and by any measure, Medicines Australia's member companies supply the vast majority of medicines to the PBS. ***Figures 1*** **to** ***12*** show the relative contribution of Medicines Australia's members to the PBS market as derived from available data-sets.[9] Measured as a proportion of total value of PBS government expenditure, Medicines Australia members supplied 86.2% of the market. As a percentage of total number of prescriptions dispensed, Medicines Australia members represented 67%. Although reduced (60.5% and 48% respectively), Medicines Australia's majority share relative to that represented by the Generic Medicines industry Association (35.1% and 46%) is maintained when considering only the off-patent F2 proportion of the PBS. This is the case even when "below co-payment" expenditure and prescriptions are included.

By any measure Medicines Australia represents the majority of the market for medicines on the PBS

Notwithstanding, it is worth emphasising that the savings measures within the MoU explicitly target "value" or the "cost-to-government" of individual medicines, and not prescription volume. By this measure, Medicines Australia members provide the vast majority of Medicines to the PBS, and as such will bear the greatest burden.

That Medicines Australia members, however, constitute a majority regardless of the choice of method for measuring market share is not surprising. Many Medicines Australia members actively compete in the off-patent F2 market with their off-patent originator medicines. It is also worth pointing other that much of the "other" category depicted in ***Figures 1*** **to** ***12*** consist of medicines that are supplied by firms that are formally affiliated to or owned by MA member companies, if not members in their own right. In reality, the inclusion of the "other" category only increases the proportion of Medicines Australia's "market-share".

[7] www.gmia.com.au
[8] www.gmia.com.au/contact
[9] Source: Pharmaceutical Benefits Pricing Authority, *Annual report 2008-09*, Department of Health and Ageing, 2009.

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Figure 1: PBS market (by value at Government cost) excludes below co-pay expenditure	Figure 2: PBS market (by volume at Government cost) excludes below co-pay scripts

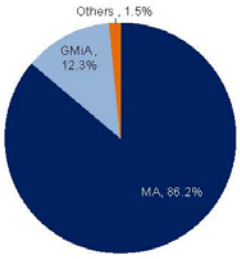
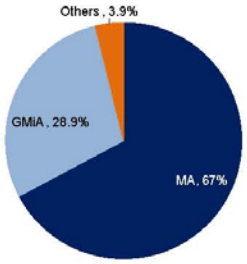

	

Figure 3: PBS market (by value at ex-manufacturer cost) excludes below co-pay expenditure	**Figure 4: PBS market (by volume at ex-manufacturer cost) excludes below co-pay scripts**

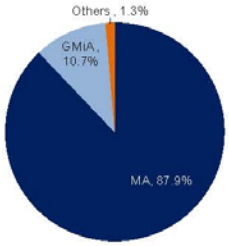
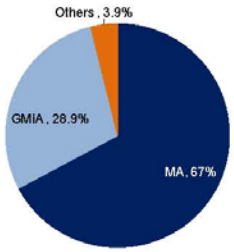

	

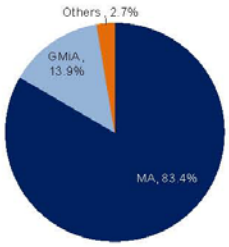
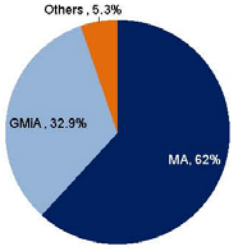
Figure 5: PBS market (by value at ex-manufacturer cost) includes below co-pay expenditure	**Figure 6: PBS market (by volume at ex-manufacturer prices) includes below co-pay scripts**
	

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Figure 7: PBS F2 formulary (by value at Government cost) excludes below co-pay expenditure	Figure 8: PBS F2 formulary (by volume by Government cost) excludes below co-pay scripts

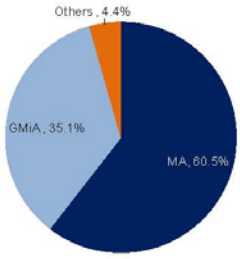
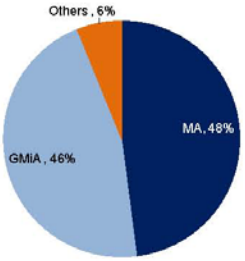

	

Figure 9: PBS F2 formulary (by value at ex-manufacturer cost) excludes below co-pay expenditure	**Figure 10: PBS F2 formulary (by volume at ex-manufacturer cost) excludes below co-pay scripts**

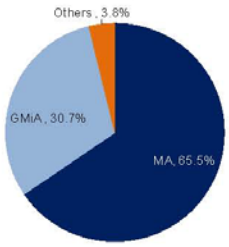
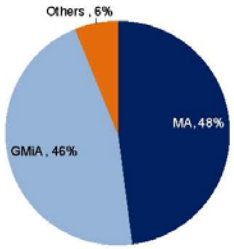
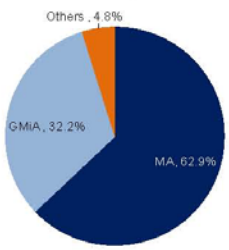
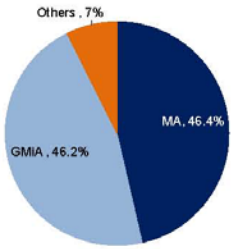

	

Figure 11: PBS F2 formulary (by value at ex-manufacturer cost) includes below co-pay expenditure	**Figure 12: PBS F2 formulary (by volume at ex-manufacturer prices) includes below co-pay scripts**
	

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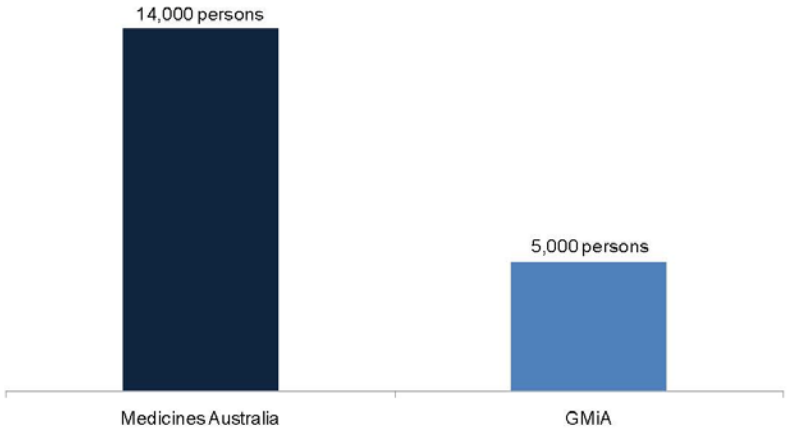
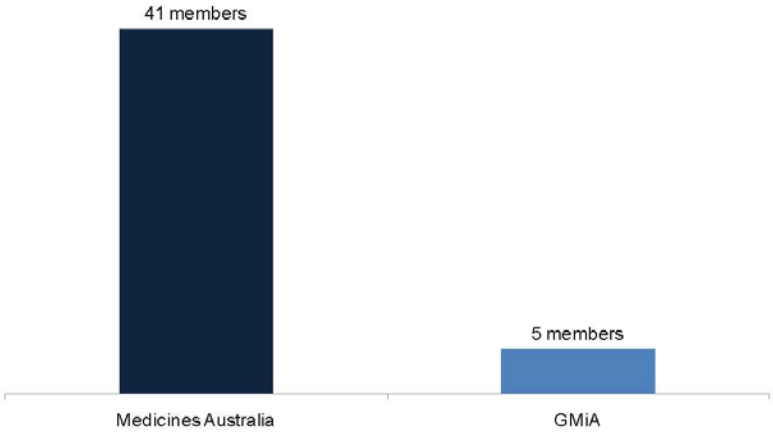
Finally, it is important to note that Medicines Australia members employ more people in the sector[10] (see Figure 13) and as an association Medicines Australia represents the vast majority of the companies that supply to the PBS[11] (see Figure 14).

Figure 13: Employment – Medicines Australia companies vs GMiA companies



Source: Medicines Australia Survey of members 2009 and GMiA survey 2009.

Figure 14: Member companies suppliers to the PBS – Medicines Australia vs GMiA



Source: Medicines Australia Survey membership 2010 and GMiA membership 2010.

[10] www.gmia.com.au
[11] www.gmia.com.au/contact

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Conclusion

The Memorandum of Understanding (MoU) between Medicines Australia and the Commonwealth is a broad package of reforms designed to ensure the sustainability of the Pharmaceutical Benefits Scheme.

The *National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010* enables changes in legislated pricing arrangements for medicines listed on the PBS, as laid out in the MoU.

The MoU benefits:

- **Consumers** – by reducing the price of many commonly prescribed medicines in the off-patent market, below the co-payment; and by introducing key process enhancements to the PBS that will improve access to medicines.
- **Taxpayers** – by delivering $1.86 billion in savings to the PBS over five years.
- **Industry** – by delivering four years of pricing policy certainty.

Medicines Australia therefore recommends that:

1. **The Parliament acknowledges that this Bill gives legislative effect to a number of the provisions contained within the MoU recently signed by the Australian Government and Medicines Australia. The MoU is a broader package of reforms designed to ensure the sustainability of the PBS and was effective from the date it was signed, 6 May 2010.**

2. **The Parliament passes the *National Health Amendment (Pharmaceutical Benefits) Bill 2010* before 1 October 2010.**

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APPENDIX 2

Memorandum of Understanding (MoU)

Australian Government

MEDICINES Australia
Better Health through Research and Innovation

MEMORANDUM OF UNDERSTANDING

1. This Memorandum of Understanding (MOU) records the understanding reached between Medicines Australia and the Commonwealth of Australia, represented by the Honourable Nicola Roxon MP, Minister for Health and Ageing, in relation to the Pharmaceutical Benefits Scheme (PBS).

2. Both parties agree that the MOU will be effective from the date of its execution until 30 June 2014.

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 the National Medicines Policy.

4. The Commonwealth undertakes not to implement new policy to generate price-related savings from the PBS during the period of agreement, that is, measures that would change the ex-manufacturer price of particular medicines, other than that reflected by this MOU.

5. The Commonwealth confirms its commitment to the principles and architecture of PBS Reform and, in particular, to maintain in accordance with the *National Health Act 1953*:
   - the separation of drugs between the F1 and F2 formularies and combination drug list; and
   - the different price setting and maintenance mechanisms which underpin the formularies.

6. Medicines Australia undertakes to support legislative changes required to effect policy changes arising from, or which reflect, this MOU.

7. Both parties undertake to jointly monitor trends in, and the drivers of, PBS expenditure through the Access to Medicines Working Group (AMWG), which will also develop a framework for this purpose. This will commence not later than 1 January 2011. The Commonwealth agrees to share with Medicines Australia, without cost, the information and analyses required to achieve this.

8. Both parties undertake to develop a mechanism to monitor and report progress on implementation of the MOU through the AMWG. This mechanism will be agreed between the parties and operational by 1 October 2010. The AMWG will report annually to the Minister for Health and Ageing on the progress and implementation of the MOU.

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9. Medicines Australia undertakes to establish a mechanism for "horizon scanning". In the context of this MOU, the purpose is to gauge the likely impact on the work of the Pharmaceutical Benefits Advisory Committee (PBAC), and on 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 AMWG provides a forum for this purpose. This will commence not later than 1 January 2011. Medicines Australia and the Commonwealth recognise that any such mechanism must have due regard to the commercially sensitive nature of much of this information.

Price reductions

10. From 1 February 2011, price reductions applied to single-brand PBS drugs on listing of a competitor brand will increase from 12.5 percent to 16 percent.

11. On 1 February 2011, a two percent price reduction will be applied to all drugs listed on F2A as at 30 September 2010. This is in addition to the two percent price reduction occurring on 1 August 2010.

12. On 1 February 2011, a five percent price reduction will be applied to all drugs listed on F2T as at 30 September 2010. Single-brand on-patent drugs listed on F2T that are subject to staged 25 percent price reductions will have this five percent price reduction applied as if the full 25 percent price reduction had already been applied.

Price disclosure

13. From 1 October 2010, strengthened price disclosure arrangements will apply as follows:

    (a) All brands of all drugs in the F2 formulary will be subject to price disclosure.

    (b) All items containing drugs in the F2 formulary, including section 100-only listings and items on the combination drug list with an F2 component, will be subject to price reductions resulting from price disclosure.

    (c) Price reduction points for the purposes of price disclosure will be 1 April, 1 August and 1 December.

    (d) The total period for a price disclosure cycle will be 18 months. This will comprise a data collection period of 12 months and a combined data analysis and notification period of six months.

    (e) Price reductions will apply in the same way as under current price disclosure arrangements (except as described below for drugs subject to price disclosure from 1 October 2010 under (g)).

    (f) The provisions requiring the first month of data for any new brand subject to price disclosure to be collected, but not used, for calculating the weighted average price disclosed will continue to apply.

    (g) For all F2 drugs not already subject to price disclosure, the first data collection period will be from 1 October 2010 to 30 September 2011. The price reductions from this cycle will apply from 1 April 2012.

    (h) The Commonwealth will not seek to amend the *National Health Act 1953* to alter the provision under subsection 99ADA(3) that an item be exempt from price disclosure.

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Price disclosure cycle of 1 October 2010 to 1 April 2012

14. (a) The weighted average price disclosure related price reduction for those F2 drugs included in the cycle, scheduled to commence on 1 October 2010 and to conclude on 1 April 2012, will be a minimum of 23 percent. As per paragraph 13(b), price reductions incurred by drugs in this cycle will flow-on to section 100 listings of the relevant drugs, and relevant F2 components of drugs listed on the combination drug list.

(b) A minimum price reduction of 23 percent from price disclosure will apply only to the 1 October 2010 to 1 April 2012 cycle. Drugs in this cycle will subsequently be subject to the rules applying to other price disclosure cycles.

(c) As a first step, the weighted average disclosed price (WADP) for each drug will be calculated.

(d) No price reduction will be applied to any drug where the difference between the initial WADP and the approved ex-manufacturer price is less than 10 percent and these drugs will remain excluded from price reduction adjustments in this cycle.

(e) If the minimum price reduction for the 1 October 2010 to 1 April 2012 cycle is reached, the calculated price disclosure related reductions will be applied.

(f) If the minimum price reduction for the 1 October 2010 to 1 April 2012 cycle, calculated in accordance with the WADP method, is not reached, the average price reduction of 23 percent will comprise:

- the price reductions calculated in accordance with WADP, plus
- additional administrative price reductions calculated according to the following guarantee adjustment proportion algorithm.

(i) A guarantee adjustment proportion (GAP) is calculated as:

$$GAP = 0.23/\text{average price reduction}$$

(ii) The GAP is applied proportionally to WADP-based price reductions calculated for each remaining drug to derive new price reductions. For example, if, say, the average price reduction is 20.9 percent, then the GAP is 1.1. This would lead to the following GAP-adjusted price reductions:

Drug	price reduction	GAP-adjusted reduction
A.	0.0%	n/a
B.	9.7%	n/a
C.	10.2%	11.2%
D.	30%	33%

(iii) No price would be reduced below the lowest disclosed price of a brand of that drug.

(iv) The average price reduction is then recalculated: and

- the algorithm is applied iteratively until the minimum 23 percent weighted average price reduction is met; or
- all items in the price disclosure cycle have reached the lowest disclosed price for a brand of that item.

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15. (a) The methodology and systems used to calculate price disclosure outcomes will be:

(i) made available to Medicines Australia and representatives of other suppliers of medicines to the PBS; and

(ii) independently verified by a third party.

(b) The calculations undertaken for price disclosure will be independently checked by a third party.

(c) Companies providing data under price disclosure arrangements will have the data verified in a manner to be agreed.

(d) The Commonwealth will work with Medicines Australia and representatives of other suppliers of medicines to the PBS to determine how quality assurance and dispute resolution processes will be implemented to ensure the accuracy of the data received under price disclosure.

Therapeutic Groups

16. The Commonwealth undertakes not to form any new Therapeutic Groups during the period of this MOU unless:

(a) the Commonwealth believes that a sponsor is seeking to list a minor variation of one of its already-listed drugs, and where the PBAC, using the evidence available to it, forms a view that the new drug offers no meaningful clinical advantage over the existing drug and is interchangeable on an individual patient basis. Some examples of minor variations for this purpose include, but are not limited to:

(i) salts;

(ii) enantiomers;

(iii) metabolites;

(iv) isomers;

(v) prodrugs; or

(vi) formulation, dosage or delivery changes; *and*

(b) the sponsor or marketer of the new drug is:

(i) the same or a related entity that listed or marketed the listed drug; or

(ii) has entered into a direct or indirect commercial arrangement with the sponsor or marketer of the listed drug.

17. The Commonwealth will provide sponsors with reasonable notice of its intention to form any new Group, and seek sponsor comment prior to determination of any new Group.

18. The three Therapeutic Groups which the Commonwealth had announced an intention to form in the 2009 Mid-Year Economic and Fiscal Outlook, do not represent new Therapeutic Groups for the purposes of paragraphs 16 and 17 and, thus, are not covered by this MOU. These comprise drugs for the treatment of depression, osteoporosis, and Paget disease.

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19. A drug which is a new or extended listing may be added to an extant Therapeutic Group, if the PBAC advises that it is interchangeable on an individual patient basis with members of the extant Therapeutic Group. Consistent with paragraph 17, the Commonwealth will provide sponsors with reasonable notice of its intention in this respect and seek sponsor comment prior to inclusion in the Therapeutic Group.

Consistent treatment of brands of drugs sold at the same price

20. During the period of this MOU, the Commonwealth undertakes not to introduce any measure (noting paragraph 21), which favours the prescribing or dispensing of generic brands of a drug over originator brands of the same drug, for which the approved price to pharmacists (or where agreed as the approved ex-manufacturer price, the ex-manufacturer price) is the same, without the agreement of Medicines Australia.

21. Both parties agree that the Commonwealth can continue with its $1.53 (or as indexed from time to time) incentive in relation to the dispensing of premium-free brands of drugs. The Commonwealth does not intend to make any variation in the amount of the incentive, without the agreement of Medicines Australia.

22. For the avoidance of doubt, nothing in this MOU is taken to exclude the Commonwealth:

    (a) undertaking awareness campaigns about any medicines (including generic medicines) where such campaigns are factual in nature, during the period of this MOU; or

    (b) acting on any recommendation of the PBAC which may impact on the price of drugs (noting the Commonwealth's undertakings under, and where this is consistent with, paragraphs 4, 5 and 16 of this MOU).

Comparators

23. The Commonwealth and Medicines Australia will work together to formally document the impact on pricing of lower comparator prices where comparators are listed in the F2 formulary and provide an annual report to the Minister for Health and Ageing. The AMWG provides a forum to develop a framework for collecting data, documenting any impact and determining reporting for this purpose.

Parallel TGA and PBAC processes

24. From 1 January 2011, the Commonwealth will no longer require the respective registration and reimbursement evaluation and assessment processes for major submissions to be undertaken sequentially, noting the following:

    (a) A PBS listing cannot occur prior to the product being listed on the Australian Register of Therapeutic Goods;

    (b) A PBAC recommendation will not be made public before a decision by the Therapeutic Goods Administration (TGA) that a product is registrable for the relevant indications;

    (c) Publication of PBAC outcomes will not occur until TGA outcomes are known; and

    (d) Current arrangements for publication that an application has been made to the PBAC will continue.

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25. Any additional costs in processing PBAC applications resulting from any consequent misalignment of applications through the two processes will be borne by applicants under cost recovery arrangements.

Managed Entry Scheme

26. From 1 January 2011, the Commonwealth undertakes to introduce a mechanism whereby the PBAC may recommend PBS coverage at a price justified by the existing evidence, pending submission of more conclusive evidence of cost-effectiveness to support listing of the drug at a higher price. The PBAC will provide advice in relation to sources of uncertainty and specific evidence required to support a subsequent application.

27. It is agreed that the application of this mechanism will initially be restricted to submissions where the PBAC agrees that there is a clinical need for the intervention, and when:

- the PBAC would not otherwise recommend the listing of the drug at the proposed price because the extent or value of the clinical effect is uncertain; and
- there is a randomised clinical trial (or comparable "fit-for-purpose" evidence), due to report within a reasonable timeframe, which the PBAC is satisfied will resolve the identified area of uncertainty.

The parties note that this does not preclude use of other tools for managing uncertainty (e.g. risk-sharing agreements) where appropriate.

Timing and Maximum Time Frames

28. The Commonwealth will work with industry to examine possible methods to reduce the time taken to finalise PBS pricing negotiations after a PBAC recommendation, including for those PBS submissions that require Cabinet approval prior to listing and this will be monitored by the AMWG through a mechanism to be agreed.

29. For those submissions required to be approved by Cabinet, the Commonwealth will use its best endeavours to implement a maximum time frame of six months for consideration and decision by Cabinet. The six months will commence from the date of notification by the Department of Health and Ageing to the sponsor that pricing is agreed.

Resolution of issues in good faith

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 medicines industry.

31. In the event that a dispute occurs between the Commonwealth and Medicines Australia in relation to the operation of this MOU, and that cannot be settled in discussion with the relevant Deputy Secretary, the Chief Executive of Medicines Australia and the Secretary of the Department of Health and Ageing will meet in the first instance to resolve the issue. In the event that the dispute is still not resolved, the matter will be referred to a meeting between the Minister for Health and Ageing and representatives of the Medicines Australia Board.

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32. In the event that circumstances eventuate that affect the parameters of this agreement, the MOU may be varied by either party subject to the agreement of the other. Where such an event occurs, the parties to this MOU undertake to negotiate in good faith.

SIGNED by for and on behalf of the **COMMONWEALTH OF AUSTRALIA** as represented by the **HONOURABLE NICOLA ROXON MP, MINISTER FOR HEALTH AND AGEING:**

6th May 2010
Date

Signature

in the presence of:

Owen Torpy
Printed name of Witness

Signature of Witness

SIGNED by **WILL DELAAT, CHAIRMAN**, for and on behalf of **MEDICINES AUSTRALIA**

5th May, 2010
Date

Signature

in the presence of:

BRENDAN SHAW
Printed name of Witness

Signature of Witness

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Attachment 2

Australian Government

MEDICINES Australia
Better Health through Research and Innovation

MEMORANDUM OF UNDERSTANDING

SEPTEMBER 2010

1. This Memorandum of Understanding (MOU) records the understanding reached between Medicines Australia and the Commonwealth of Australia, represented by the Honourable Nicola Roxon MP, Minister for Health and Ageing, in relation to the Pharmaceutical Benefits Scheme (PBS).

2. Both parties agree that the MOU will be effective from the date of its execution until 30 June 2014.

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 the National Medicines Policy.

4. The Commonwealth undertakes not to implement new policy to generate price-related savings from the PBS during the period of agreement, that is, measures that would change the ex-manufacturer price of particular medicines, other than that reflected by this MOU.

5. The Commonwealth confirms its commitment to the principles and architecture of PBS Reform and, in particular, to maintain in accordance with the *National Health Act 1953*:
   - the separation of drugs between the F1 and F2 formularies and combination drug list; and
   - the different price setting and maintenance mechanisms which underpin the formularies.

6. Medicines Australia undertakes to support legislative changes required to effect policy changes arising from, or which reflect, this MOU.

7. Both parties undertake to jointly monitor trends in, and the drivers of, PBS expenditure through the Access to Medicines Working Group (AMWG), which will also develop a framework for this purpose. This will commence not later than 1 January 2011. The Commonwealth agrees to share with Medicines Australia, without cost, the information and analyses required to achieve this.

8. Both parties undertake to develop a mechanism to monitor and report progress on implementation of the MOU through the AMWG. This mechanism will be agreed between the parties and operational by 1 October 2010. The AMWG will report annually to the Minister for Health and Ageing on the progress and implementation of the MOU.

9. Medicines Australia undertakes to establish a mechanism for "horizon scanning". In the context of this MOU, the purpose is to gauge the likely impact on the work of the Pharmaceutical Benefits Advisory Committee (PBAC), and on 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 AMWG provides a forum for this purpose. This will commence not later than 1 January 2011. Medicines Australia and the Commonwealth recognise that any such mechanism must have due regard to the commercially sensitive nature of much of this information.

Price reductions

10. From 1 February 2011, price reductions applied to single-brand PBS drugs on listing of a competitor brand will increase from 12.5 percent to 16 percent.

11. On 1 February 2011, a two percent price reduction will be applied to all drugs listed on F2A as at 11 October 2010. This is in addition to the two percent price reduction occurring on 1 August 2010.

12. On 1 February 2011, a five percent price reduction will be applied to all drugs listed on F2T as at 11 October 2010. Single-brand on-patent drugs listed on F2T that are subject to staged 25 percent price reductions will have this five percent price reduction applied as if the full 25 percent price reduction had already been applied.

Price disclosure

13. From 1 December 2010, strengthened price disclosure arrangements will apply as follows:

    (a) All brands of all drugs in the F2 formulary will be subject to price disclosure.

    (b) All items containing drugs in the F2 formulary, including section 100-only listings and items on the combination drug list with an F2 component, will be subject to price reductions resulting from price disclosure.

    (c) Price reduction points for the purposes of price disclosure will be 1 April, 1 August and 1 December.

    (d) Apart from the first main cycle, the total period for a price disclosure cycle will be at least 18 months. This will comprise a data collection period, and a combined data submission, analysis and notification period, of not less than 12 months and six months, respectively. The first main cycle commencing 1 December 2010, will be 16 months, incorporating a 10 month data collection period.

    (e) Price reductions will apply in the same way as under current price disclosure arrangements (except as described below for drugs subject to price disclosure in the cycle commencing 1 December 2010 under (g)).

    (f) The provisions requiring the first month of data for any new brand subject to price disclosure to be collected, but not used, for calculating the weighted average price disclosed will continue to apply.

    (g) For all F2 drugs not already subject to price disclosure, the first data collection period will be from 1 December 2010 to 30 September 2011. The price reductions from this cycle will apply from 1 April 2012.

    (h) The Commonwealth will not seek to amend the *National Health Act 1953* to alter the provision under subsection 99ADA(3) that an item be exempt from price disclosure.

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Price disclosure cycle of 1 December 2010 to 1 April 2012

14. (a) The weighted average price disclosure related price reduction for those F2 drugs included in the cycle, scheduled to commence on 1 December 2010 and to conclude on 1 April 2012, will be a minimum of 23 percent. As per paragraph 13(b), price reductions incurred by drugs in this cycle will flow-on to section 100 listings of the relevant drugs, and relevant F2 components of drugs listed on the combination drug list.

(b) A minimum price reduction of 23 percent from price disclosure will apply only to the 1 December 2010 to 1 April 2012 cycle. Drugs in this cycle will subsequently be subject to the rules applying to other price disclosure cycles.

(c) As a first step, the weighted average disclosed price (WADP) for each drug will be calculated.

(d) No price reduction will be applied to any drug where the difference between the initial WADP and the approved ex-manufacturer price is less than 10 percent and these drugs will remain excluded from price reduction adjustments in this cycle.

(e) If the minimum price reduction for the 1 December 2010 to 1 April 2012 cycle is reached, the calculated price disclosure related reductions will be applied.

(f) If the minimum price reduction for the 1 December 2010 to 1 April 2012 cycle, calculated in accordance with the WADP method, is not reached, the average price reduction of 23 percent will comprise:

- the price reductions calculated in accordance with WADP, plus
- additional administrative price reductions calculated according to the following guarantee adjustment proportion algorithm.

(i) A guarantee adjustment proportion (GAP) is calculated as:

$$GAP = 0.23/\text{average price reduction}$$

(ii) The GAP is applied proportionally to WADP-based price reductions calculated for each remaining drug to derive new price reductions. For example, if, say, the average price reduction is 20.9 percent, then the GAP is 1.1. This would lead to the following GAP-adjusted price reductions:

Drug	**price reduction**	**GAP-adjusted reduction**
A.	0.0%	n/a
B.	9.7%	n/a
C.	10.2%	11.2%
D.	30%	33%

(iii) No price would be reduced below the lowest disclosed price of a brand of that drug.

(iv) The average price reduction is then recalculated: and

- the algorithm is applied iteratively until the minimum 23 percent weighted average price reduction is met; or
- all items in the price disclosure cycle have reached the lowest disclosed price for a brand of that item.

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15. (a) The methodology and systems used to calculate price disclosure outcomes will be:

    (i) made available to Medicines Australia and representatives of other suppliers of medicines to the PBS; and

    (ii) independently verified by a third party.

    (b) The calculations undertaken for price disclosure will be independently checked by a third party.

    (c) Companies providing data under price disclosure arrangements will have the data verified in a manner to be agreed.

    (d) The Commonwealth will work with Medicines Australia and representatives of other suppliers of medicines to the PBS to determine how quality assurance and dispute resolution processes will be implemented to ensure the accuracy of the data received under price disclosure.

Therapeutic Groups

16. The Commonwealth undertakes not to form any new Therapeutic Groups during the period of this MOU unless:

    (a) the Commonwealth believes that a sponsor is seeking to list a minor variation of one of its already-listed drugs, and where the PBAC, using the evidence available to it, forms a view that the new drug offers no meaningful clinical advantage over the existing drug and is interchangeable on an individual patient basis. Some examples of minor variations for this purpose include, but are not limited to:

        (i) salts;

        (ii) enantiomers;

        (iii) metabolites;

        (iv) isomers;

        (v) prodrugs; or

        (vi) formulation, dosage or delivery changes; *and*

    (b) the sponsor or marketer of the new drug is:

        (i) the same or a related entity that listed or marketed the listed drug; or

        (ii) has entered into a direct or indirect commercial arrangement with the sponsor or marketer of the listed drug.

17. The Commonwealth will provide sponsors with reasonable notice of its intention to form any new Group, and seek sponsor comment prior to determination of any new Group.

18. The three Therapeutic Groups which the Commonwealth had announced an intention to form in the 2009 Mid-Year Economic and Fiscal Outlook, do not represent new Therapeutic Groups for the purposes of paragraphs 16 and 17 and, thus, are not covered by this MOU. These comprise drugs for the treatment of depression, osteoporosis, and Paget disease.

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19. A drug which is a new or extended listing may be added to an extant Therapeutic Group, if the PBAC advises that it is interchangeable on an individual patient basis with members of the extant Therapeutic Group. Consistent with paragraph 17, the Commonwealth will provide sponsors with reasonable notice of its intention in this respect and seek sponsor comment prior to inclusion in the Therapeutic Group.

Consistent treatment of brands of drugs sold at the same price

20. During the period of this MOU, the Commonwealth undertakes not to introduce any measure (noting paragraph 21), which favours the prescribing or dispensing of generic brands of a drug over originator brands of the same drug, for which the approved price to pharmacists (or where agreed as the approved ex-manufacturer price, the ex-manufacturer price) is the same, without the agreement of Medicines Australia.

21. Both parties agree that the Commonwealth can continue with its $1.53 (or as indexed from time to time) incentive in relation to the dispensing of premium-free brands of drugs. The Commonwealth does not intend to make any variation in the amount of the incentive, without the agreement of Medicines Australia.

22. For the avoidance of doubt, nothing in this MOU is taken to exclude the Commonwealth:

    (a) undertaking awareness campaigns about any medicines (including generic medicines) where such campaigns are factual in nature, during the period of this MOU; or

    (b) acting on any recommendation of the PBAC which may impact on the price of drugs (noting the Commonwealth's undertakings under, and where this is consistent with, paragraphs 4, 5 and 16 of this MOU).

Comparators

23. The Commonwealth and Medicines Australia will work together to formally document the impact on pricing of lower comparator prices where comparators are listed in the F2 formulary and provide an annual report to the Minister for Health and Ageing. The AMWG provides a forum to develop a framework for collecting data, documenting any impact and determining reporting for this purpose.

Parallel TGA and PBAC processes

24. From 1 January 2011, the Commonwealth will no longer require the respective registration and reimbursement evaluation and assessment processes for major submissions to be undertaken sequentially, noting the following:

    (a) A PBS listing cannot occur prior to the product being listed on the Australian Register of Therapeutic Goods;

    (b) A PBAC recommendation will not be made public before a decision by the Therapeutic Goods Administration (TGA) that a product is registrable for the relevant indications;

    (c) Publication of PBAC outcomes will not occur until TGA outcomes are known; and

    (d) Current arrangements for publication that an application has been made to the PBAC will continue.

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25. Any additional costs in processing PBAC applications resulting from any consequent misalignment of applications through the two processes will be borne by applicants under cost recovery arrangements.

Managed Entry Scheme

26. From 1 January 2011, the Commonwealth undertakes to introduce a mechanism whereby the PBAC may recommend PBS coverage at a price justified by the existing evidence, pending submission of more conclusive evidence of cost-effectiveness to support listing of the drug at a higher price. The PBAC will provide advice in relation to sources of uncertainty and specific evidence required to support a subsequent application.

27. It is agreed that the application of this mechanism will initially be restricted to submissions where the PBAC agrees that there is a clinical need for the intervention, and when:

    - the PBAC would not otherwise recommend the listing of the drug at the proposed price because the extent or value of the clinical effect is uncertain; and
    - there is a randomised clinical trial (or comparable "fit-for-purpose" evidence), due to report within a reasonable timeframe, which the PBAC is satisfied will resolve the identified area of uncertainty.

    The parties note that this does not preclude use of other tools for managing uncertainty (e.g. risk-sharing agreements) where appropriate.

Timing and Maximum Time Frames

28. The Commonwealth will work with industry to examine possible methods to reduce the time taken to finalise PBS pricing negotiations after a PBAC recommendation, including for those PBS submissions that require Cabinet approval prior to listing and this will be monitored by the AMWG through a mechanism to be agreed.

29. For those submissions required to be approved by Cabinet, the Commonwealth will use its best endeavours to implement a maximum time frame of six months for consideration and decision by Cabinet. The six months will commence from the date of notification by the Department of Health and Ageing to the sponsor that pricing is agreed.

Resolution of issues in good faith

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 medicines industry.

31. In the event that a dispute occurs between the Commonwealth and Medicines Australia in relation to the operation of this MOU, and that cannot be settled in discussion with the relevant Deputy Secretary, the Chief Executive of Medicines Australia and the Secretary of the Department of Health and Ageing will meet in the first instance to resolve the issue. In the event that the dispute is still not resolved, the matter will be referred to a meeting between the Minister for Health and Ageing and representatives of the Medicines Australia Board.

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32. In the event that circumstances eventuate that affect the parameters of this agreement, the MOU may be varied by either party subject to the agreement of the other. Where such an event occurs, the parties to this MOU undertake to negotiate in good faith.

SIGNED by for and on behalf of the **COMMONWEALTH OF AUSTRALIA** as represented by the **HONOURABLE NICOLA ROXON MP, MINISTER FOR HEALTH AND AGEING**:

28/9/10
Date

Signature

in the presence of:

PHUONG PHAM
Printed name of Witness

Signature of Witness

SIGNED by **WILL DELAAT**, **CHAIRMAN**, for and on behalf of **MEDICINES AUSTRALIA**

28 September 2010
Date

Signature

in the presence of:

Dr Brendan Shaw
Printed name of Witness

Signature of Witness

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Attachment 3

Australia's medicines industry – supporting facts

- Medicines Australia's members are the providers of over 86 per cent of medicines on the PBS (originator and generic), and the majority of sales of off-patent medicines on the PBS (about two-thirds of the value of the off-patent/generics market).
- Medicines Australia's members will bear the overwhelming burden of the savings imposts under the MoU and the Bill.
- Despite the 2007 PBS reforms, the Australian Government continues to pay significantly more for many high volume off-patent/generic medicines than many other OECD countries. By contrast, Australian prices for originator medicines are 81 per cent of the OECD average; Australia pays the fourth lowest prices for these medicines relative to economy-wide prices in the OECD.[1] This is because the current regulatory system which imposes rigorous cost-effectiveness standards and reference pricing on new, innovative medicines, keeps the price of these medicines low by international standards.
- The MoU and the Bill neither mandate nor prohibit new discounting by manufacturers of off-patent medicines. Rather, they capture the discounting already occurring in the marketplace. Price disclosure simply ensures that information about what is currently occurring in the market – the type and level of discounting – can be provided to the Australian Government. In this sense, the Australian Government is restored to the position of fully informed consumer, a principle upon which many other market sectors operate. In the absence of price disclosure, the Australian Government and taxpayers, pensioners, concessionaires and other consumers will continue to pay much higher prices for off-patent medicines than the actual price at which manufacturers *already sell them* to pharmacists. Products that are not experiencing discounting will suffer no price cuts.
- The drug development process is high-cost, lengthy and characterised by an unusually high level of risk relative to other industries. It is critical for the maintenance of a viable and responsible medicines industry to be provided with price-related certainty.
- Many patents are due to expire in the short-term. Nineteen (19) medicines worth $2.3 billion annually on the PBS are coming off patent in coming years. Globally, some $78 billion in patent-expired medicines sales will occur in the time period to 2014.
- The Bill will not lead to disruptions in the supply of medicines or stock outs. The Bill does not remove the obligations already imposed on pharmacists and their wholesalers to ensure that consumers have timely access to medications.
- In many cases, the administration and reporting systems that are required under the MoU and the Bill to support price disclosure arrangements will already have been in place to comply with the 2007 reforms.
- To realise the nearly $1.9 billion of savings it is imperative that the special round of price disclosure commence no later than 1 December 2010. Any further delays will impede the ability to obtain the necessary amount of data for a full, market-based assessment of what discounting is occurring in the off-patent/medicines market in Australia.

[1] OECD Pharmaceutical Pricing Policies in a Global Market Health Policy Studies report 2008.