SENATE COMMUNITY AFFAIRS LEGISLATION COMMITTEE

INQUIRY INTO THE NATIONAL HEALTH AMENDMENT (PHARMACEUTICAL BENEFITS) BILL 2015

SUBMISSION

AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH

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CONTENTS

1. ACCESS AND SUSTAINABILITY PACKAGE

The PBS Access and Sustainability Package

The National Health Amendment (Pharmaceutical Benefits) Bill 2015 (the Bill) will amend the *National Health Act 1953* (the Act) to implement a number of measures in the Pharmaceutical Benefits Scheme (PBS) Access and Sustainability Package (the Package).

The Package will deliver community pharmacy funding through a Sixth Community Pharmacy Agreement (6CPA), the new five-year agreement with the Pharmacy Guild of Australia (Guild), in a way that reflects recommendations from the Australian National Audit Office's audit of the 5CPA. It will also improve consumer access to medicines, change pricing arrangements for PBS medicines and facilitate improvements to the pharmaceutical sector. The Package is expected to result in gross savings to the Budget of approximately $6.6 billion over five years. After reinvestment in various parts of the pharmacy and pharmaceutical sectors, net savings to the Budget are expected to be $3.7 billion over five years.

In developing the Package, the Government recognised the important role that all parties play in the pharmaceutical supply chain and the need to manage financial viability risks for pharmacy and pharmaceutical companies, in the context of access for consumers.

Consultation on the Package

The Package is the result of extensive consultation and negotiation across the entire PBS supply chain. It reflects input and ideas from all sectors, and contains savings from across the supply chain. The Government has worked closely over the past five months with the Pharmacy Guild of Australia (the Guild), the Generic Medicines Industry Association (GMiA), the Consumers Health Forum of Australia, Medicines Australia and more than 20 other stakeholders to develop the package of measures that will ensure ongoing access to innovative medicines through a sustainable PBS.

This is the first time negotiations on five year strategic agreements with the pharmacy and pharmaceutical sectors were not confined to the Guild and Medicines Australia. Consultation included a roundtable meeting, group discussions and one-on-one meetings.

Although not all stakeholders agree with all elements of the package, each component does have support from across the stakeholder groups, who recognise that everyone must contribute to the savings needed, in order to share the benefits.

Details of the measures contained in the whole Package are at Attachment A.

2. OVERVIEW OF MEASURES IN THE BILL

The measures in the Bill are designed to ensure the long-term sustainability of the PBS and patient access to new and innovative medicines when and where they need

them, at a price both they and Australian taxpayers can afford. The amendments will enable:

- pharmacy location rules to continue until 30 June 2020;
- reductions in the cost of both innovative and generic medicines;
- increased competition by allowing pharmacies to discount patient co-payments;
- expansion of the PBS early supply provisions;
- streamlining of Pharmaceutical Benefits Advisory Committee (PBAC) processes; and
- technical amendments, including to support the intended operation of the Act in relation to recognising biosimilar medicines for the purposes of the application of statutory price reductions.

Together, the measures provide a fair and balanced approach, where all participants in the PBS contribute to the required savings, risks are managed, efficiencies are gained, and access to medicines and pharmacy services for consumers is improved. The changes will help create the capacity needed to respond to the increasing demand for very expensive medicines and allow pharmacy to continue to evolve.

3. MEASURES IN THE BILL

The Bill will amend the *National Health Act 1953* to implement the following measures from the Package:

- from 1 April 2016, applying a one-off statutory price reduction of five per cent to brands of pharmaceutical items on the F1 formulary after they have been listed on the PBS for at least five years;
- from 1 October 2015, removing the originator brand from the calculation of the weighted average disclosed price of medicines under the price disclosure arrangements in the Act for those medicines that have been listed on the F2 formulary for at least three years;
- from 1 April 2016, flowing-on price disclosure reductions from single ingredient medicines to combination items;
- from 1 January 2016, expanding PBS early supply provision so that it applies to all PBS medicines where it is considered appropriate for the patient population, as recommended by the PBAC;
- from 1 January 2016, permitting approved pharmacists to (but not obliging them to) discount the PBS patient co-payment by a maximum of $1 per script;
- from 1 July 2015, revising PBAC membership arrangements to provide more capacity and allow for streamlining of PBAC processes;
- extending the expiry date for legislative provisions for pharmacy location rules and the role of the Australian Community Pharmacy Authority to 30 June 2020; and

- technical amendments, including to support the intended operation of the Act in relation to recognising biosimilar medicines for the purposes of the application of statutory price reductions.

Price reduction for F1 medicines

This measure applies a one-off statutory price reduction of five per cent for all medicines in the F1 formulary after they have been listed on the PBS for at least five years. Reductions will occur on 1 April of each year from 2016 to 2020, on or after the drug's fifth anniversary on F1.

F1 is the fastest growing area of the PBS. 45% of PBS expenditure is on F1 formulary medicines.

All new listings on F1 are direct reinvestment in the innovative medicines sector. That reinvestment is significant and is ongoing. The PBAC recommended new listings worth more than $4 billion over five years at its November 2014 and March 2015 meetings. The vast majority of these medicines are F1 listings.

Since 2010, Government has invested over $4.25 billion in new listings. In addition, it is currently considering a further $2.5 billion in new listings from the November 2014 and March 2015 PBAC meetings, such as pembrolizumab (Keytruda®), for the treatment of advanced melanoma, which means patients will pay no more than $37.70 per script rather than the full cost of $8,000 - $15,000 per month. It also includes the new listings for hepatitis C - sofosbuvir , ledipasvir with sofosbuvir and daclatasvir which were recommended at the March 2015 PBAC. They are expensive medicines that are expected to be widely-used.

This sustained level of investment in new medicines required on the PBS now and into the future, highlights the need to have a portion of savings delivered from F1. It is important to find a sustainable way to fund new listings, as it is new money the Government has to find continually. Asking the innovative medicines sector to contribute to the long term growth of its market access is not unreasonable. It is sensible that medicines established on F1 for five years make some contribution to the savings required to fund more new medicines.

It has been estimated that it takes five years for pharmaceutical companies to recoup the research and development costs associated with bringing a new medicine to market. The F1 statutory price reduction measure takes this into account so the reductions apply only to drugs on F1 that have been listed for at least five years.

The Government is currently working with industry to ensure this policy is implemented in a way that supports the National Medicines Policy objectives while limiting unintended consequences, including through safeguards and exemptions as determined by the Commonwealth.

Removing the originator from price disclosure calculations

This measure will accelerate price disclosure arrangements for medicines which have been listed under the PBS F2 formulary for at least three years through removal of

the originator brand as part of the calculation of the weighted average disclosed price (WADP) for medicines. This means higher price reductions will occur earlier.

The first data collection period under the measure will be 1 October 2015 to 31 March 2016. The first reduction day will be 1 October 2016.

Prices for originator brands tend to keep average prices up as they generally maintain higher prices than other brands. This reduces the effect of price reductions achieved by price disclosure.

The three-year delay in the application of this policy mitigates the risk of generics not achieving market share and market stability prior to the removal of the originator. The originator brand will remain available and will be subsidised at the level of other brands.

Safeguards will be put in place to maintain patient access to low-volume high need medicines and foster viability of the pharmaceutical industry. For example, the Regulations will provide that the three years will commence only when there are two or more brands of a form of a medicine such as oral or injection. These safeguards are in addition to those that exist under the current price disclosure arrangements.

Implementation of this measure will also include consultation with relevant stakeholders in relation to the draft Regulations and details of originator brands.

Consumers, taxpayers and the Government will benefit from cheaper medicine prices, and this measure will contribute to much-needed capacity for new and innovative medicines to be listed on the PBS.

Flowing-on price disclosure reductions from single ingredient medicines to combination items

This measure will ensure that price disclosure reductions from discounts on component ingredient drugs are applied consistently to the price of combination items containing those component drugs.

Currently there can be significant price differences between component drug prices and the price of that component in a combination item, in some cases more than 80 per cent difference. In many cases this difference was created by an existing loophole in the price disclosure framework. The measure will address the loophole by ensuring appropriate price reductions are applied to combination items on the PBS. An example of the large gaps developing in the prices between some component drugs (taking reductions) and their combination counterparts (avoiding reductions) is amlodipine and atorvastatin. A patient paying the full price for the two medicines separately (5mg/10mg) pays $18.03 less than buying the combined medicine. The general patient co-payment for the combination is $37.70. The dispensed price of the two drugs separately is $19.67 ($8.26 + $11.41).

This measure will result in savings for both the Government and consumers through reduction in prices paid for PBS-listed medicines.

The existing capacity will be retained for higher prices for combination items where the PBAC has given advice that the combination item provides a significant improvement over alternative therapies.

Discounting co-payments

This measure will allow pharmacists to discount the PBS co-payment and will save patients money.

The discounting of the PBS co-payment is not mandatory for pharmacists. It will provide them with the ability to discount, if they choose to. The optional nature and the amount of the discount will limit the impact on pharmacy but will also encourage competition.

This measure will deliver four main benefits:

- increased competition between pharmacies, driven by consumers;
- increased substitution of generic medicines;
- immediate benefit to patients through reduced out-of-pocket costs at the point of sale; and
- subsidised PBS concessional prescriptions with be able to be discounted consistently with general patient scripts.

As the average concession card holder uses 17 scripts per year, they could save $17 per year. Older concessional patients over 65 could save, on average, $43. Concessional patients will be able to benefit from the same $1 discount as applies for general patients, where currently they have been unable to benefit from the discounting offered to general patients on medicines that fall below the general co-payment.

If a person takes longer to reach their safety net, it is because they have received the discount up front. The amount of the safety net stays the same, so the out-of-pocket cost for the consumer to reach the threshold is the same. Patients will not be worse off under this measure.

It is also important to note that although the majority of PBS subsidised medicines are dispensed to concessional patients, the majority of concessional patients, around 80 per cent, do not reach the safety net. That means the average concessional patient over 65 could be $43 better off each year if they use a pharmacist that offers a discounted co-payment.

Rural and remote patients

Some commentators argue that consumers in rural and remote areas will not have access to discounting due to the lack of pharmacy competition, resulting in higher costs for some medicines compared to their city counterparts.

Consumers in rural and remote areas can request their community pharmacy to offer the discount, although as noted above, it is not mandatory for pharmacists to provide it. Irrespective of the discounting practices of their pharmacists, consumers

in rural and remote areas will not be worse off than under current arrangements and will continue to be safeguarded in relation to how much they pay for PBS medicines under PBS co-payment and safety net arrangements.

Changes to the pharmacy location rules in 2011 made it possible for a second pharmacy to be established as a new pharmacy in rural towns rather than having to relocate from another community. As at 30 June 2014, there were 614 rural towns in Australia that had only one pharmacy. However, just because there is only one pharmacy in a town does not mean it will not offer discounts on patient co-payments.

Extending safety net early supply rule

The current safety net early supply provisions will be amended to include a wider range of medicines and a wider range of resupply intervals. This will allow the use of a medicine, the listed quantity and the resupply interval for a medicine to be better aligned.

Safety net early supply arrangements have been in place since 2006, when the current policy, known as the Safety Net 20 day rule, was introduced. Under the policy, the financial incentive for patients to obtain excess supplies of PBS medicines in advance of treatment need is removed. If a repeat dispensing of a prescription is obtained earlier than the specified resupply date, the person's usual co-payment applies - not the reduced safety net amount - and the payment does not count towards the safety net threshold. Early supply rules promote responsible use of PBS entitlements, discourage waste, and reduce the quantity of unused medicines in the community.

These rules currently apply to certain medicines used for chronic conditions and for which the resupply interval is 20 days. The changes in the Bill will enable early supply rules to apply to PBS medicines as recommended by the PBAC and for any resupply interval appropriate for that medicine.

The change to the early supply rules are being made on the basis of recommendations from the PBAC. The Committee has recommended additional medicines it considers suitable for inclusion under early supply rules. It has also advised on medicines it considers are not suitable for inclusion under the extended rule. These include treatments for cancer, palliative care items, and medicines with high dosage variability.

Existing arrangements that allow pharmacists to dispense an early repeat supply with the usual PBS subsidy but with no safety net benefits will continue.

PBAC Membership

Over recent years, there has been a marked increase in the number and complexity of submissions made to the PBAC. The average number of major submissions is more than 30, compared to an average of 19 five years ago. The agenda for the March 2015 meeting included the largest number of major submissions ever with 40 major submissions and 21 minor submissions. In addition, submissions for new

medicines are involving increasingly complex new technologies, biological products, drug-test combinations, and very high treatment costs. Although the workload has increased, the size of the PBAC has not increased since 2006.

This measure will expand the PBAC membership from 18 to 21 members, including a new Deputy Chair, and create a PBAC Executive for triaging and considering certain applications. It will also provide the opportunity for members to be nominated and appointed from industry.

These changes will improve transparency, flexibility and efficiency of PBAC processes, reducing PBS listing times for some medicines. They will streamline and strengthen the PBAC's capacity to consider the increasing number and complexity of submission and make recommendations for listings in the most effective and efficient way.

Importantly, the new processes will allow for an improved level of engagement with key stakeholders, such as consumers and clinicians. A PBAC Executive to triage submissions and consider some applications will help reduce the number of resubmissions, and expedite more straightforward submissions.

This measure will also help address some of the issues raised during the Senate Inquiry into the availability of cancer drugs in Australia in early 2015.

Location rules

Amendments in the Bill will enable location rules and the Australian Community Pharmacy Authority which administers them, to continue until 30 June 2020.

The current location rules are due to expire on 30 June 2015. The effect of extending the expiry is that current arrangements can continue without interruption past 30 June 2015. If there is no legislative basis for pharmacy location rules and the Australian Community Pharmacy Authority, which makes recommendations based on the rules, consideration of applications by pharmacies for approval to dispense PBS medicines will be affected. This could affect the geographical spread of community pharmacies.

In the four years since the commencement of the Fifth Community Pharmacy Agreement (i.e. from 1 July 2010 to 30 June 2014) there has been an increase of 369 approved pharmacies to a total of 5,457 pharmacies (119 of those in rural localities) and a marked improvement in the pharmacy to population ratios. Rural communities, in particular, have benefited from the 2011 location rules changes, with the population to pharmacy ratio in rural areas improving significantly.

Pharmacy location rules have been important to the supply of medicines, particularly in rural and remote regions of Australia. However, the recommendations from several reviews have highlighted the need to consider a comprehensive review of government regulations, which are claimed to protect Australian pharmacies from competition. This includes the remuneration for supplying subsidised medicines, and the rules about the ownership and location of pharmacies.

The pharmacy sector and Government have agreed to a review of both remuneration and regulation, including location rules. That will happen from 1 July 2015.

Biosimilars

The Bill also contains technical amendments, including those relating to the naming of biosimilar medicines and schedule equivalence.

The technical amendments in the Bill regarding schedule equivalence (commonly known as 'a flagging') are designed to reflect the Department's current practice, while ensuring a legally robust framework in which decisions regarding schedule equivalence can be made.

The Commonwealth was put on notice in *Servier Laboratories (Aust.) Pty Ltd v Commonwealth of Australia [2009] FCA 31*, (a case on 'a' flagging perindopril erbumine and perindopril arginine) that the provisions in the Act regarding schedule equivalence required clarification. Specifically Justice Gray noted '….there is some difficulty determining exactly what power the Department was exercising when making the representations about equivalence..'.

To avoid future uncertainty regarding the legislative basis for decisions relating to schedule equivalence, the Government has taken this opportunity to set out a clear framework in the Act, which is intended to provide certainty for all stakeholders.

The amendments in the Bill expressly provide both the Minister with a decision-making power regarding Schedule equivalence and the PBAC with a specific function to provide advice to the Minister on Schedule equivalence.

Currently the PBAC provides this advice under its general advice power in section 101(3) of the Act, and the decision regarding Scheduled equivalence is made by Department. In practice these changes will result in minimal changes to the 'a flagging' process.

The PBAC has since outlined its intended approach to 'a flagging' with respect to biosimilar medicines at its April 2015 meeting.

When making a decision on schedule equivalence the Minister must consider any PBAC advice and may consider advice provided by the TGA on matters it considers in performing its roles and functions. It is not required, or intended, that the PBAC provides advice on each occasion that the Minister considers whether to determine if two brands of pharmaceutical items are schedule equivalent. This is consistent with current practice where PBAC advice is not sought regarding the listing of most generics.

The Bill also includes an amendment clarifying that biosimilar medicines will be listed as having the same drug as their reference biologic medicine. This amendment supports the intended operation of the PBS since the 2007 Act amendments introduced statutory price reduction.

4. CHANGES NOT INCLUDED IN BILL

Pharmacy remuneration

The 6CPA will provide certainty to the community pharmacy sector through a five year agreement between the Australian Government and the Guild. It will deliver up to $18.9 billion to community pharmacy and wholesalers over the next five years. This is an increase of over $3 billion on the 5CPA. In addition, an estimated $4.8 billion in under co-payment scripts provide additional revenue to community pharmacy. In total, the potential revenue for this sector from the PBS is $23.7 billion over the next five years.

The 6CPA will reduce the direct impact of PBS pricing policy on pharmacy, through the introduction of a fixed 'Administrative, Handling and Infrastructure' (AHI) fee into the remuneration model for pharmacy. This model will, in essence, de-link pharmacy remuneration from PBS prices and provide stability for pharmacists, by paying them the same fee for a box of medicine no matter the price of the drug. The stable fee gives pharmacists more remuneration certainty, which is an incentive to discount the price Australians pay for medicines.

In the very short-term, this change to AHI may impact on the price paid by some general consumers for some medicines. There will be no difference in the price the consumer is paying for medicines subsidised under the PBS. However, some medicines priced below the general PBS co-payment will be more expensive, and some will become less expensive if they are not being discounted by the pharmacy already, as the 6CPA only sets the maximum that pharmacy can charge.

Any price increases are likely to be temporary as these medicines will undergo two cycles of price disclosure reductions will continue. The next reductions are on 1 October 2015 and 1 April 2016. Further price reductions will follow with implementation of the measure to remove the originator from price disclosure calculations. The first reduction under that measure will be 1 October 2016.

Review of Pharmacy Remuneration and Regulation

The pharmacy sector and Government have agreed to a review of both remuneration and regulation, including location rules. This comprehensive and publicly accountable review will occur from 1 July 2015 and will give full consideration to the effectiveness and appropriateness of location rules. Its findings will be published within two years of the 6CPA commencing.

It will be an opportunity to consider concerns raised by the National Commission of Audit, the Australian National Audit Office, the Productivity Commission and other stakeholders. It may also represent an opportunity to consider how best to transition community pharmacy into a new model - one which is less reliant on Government subsidies and which can be implemented over time.

Funding of chemotherapy medicines

This measure will enable compounders of chemotherapy infusions to receive a direct payment from Government of:

- $60 per infusion if the compounder holds a Therapeutic Goods Administration (TGA) licence; or
- $40 per infusion if the compounder does not hold a TGA licence.

Without the introduction of these new arrangements, the additional $60 introduced following the 2013 Chemotherapy Review would otherwise have ceased on 30 June 2015.

This direct payment ensures transparency in Government funding for the compounding of chemotherapy infusions which was previously not flowing through in full when payments were made to community pharmacies rather than compounders. This was raised as an issue in the 2013 Chemotherapy Review, as well as directly with the Minister for Health during her consultations on the PBS Access and Sustainability Package.

Importantly, community pharmacies which compound onsite will continue to receive their $80.26 dispensing fee, plus mark ups, on top of the new compounding payments. This is compared to the standard $6.93 dispensing fee and other mark ups for other PBS medicines.

A direct payment to suppliers is similar to the Community Service Obligation where Government pays pharmaceutical wholesalers directly for the supply of PBS medicines.

The new two tiered structure reflects the substantial costs associated with the quality and safety processes, and infrastructure that need to be in place to receive and maintain a TGA compounding licence.

The Government is working with compounders to ensure that the transition to the new arrangements will be as smooth as possible to reduce the administrative burden on compounders. This will occur from 1 September 2015 to allow transitioning to the new arrangements. It is expected payment arrangements will be further streamlined over time, making it even easier and more transparent, through data linking and software system changes.

Removal of some over-the-counter medicines

As part of the implementation of the Package, some over-the-counter medicines will be removed from the PBS. Over-the-counter items are a class of medicines that can be sold directly to a consumer without a prescription from a healthcare professional. Examples are medicines that relieve aches, pains and itches. Around ten per cent of all PBS medicines – 20 million prescriptions – are for over-the-counter medicines.

Under this measure, medicines will only be delisted on the advice of the PBAC. Over-the-counter medicines including asthma inhalers such as Ventolin and

adrenaline injectors such Epipen will remain on the PBS. Medicines listed for use by Aboriginal and Torres Strait Islander people and palliative care listings will also remain on the PBS.

The Department of Health (the Department) has contacted sponsors with products identified as meeting the principles for de-listing which have a proposed de-listing date of 1 January 2016. Sponsors have been offered the opportunity to provide input for the PBAC's consideration of these items at its July 2015 meeting. This measureaffects around 15 per cent of the 352 over-the-counter items currently listed on the PBS.

Some commentators have highlighted the impact on concessional patients who use paracetamol for their arthritis. In making its recommendations, the PBAC has regard to current and changing evidence. This could include an article in the British Medical Journal on 31 March 2015, which questioned the clinical effectiveness of paracetamol for treating osteoarthritis.

Out-of-pocket expenses for some low-cost medicines will increase for some consumers. However, PBS funding should focus on essential medical treatments which carry a high cost to consumers and would otherwise be unaffordable. The measure will help create the capacity needed to continue to list new and innovative medicines on the PBS as quickly as possible.

It is important to remember the purpose of the PBS. PBS funding should be focused on providing access to essential medical treatments which carry a high cost to consumers and would otherwise be unaffordable. The $73 million spent subsidising paracetamol in 2013-14 alone would have funded the potentially lifesaving drug ipilimumab for late stage melanoma.

As noted above, while there may be higher out-of-pocket costs for some consumers, these will be mitigated by the immediate savings from discounting of the PBS co-payment.

Professional programmes funded under the 6CPA

The 6CPA provides up to $1.26 billion over five years to fund a range of professional programmes and services delivered by pharmacy and pharmacists. This includes:

- $613 million to support continuing programmes, including medication management and adherence programmes (for example, Home Medicine Reviews and Dose Administration Aids) and a range of targeted initiatives that focus on rural and remote Australia as well as Aboriginal and Torres Strait Islander peoples;
- $50 million to support a new Pharmacy Trial Programme, which will look at funding a range of trials to expand the role of pharmacy in delivering a wider range of primary healthcare services; and,
- $600 million which has been reserved to implement a range of new, expanded and continuing programmes, based on assessment by an

independent health technology assessment group such as the Medical Services Advisory Committee.

The 6CPA ensures that programmes previously funded under the 5CPA will continue for the first year of the Agreement. However, it is vital that any investment in services which are designed to improve health outcomes for consumers are effectively targeted, evidence-based and represent a cost-effective investment on behalf of the Australian taxpayer.

For this reason, all continuing and new programmes funded under the 6CPA, will be assessed for clinical and cost-effectiveness by an independent health technology assessment committee, such as the MSAC.

This will ensure services and programmes delivered through pharmacists and pharmacy are held to the same level of standard as other areas of the health profession. Further, this approach was determined in consultation with a range of stakeholder groups (including pharmacy groups) during consultations for the PBS Access and Sustainability Package.

In addition, as part of the community pharmacy programmes, the Government requires the achievement of real improvement in patient access to community pharmacies, including through increased opening hours. Funding for existing and any new or expanded community pharmacy programmes under the 6CPA will be contingent on the Guild and approved pharmacist actively working with the Department over the first financial year of the term of the 6CPA, and then on an ongoing basis, to achieve such improvement, including setting targets for improvement in the second financial year of the term and beyond.

5. OTHER ISSUES

ANAO Audit

In negotiating the 6CPA, the Government ensured the recommendations from the ANAO's audit of the 5CPA were not only actioned, but were also reflected in the Agreement itself.

The ANAO made eight recommendations, several relating to strengthening procedures and oversight. The 6CPA has addressed these recommendations through the following mechanisms:

- A strong emphasis on maintaining adequate records of the negotiating process, and consulting with a broader range of stakeholders through that process;
- Improving the accuracy and transparency of reporting and estimating government expenditure by identifying estimated government and patient remuneration contributions for both subsidised and unsubsidised PBS and RPS prescriptions;
- Annual reconciliations of expenditure in both script volumes and pharmacy programmes which will be reported back to Government;

- De-linking pharmacy remuneration from the price of medicines, thought the Administrative Handling and Infrastructure fee;
- Re-focusing the Premium Free Dispensing Incentive to only apply in circumstances where there where there is an equivalent brand with a special patient contribution to the brand that is dispensed;
- Pharmacy Programmes under the agreement will now be the subject of greater evaluation, with cost-effective reviews undertaken for continuing programs and new and expanded programs only to proceed where recommended by an independent health technology assessment body;
- A formal process will be undertaken to test the market for persons interested in, and capable of, providing administration support for the Pharmacy programs, after the end of the first year of the 6CPA;
- Costs for administration of Pharmacy Programmes is clearly specified in the Agreement; and
- A comprehensive and independent review of pharmacy remuneration and regulation will be undertaken within the first two years of the Agreement, noting that cost effectiveness of remuneration has not been assessed since 1989.

Attachment A

Table: Access and Sustainability Package – Savings measures

Savings measures	**$ millions (cash)**
One-off 5% statutory price reduction after drug listed for at least five years on F1 formulary	997
Price Disclosure – Remove originator after at least 3 years on F2	1,990
Price Disclosure – Flow-on to F2 combination items	610
Allowing Discounting PBS Patient Co-Payment	366
Expansion of PBS early supply provision 'Safety Net 20 Day rule', on PBAC advice	474
Removing OTC medicines from PBS, on PBAC advice	507
Uptake of biosimilars, including substitution at the pharmacy level on PBAC recommendation	883
Increasing PBS price change points from three to six a year	53
Re-focusing premium-free dispensing incentive to only apply where there is a brand premium	568
Move National Diabetes Services Scheme supply and delivery arrangements to Community Services Obligation (CSO) wholesalers	53
Freezing CSO wholesaler supply indexation for five years	47
Total	**6,548**