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Generic Medicines Industry Association

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

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Executive Summary

Members of GMiA support the Government's objectives to achieve a more efficient and sustainable Pharmaceutical Benefits Scheme (PBS), better value for money for Australian taxpayers and policy stability for the pharmaceutical sector. The PBS reforms introduced in 2007 were designed to meet these objectives and were forecast to save about $3 billion over ten years. Three recent and separate analyses – including the Government's own – show the savings will be about double that.

The reforms proposed under the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 ("the Bill") are unnecessary and the additional savings proposed are not justified. Currently, the PBS provides good value for money, the costs are not out of control and the ten-year reform process that began in 2007 ensures that the PBS will remain sustainable.

The proposed 2010 reforms will jeopardise the ongoing viability of the generic medicines sector and more broadly the pharmaceutical industry, Australia's leading exporter of manufactured goods. The proposed Bill will cut $1.9 billion out of the F2 formulary (generic medicines) over 5 years when the cost to Government of the entire F2 formulary fell by 21.4 per cent between 2005/06 to 2009/10 from $2.8 billion to $2.2 billion (Government annual contribution).

Conversely, the Bill does not address the growth of the F1 formulary (originator medicines) that has more than doubled over the same period from $2.8 billion to $4.8 billion (Government annual contribution) and the increasing costs of the F1 formulary will be the key growth driver to the PBS in the future.

The Bill underpins a Memorandum of Understanding (MoU) negotiated exclusively between the Government and the suppliers of originator medicines. The MoU was negotiated without consultation with the GMiA whose members supply 70 per cent of the volume of generic medicines.

The reforms heavily target the suppliers of generic medicines as their whole business is impacted by the proposed reforms. In contrast, only a limited number of products supplied by sponsors of originator medicines will be affected, with limited financial impact to them.

The proposed 2010 amendments

The proposed 2010 amendments to the PBS introduce two significant and damaging reforms:

1) further additional statutory price reductions to the F2 formulary (generic medicines); and

2) the expansion and acceleration of price disclosure.

This submission explains why the proposed further statutory price reductions and the accelerated and expanded introduction of price disclosure:

- Are not necessary as the 2007 reforms will deliver significant savings to the Government;
- Are not necessary as expenditure on pharmaceuticals is low as a % of GDP compared with other OECD markets;
- Are not necessary as pharmaceuticals already deliver good value for money to the Australian public;

- Will deliver additional savings to the Government that will jeopardise the viability of the generic medicines sector and will fundamentally change the way generic medicines are supplied in the Australian market;
- Will rapidly remove the key market mechanism by which suppliers of generic medicines compete, removing the incentive for suppliers of generic medicines to enter the market.

Sectional interests have been promoted through the exclusive nature of the MoU and the reform is piecemeal, threatening the optimal functioning of the PBS. As such, the Bill fails to provide for balanced reform to the PBS:

- The reforms to the F2 PBS formulary are heavily weighted towards the older F2 medicines, where typically the greater market share is held by members of GMiA. The reforms have a much smaller impact on the medicines more recently added to the F2 formulary, where typically the greater market share is held by the originator sponsor.
- The reforms do not address growth of the F1 PBS formulary (originator medicines) which will be the key driver of growth of PBS expenditure in the future.
- The elimination of reference pricing outside of therapeutic groups has imposed a significant cost impost on the PBS as there are no demand side limitations concurrently imposed on the more expensive F1 medicine.

Members of GMiA welcome the important scrutiny that the Community Affairs Legislation Committee will bring to this Bill that has to date been drafted without the benefit of proper, industry-wide consultation.

If an amended version of the Bill is introduced in the new Parliament, members of GMiA should be consulted about the content of any new legislation.

1. Introduction

This submission, prepared by the Generic Medicines Industry Association (GMiA) , responds to an invitation received from the Community Affairs Legislation Committee on 18 June 2010 to comment on the provisions of the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 .

The submission discusses the serious concerns held by members of the GMiA concerning the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 (the Bill) amending the *National Health Act 1953* (the Act) to provide the legislative framework enacting the provisions of the Memorandum of Understanding (MoU) between Government and Medicines Austr alia.

GMiA advocates further scrutiny of the Bill and members of GMiA are mobilised to work with all sectors of Government and relevant stakeholders to continue to achieve an efficient and sustainable Pharmaceutical Benefits Scheme (PBS), value for money for Australian taxpayers and policy stability for the pharmaceutical sector.

If an amended version of the Bill is introduced in the new parliament, GMiA wishes to reserve the right to make new submissions.

2. Summary of recommendations

Recommendation 1: **The Government should put on the public record the detailed breakdown and composition of forecast savings stemming from the proposed 2010 and the 2007 PBS reforms.**

Recommendation 2: **The Government should work with the GMiA to develop a reporting mechanism that enables inclusion in the Commonwealth Budget forward estimates of all savings resulting from the 2007 PBS reforms.**

Recommendation 3: **The presence of a generic medicines sector is already delivering and will continue to prospectively deliver substantial savings to the F2 formulary and no further reforms are necessary.**

Recommendation 4: **Should the Government contemplate further reforms to the PBS, all relevant stakeholders should be consulted before further reforms are drafted.**

3. The PBS

The PBS provides necessary medicines that contribute greatly to the health and well-being of the nation, at a cost the community, taxpayers and the Government can afford. Currently, the PBS provides good value for money, the costs are not out of control and a ten-year reform process that began in 2007 ensures it will remain sustainable.

3.1 The PBS provides good value for money

The PBS is the most cost-effective element of the health care system in Australia. Since 1993, every product put on the PBS has undergone rigorous, independent health economic assessment to ensure it is cost-effective to the nation. This means the price paid for each product reflects the health outcome it produces.

3.2 The cost of the PBS is not out of control

When benchmarked against expenditure on pharmaceuticals by OECD nations, the PBS is affordable. PBS cost as a percentage of GDP peaked in 2004/05 at 0.67 per cent and has since declined to 0.62 per cent in 2007/08. Cost-effective expenditure on pharmaceuticals should rise with the increasing and ageing population. Anything less reflects insufficient investment in health care by government.

3.3 The PBS is sustainable

PBS costs are sustainable, especially as a result of the 2007 PBS reforms that introduced a mechanism to ensure the prices paid by government for pharmaceuticals reflect their true market prices. The 2007 PBS reforms, initially expected to return some $3 billion to government over ten years, are now expected – according to three separate analyses, including the Government's own - to return double that.

Recently released Medicare Australia figures show that the rate of growth in PBS spending is 30 per cent lower than for the previous 12 months.

3.4 All sectors of the pharmaceutical industry must remain viable

For the PBS to remain cost-effective, affordable and sustainable, all sectors of the pharmaceutical industry must be viable. The PBS cannot function without both the originator and generic sectors of the industry interacting appropriately.

Originator companies play an important role in discovering new therapies to treat or control diseases. The patent period enables originator companies to negotiate higher prices for new, innovative medicines to recoup their research investment costs. Once the patent expires, the entry of generic medicines allows consumers access to medicines at a more affordable price. In fact, the introduction of generic medicines stimulates innovation by virtue of the reduced profitability of medicines post patent expiry.

Generic medicines are therefore essential in balancing reward for innovation against long term medicines affordability, and sustainability of the PBS

3.5 Viability of all sectors of the industry requires policy certainty

The 2007 reforms were the most major reform to the PBS since its inception in 1948. They were supposed to begin a ten-year period of policy stability. Layering additional reforms on a system still undergoing major reform is like building on a foundation of wet cement. Repeated reform that continuously reduces the profitability of the sector will critically harm the sector and is entirely incompatible with making investment decisions that require long term horizons, as required in the pharmaceutical industry.

4. Description of PBS reform

On 28 June 2007, amendments to the National Health Act 1953 received royal assent which gave effect to a significant restructure of PBS pricing arrangements to ensure the long-term sustainability of the PBS. This restructure is referred to as PBS reform. On 2 June 2010, the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 (the Bill) was introduced in the House of

Representatives. The Bill provides the legislative framework enacting the provisions of the Memorandum of Understanding between Government and Medicines Australia.

4.1 2007 PBS reforms

In 2007, the Government implemented the significant reform to the PBS since its inception in 1948. The reforms were to play out over a decade and were originally projected to save $3 billion. Two years into the 10-year reform process, three separate analyses have estimated that the total savings will be about double that. Even the Government's own analysis shows the savings will be between $3.4 and $5.8 billion.

The reforms split the pharmaceutical benefits scheme into two formularies, namely the F1 formulary comprising single branded medicines (typically protected by patent and referred to as originator medicines) and F2 comprising predominantly multi-branded medicines subject to competition (typically from generic medicines). The reforms imposed statutory price reductions to medicines on the F2 formulary. In addition, the reforms introduced the price disclosure policy applicable to the F2 formulary. The policy seeks to retrospectively claw back discounts given to pharmacists by suppliers of generic medicines. The bigger the discounts given to pharmacists, the bigger the amount clawed back by the Government.

As at 30 June 2009, the net cost of the 2007 PBS reforms was $85 million due to the high cost of the structural adjustment package provided to pharmacy and a small compensation package to wholesalers. Table 4.1 presents the breakdown of the net impact to Government from PBS reforms as at 30 June 2009, as reported by Government.

Table 4.1: Net impact to Government from PBS reforms as at 30 June 2009

$102 m	Pharmacy premium free incentive payment
$146 m	Pharmacy on-line incentive payment
$89 m	Pharmacy additional mark-up fees
$22 m	CSO payments
-$274 m	Reduced industry payments
$85 m	Net cost to Govt as at 30 Jun '09

Source: Commonwealth of Australia, *The impact of PBS reform: report to the Parliament on the National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007*, Commonwealth of Australia, Canberra, February 2010, pp. 8–9, http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs-reform-report

4.2 2010 PBS reforms

The proposed 2010 amendments are projected to save $1.9 billion over five years and layer further reforms on top of the 2007 reforms. The Government has not made transparent the rationale for these additional reforms, the breakdown of these proposed savings, nor how these savings interrelate with the savings that are still flowing from the 2007 reforms.

The costs associated with the implementation and ongoing administrative costs of the 2010 reforms were only made available through the Senate Estimates process on 2 June 2010, where it was revealed that the cost of implementing this measure is $8.64 million over five years. This is included in the $1.9 billion and thus will also be borne by industry.

The proposed 2010 amendments introduce two significant and damaging reforms:

A. Further additional statutory price reductions to the F2 formulary (generic medicines):

i. An increase from 12.5% to 16% of the statutory price reductions applied to single - brand PBS medicines on PBS listing of a competitor brand on or after 1 February 2011.

ii. A 5% reduction to all F2T products effect ive 1 February 2011. This is in addition to the statutory price reductions introduced in 2007 comprising a 25% statutory price reduction effective 1 August 2008. Further, these products were also subject to the statutory price reduction of 12.5% upon marke t entry of a competitor brand.

iii. A 2% reduction to all F2A products effective 1 February 2011. This is in addition to the statutory price reductions introduced in 2007 comprising 3 x 2% price reductions effective 1 August 2008, 2009 and 2010. Further, these products were also subject to the statutory price reduction of 12.5% upon market entry of a competitor brand.

iv. A weighted average price disclosure related statutory price reduction proposed to occur on 1 April 2012. All F2 products newly subject to price disclosure on 1 October 2010 will be subject to a minimum average price reduction of 23%. However, due to the complicated methodology proposed under the legislation, the actual average statutory price reduction for effected products is expected to be in ex cess of 30%.

Table 4.2 presents a summary of the statutory price reductions stemming from the 2007 reforms and the proposed 2010 reforms.

Table 4.2: Components of PBS reforms

2007 Reforms	2010 Reforms
• 25% price reduction to F2T 1 August 2008	• 5% price reduction to F2T 1 February 2011
• 3 x 2% price reduction to F2A 1 August '08, '09, '10	• 2% price reduction to F2A 1 February 2011
• 12.5% market entry of new brand	• Additional 3.5% (16%) market entry of new brand
	• Savings from minimum weighted average 23%
• Price disclosure	• Expanded and accelerated price disclosure
• Administrative costs	• Administrative costs
Forecast $ 3 billion over 10 years	**Forecast $ 1.9 billion over 5 years**

B. **The expansion and acceleration of the price disclosure as follows:**

i. All brands of all medicines in the F2 formulary will be subject to price disclosure effective 1 October 2010. Under the 2007 reforms price disclosure was only triggered when a new brand entered the market on the F2A formulary and after 1 January 2011, when a new brand en tered the market on the F2 formulary. This reform increases the number of brands subject to price disclosure from 160 items to 1600 items.

ii. The inclusion of multi-branded section 100 medicines in price disclosure .

iii. An additional price reduction time point of 1 December has been introduced; currently price reductions are restricted to 1 April and 1 August.

iv. The total period of the price disclosure cycle has been reduced from 24 months to 18 months, introducing price reductions six months earlier than anticipa ted and placing significant additional administrative burden on companies.

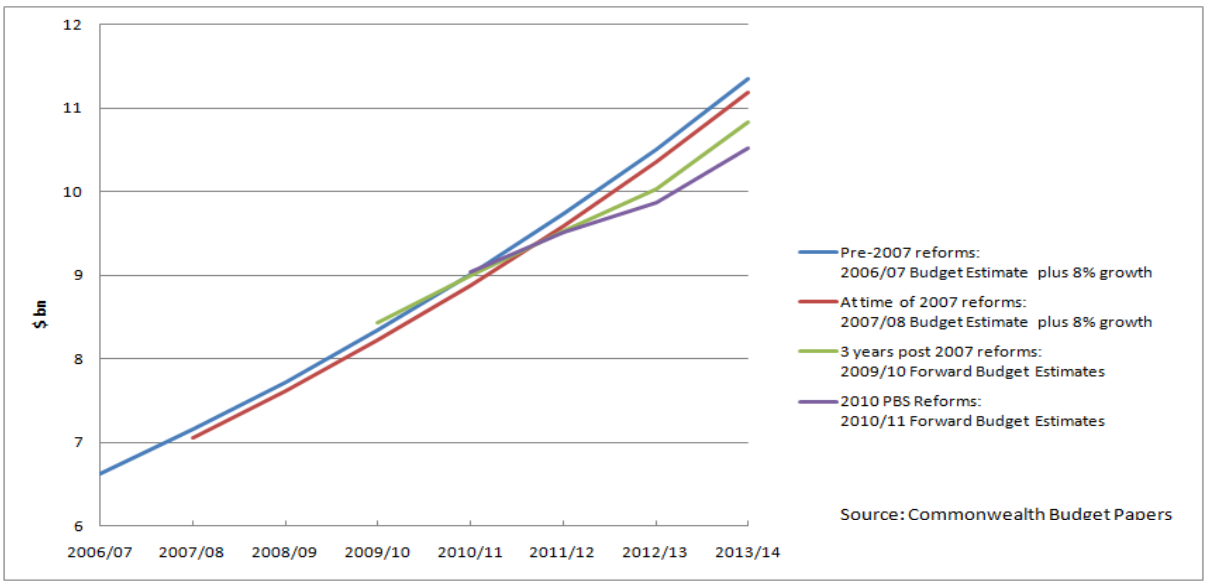
These reforms heavily target the suppliers of generic medicines with limited financial impact to the originator brands. Most generic companies supply a large range of F2 products wh ereas originator companies only have a limited number of F2 products.

4.3 Composition of 2007 and 2010 PBS reforms

Members of GMiA are concerned that there is no public transparency to the stated saving of $1.9 billion dollars over five years from the 2010 reforms. The PBS reforms from 2007 will generate savings to the PBS and it is not be possible to disaggregate savings generated through the 2007 and 2010 reforms. The savings expected to be generated from these different initiatives are have not been put in the public domain.

GMiA has plotted the budget forward estimates of annual PBS expenditure as presented in table 4.3, noting that the full dataset is not readily available. The blue curve represents the 2006/07 budget estimate of PBS expenditure and pro jects 8% growth out to 20013/14. The 2007/08 Budget announcement introduced significant reforms and consequential savings to the PBS that is depicted by the red curve. The savings projected in 2007/08 were subsequently found to have underestimated actual savings. Three years after the 2007 PBS reforms, the 2009/10 budget forecasts (as depicted by the green curve) suggest that the budget forecasts were adjusted to reflect additional savings stemming from the 2007 reforms. The purple curve plots the 2010/11 forward budget estimates including savings stemming from the proposed 2010 reforms.

Table 4.3: Forward budget estimates of annual PBS expenditure



Source: Commonwealth Budget Papers and GMiA assumptions

GMiA advocates that it is in the public's interest to understand composition of the forward budget estimates of annual PBS expenditure over time. This would provide the community the opportunity to review and comment on proposed budget cuts to the PBS.

Recommendation 1: **The Government should put on the public record the detailed breakdown and composition of forecast savings stemming from the proposed 2010 and the 2007 PBS reforms.**

Recommendation 2: **The Government should work with the GMiA to develop a reporting mechanism that enables inclusion in the Commonwealth Budget forward estimates of all savings resulting from the 2007 PBS reforms.**

5. The 2010 Bill is not necessary, growth of PBS is manageable and the Bill does not address growth of the F1 formulary

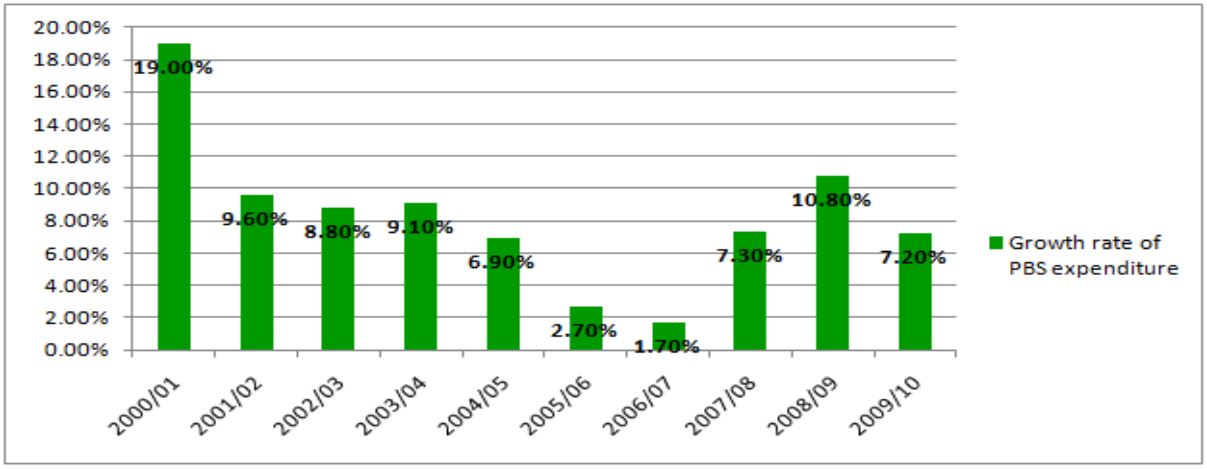
Growth of the PBS is already projected to reduce as a result of the 2007 reforms to the PBS. These reforms were to play out over a decade and were initially projected to save $3 billion. Two years into the 10-year reform process of 2007, three separate analyses have projected the savings will be about double that, including the Government's own analysis shows the savings will be between $3.4 and $5.8 billion. The 2010 Bill is not necessary.

The Minister for Health and Ageing stated in Parliament on 2 June 2010, "While those earlier reforms [referring to the 2007 reforms] will provide more savings than originally estimated, these will be more than outweighed by higher growth in PBS costs. The PBS Reform Report estimates that PBS costs will reach $13 billion in 2018, compared to about $9 billion in 2010."

The projected growth of the PBS cited by the Minister, in fact, demonstrates that the 2007 reforms have achieved control of PBS expenditure. PBS expenditure of $13 billion in 2018 represents an annual growth rate of 5.7 per cent, considerably below the historic average growth rate of the PBS of 8.3 per cent over the last ten years.

Table 5.1 plots the annual growth of PBS expenditure over the last ten years. Growth of the PBS fluctuates over time and the current growth rate of 7.2% is below historic averages, demonstrating that current PBS reform is keeping growth of the PBS to manageable levels.

Table 5.1: Annual growth rate of PBS expenditure (2000/01 – 2009/10)



Source: "Expenditure and prescriptions twelve months to 30 June 2009" Data and Modelling Section, Pharmaceutical Policy and Analysis Branch, Department of Health and Ageing

PBS cost as a percentage of GDP peaked in 2004/05 at 0.67 per cent and has since declined to 0.62 per cent in 2007/08. Australia's expenditure on pharmaceuticals is low by international standards. Of 24 reporting OECD countries in 2005 and 23 countries in 2006, Australia has the third lowest spend on pharmaceutical sales relative to the size of the economy showing that Australia gets relative value for money out of the universal access to medicines from the PBS.

Further, since 1993, every single medicine that has been listed on the PBS has had to undergo rigorous health economic assessment. Medicines must demonstrate cost effectiveness to the satisfaction of the Pharmaceutical Benefits Advisory Committee, an independent expert committee. The efficiency of every dollar spent on medicines on the PBS is maximised through this process and results in optimal gains in health benefits per dollar spent. Growth of spending on the PBS is therefore a good thing and certainly expected when the population is growing.

The proposed 2010 reforms represent an irresponsible gouging of monies from the PBS, a scheme that exists to improve the health of all Australian residents by ensuring they have timely access to necessary and lifesaving medicines at an affordable price. The rigorous health economic assessment of every medicine means that compared to other goods and services funded through the Commonwealth Health Budget, there is a well established and tested link between expenditure on medicines and health gains to the Australian population.

5.1 Burden of PBS reform falls on F2 formulary that is already declining in growth

A review of PBS data shows that the growth of the PBS is driven by growth of expenditure in the F1 formulary. Contradictorily, the burden of PBS reforms falls on the suppliers of medicines in the F2 formulary. A full retrospective analysis of PBS expenditure can be found in appendix 1 of this submission.

The presence of a competitive and viable generics sector has saved the PBS $1.4 billion (Government contribution) from July 2005 to June 2009. Further, savings stemming from the presence of the generic medicines sector are already increasing over time, with $681.7 million (Government contribution) of savings stemming from 2008/09.

From April 2005 to April 2009 the share of PBS receipts to the F2 formulary has declined by 17.7 per cent. In contrast, the share of PBS receipts to the F1 formulary has increased by 35.4 per cent (Government contribution).

PBS receipts to the pharmacist and the F1 manufacturer have increased from 1 April 2005 to 1 April 2009. In contrast, PBS receipts to the F2 manufacturer and the distributor have declined over the same period.

- The pharmacist has received an increase in PBS receipts from $1.24 billion to $1.56 billion (pharmacy mark up plus dispensing fee); or from 20% to 22% of the total PBS spend.
- The F1 manufacturer has received an increase in PBS receipts from $2.13 billion to $3.39 billion (price to wholesaler); or from 35% to 48% of the total PBS spend.
- The F2 manufacturer has experienced a decrease in PBS receipts of $2.25 billion to $1.74 billion (price to wholesaler); or from 37% to 25% of the total PBS spend.
- The distributor has experienced a decrease in PBS receipts from $0.49 billion to $0.39 billion (wholesaler mark up); or from 8% to 6% of the total PBS spend.

It is hard to comprehend how responsible Government policy can be proposing further budget cuts of $1.9 billion to the F2 formulary over five years, when the cost to Government of the entire F2 formulary has fallen by 18.0 per cent over the past four years from $2.8 billion to $2.3 billion.

Recommendation 3: The presence of a generic medicines sector has already delivered and will continue to deliver substantial savings to the F2 formulary and no further reforms are necessary.

5.2 The Bill does not address the growth of the F1 formulary

The proposed Bill will cut $1.9 billion out of the F2 formulary over 5 years when the cost to Government of the entire F2 formulary fell by 21.4 per cent between 2005/06 to 2009/10 from $2.8 billion to $2.2 billion (Government contribution).

Conversely, the Bill does not address the growth of the F1 formulary that has increased by 35.4 per cent (Government contribution) over the same period and increasing costs of the F1 formulary will be the key growth driver to the PBS in the future.

Government expenditure by F1 and F2 formulary over the past five years is presented in table 5.2.

Table 5.2: PBS Benefits (Government Contribution) and growth rates by F1 and F2 formulary* ($ bn)

Year	PBS Benefits: F2 formulary	Growth Rate	PBS Benefits: F1 formulary	Growth Rate
2005/06	2.8		2.8	
2006/07	2.6	-8.2%	3.1	11.0%
2007/08	2.4	-5.3%	3.6	17.4%
2008/09	2.3	-6.0%	4.4	20.9%
2009/10	2.2	-4.0%	4.8	9.4%

* For the purposes of this analysis products are included in F1 or F2 as at 1 August 2008.

Source: PBS dataset compiled by Medicare Australia that is available to the general public. The dataset was copied into a database and the analysis was performed by GMiA using MS Excel and MS Access. Combination and repatriation only medicines are excluded.

The elimination of reference pricing outside of therapeutic groups has imposed a significant cost impost on the PBS as there are no demand side limitations concurrently imposed on the more expensive F1 medicines. This provides an additional incentive to the Sponsors of F1 medicines to switch patients from F2 products to F1 products through heavy market promotional activities. Not only do the Sponsors of F1 medicines receive the benefit of the monopoly market in F1, under the separated formularies Sponsors receive a higher price per health outcome, in some instances.

The PBS provides a social subsidy for medicines and the Australian Government has traditionally and appropriately stated that the Government pays for the health outcomes delivered by the medicines listed on the PBS. A policy that provides for a higher subsidy on the basis of formulary status breaks this fundamental tenet. The separation of the PBS formularies results in the Government paying higher prices for F1 medicines that deliver the same health outcomes as F2 medicines, in some instances.

Sponsors should be incentivised to develop and bring to market products that deliver improved patient health outcomes. Products that offer a true advancement in the delivery of health outcomes have the opportunity to secure a price premium over F2 products via the demonstration of cost-effectiveness as evaluated by the PBAC. Where products cannot demonstrate an additional health benefit, it is inappropriate that a publicly funded scheme, such as the PBS, should pay a higher price for a new medicine if a less expensive alternative can deliver the same health outcomes.

GMiA notes that one of the key consequences of PBS reform is the reduction of prices of generic medicines. Under a system of cost effectiveness analysis such as the Australian PBAC system, the price of a new medicine is referenced to an older medicine via the comparator. GMiA recommends that the PBAC actively take into account the reduced price of comparators as a result of PBS reform and consider adjusting upwards its acceptable level of cost per health outcome post PBS reforms as compared to pre PBS reforms.

While there are a number of products that would undergo a price reduction if the recommendation to re-instate reference pricing within and between the F1 and F2 formularies is adopted, GMiA notes a particularly prominent example. Currently rosuvastatin and atorvastatin sit in a therapeutic group in F1

separate from the other cholesterol lowering agents that sit in the F2 therapeutic group of cholesterol lowerers. There is no apparent clinical justification for a price premium on rosuvastatin and atorvastatin over the F2 products. Thus, the public is paying a premium for these agents over other treatments available in the F2 formulary with no clear additional health benefit.

Rosuvastatin and atorvastatin represent a significant cost to the PBS of $785 million (Government contribution) from May 2008 to April 2009. GMiA has estimated that the annual saving of including rosuvastatin and atorvastatin in the same cholesterol lowering therapeutic group as the F2 cholesterol lowerers and applying the relevant price adjustments to these products would be in the order of $391 million (Government contribution) annually.

A fuller review substantiating the inclusion of rosuvastatin and atorvastatin in the same cholesterol lowering therapeutic group as the other cholesterol lowerers is presented in Appendix 2.

6. GMiA was not consulted on the MoU nor the underpinning Bill

The Deputy Secretary of the Department of Health and Ageing at Senate Estimates on 2 June stated that discussions relating to the Memorandum of Understanding underpinned by the Bill were had between Government and Medicines Australia (representing the interest of suppliers of originator or F1 medicines) as this was considered, "the appropriate venue and way in which to conduct that discussion and to reach agreement with the industry".

Members of GMiA strongly refute this approach.

There was no consultation, negotiation or agreement about the MoU or the underpinning Bill with the GMiA. Members of GMiA supply approximately 70% of the volume of generic products. Without the insight and contribution of this significant sector of the industry, both the MoU and the Bill lack balance and detail flawed and irresponsible public policy. Sectional interests have been promoted at the expense of unfavourable financial consequences for the PBS, taxpayers and other sectors of the industry.

The implementation of the MoU will further widen the gap between the share of PBS expenditure between the originator or F1 segment and the generic or F2 segment, as highlighted in Section 5 of this paper.

There exist committees, such as the Pharmaceutical Industry Working Group providing broader stakeholder perspectives including the portfolio for Innovation, Industry, Science and Research, which provide substantially more suitable fora for such discussions.

The National Medicines Policy (NMP) makes repeated references to the Government and other stakeholders, including the medicines industry, working as partners, collaboratively and in consultation to achieve the objectives of the NMP. The Minister's decision to consult only with part of the medicines industry (that represented by Medicines Australia) rather the industry as a whole appears to be inconsistent with the principles of the NMP.

Policy making and attempts to pass legislation that promote sectional interests should not be tolerated.

Recommendation 4: Should the Government contemplate further reforms to the PBS, all relevant stakeholders should be consulted before further reforms are drafted.

6.1 GMiA wishes to contribute to policy discussions concerning PBS expenditure

GMiA has made repeated requests to Government to contribute to policy discussions concerning PBS expenditure. GMiA has made requests to have access to both PBS expenditure data and to discussions concerning the drafting of the Bill.

- 11 June 2009 GMiA made a formal request to Medicare Australia for access to statistical data collected by Medicare on PBS benefits. The request was partially met on 13 July 2009 with key data excluded. The limited data were made available at a cost to GMiA. Other avenues were subsequently pursued and GMiA was able to source the offered data more effectively through member companies.
- 1 July 2009 GMiA made a formal request to the Department of Health and Ageing for access to statistical data collected by Medicare on PBS benefits, this was declined on 15 September 2009.
- 6 November 2009 GMiA forwarded Government a well researched discussion paper on the impact of the 2007 PBS reform that advocated for the implementation of some important amendments to the 2007 reforms.
- GMiA subsequently became aware that Government policy was not consistent with the general tenant of the GMiA proposal dated 6 November 2009. GMiA repeatedly requested an opportunity to discuss with Government the detail of the likely further reforms so that any potential concerns from the generic medicines' sector could be addressed ahead of the announcement of the reforms, including three letters to the Minister for Health and Ageing dated 21 April 2010, 22 March 2010 and 5 March 2010. GMiA also sought to make several constructive proposals that might reasonably deliver the proposed, but undisclosed, reforms, whilst providing a predictable business impact on our members.
- 10 June 2010 GMiA submitted a request under Freedom of Information for the data used by the Government to determine the PBS savings sought in the Budget. 8 July 2010 GMiA received the response by email (the letter was dated 2 July) from the Department of Health and Ageing, requesting the sum of $19,260.66 to fulfil the FOI request.
- 1 July 2010, upon suggestion from the office of the Minister for Health and Ageing, GMiA wrote to the Department of Health and Ageing requesting access to data underpinning the PBS reforms. This request was declined by letter dated 8 July 2010.

7. Flaws in the Memorandum of Understanding (MoU)

Members of GMiA note the following flaws in the Memorandum of Understanding (MoU) that was released on Budget night on 11 May 2010 and that is underpinned by the Bill.

7.1 The MoU will increase costs of the PBS by the earlier introduction of new medicines at higher prices

While these initiatives are designed improve access to medicines, the additional costs are not included in the Budget estimates and the proposed saving of $1.9 billion is over-stated.

Provisions include parallel TGA and PBAC review; a managed entry scheme for medicines without clear evidence of improved health outcome delivery; and potential increases to prices of new medicines where the older medicine to be replaced is of low price.

7.2 The MoU prevents the Government from introducing any new Therapeutic Groups, except in specific circumstances

It is poor policy and unnecessary for Government to agree not to utilise a policy tool that ensures medicines on the PBS delivering the same health outcomes receive the same level of Government subsidy.

The merit of the Therapeutic Group policy is currently the subject of a Senate Inquiry, a commitment by Government not to use the policy tool before the Senate Inquiry has reported is premature and confusing.

7.3 The MoU provides access to additional information to Medicines Australia

The MoU provides for the Access to Medicines Working Group (AMWG) to monitor: PBS expenditure trends; implementation and progress of the MoU; horizon sca nning; and technical methods for health technology assessment.

The Department of Health and Ageing and Medicines Australia are the members of AMWG. That is, the MoU provides for ongoing policy development with preferential treatment by Government of members of Medicines Australia. It also shuts out other sectors from developing working relationships with Government and having access to key data.

The Deputy Secretary stated at Senate Estimates on 2 June 2010 that he regularly meets with stakeholders to talk about the activities of the AMWG. In fact, GMiA did not receive a briefing from the Department on the activities of AMWG once during 2009 or to date in 2010, despite the fact that there was clearly much activity within the AMWG over this period.

This inconsistency further increases concern from members of GMiA that Government action is increasingly favouring the originator or F1 segment of the Industry, whilst further threatening the viability of the generic or F2 segment.

7.4 The MoU prevents the Government from introducing any measure that favours the prescribing or dispensing of the generic brand of medicines

The Bill prevents the Government from introducing needed incentives for the market to choose a generic branded medicine.

The Sponsor of an originator product has a lengthy monopoly period to establish brand loyalty and has 100 per cent of the market when the generic medicine is launched. The Sponsor of a generic product does not face a level playing field upon market entry. By definition, the originator product and the generic product have the same active ingredient and provide the same health outcome. There is limited

ability for the supplier to differentiate product. As well, suppliers cannot sell direct to the patient, they cannot advertise to the patient and they cannot discount to the patient.

The advent of price disclosure removes the key market mechanism that suppliers of generic medicines have traditionally used to grow market share without the concomitant introduction of an alternative mechanism.

If a generic medicine sector is to be viable, it is essential that there are incentives in place to encourage doctors, pharmacists and patients to consider choosing a generic medicine.

8. Methodological problems with the Bill

There are many serious methodological problems with the Bill that are outlined below.

8.1 The price disclosure formula in the Bill is unbalanced and inconsistent

The Bill specifies that under the price disclosure formula, a key number is "the total number of supplies of the ***agreed quantity*** for that brand that were supplies in respect of which the Commonwealth provided benefits". That is, the number of such supplies in respect of which the Commonwealth paid a benefit during the twelve month period. It is not the number of supplies that were made during the twelve month period.

There will be a lag between when a supply is made and when a payment is made by the Commonwealth in respect of that supply. The number of products supplied and the benefit paid by the Commonwealth over the twelve month period may differ considerably and substantially distort the price disclosure calculation.

In contrast, the discount included in the numerator will be derived from the number of supplies that were made by the supplier to the pharmacist in the twelve month period.

8.2 The Bill erroneously portrays a minimum 23 per cent price reduction as an extension of the 2007 price disclosure policy

The Bill includes provisions for a minimum weighted average price reduction of 23 per cent across the F2 formulary adopting very complicated methodology. Price disclosure as described in the 2007 reforms is about ensuring Government prices reflect actual market prices and dynamics. Imposition of a compulsory price reduction does not reflect the market dynamic and should not be portrayed as price disclosure.

Products subject to price reductions under the proposed 2010 reformed price disclosure policy are exposed to substantially greater price reductions than price reductions outlined under the price disclosure policy introduced in 2007.

8.3 The Bill proposes expanding the number of products subject to price disclosure policy

The Bill proposes expanding the number of products subject to the price disclosure policy. Price disclosure requires the provision of substantive data by suppliers of generic medicines to the Government. These data are not readily available within current business practices and this places a large administrative burden on suppliers.

Data required to meet the price disclosure reporting requirements must be sourced from external suppliers and there are time lags associated with the provision of these data. Data are provided in different formats and are not readily compatible with data sources, currently utilised as business tools by our members.

Currently price disclosure applies to no more than a dozen products for any one supplier of generic medicines. Suppliers are currently meeting the price disclosure reporting requirements predominantly by manual accumulation of multiple data sources within their internal business systems. Under the Bill, the number of products reportable under price disclosure will increase to over 300 items for some suppliers, necessitating the introduction of automatic systems or other solutions.

Suppliers of large numbers of products require time and resource to be mobilised to meet the expanded reporting requirements.

8.4 The proposed timeline for implementation of the expanded price disclosure policy is too short

The proposed timeline for implementation of the expanded price disclosure policy is too short. It is proposed under the Bill that the first reporting period for price disclosure commence 1 October 2010. The Bill must still be enacted and the regulations published. Suppliers of generic medicines must make considerable preparations in order to meet the onerous reporting requirements. It is critical that suppliers of generic medicines have sufficient time to set up, pilot and validate internal reporting systems before the reporting period commences.

Furthermore, necessary agreement on important issues such as quality assurance requirements, audit requirements and data collection platforms have not yet been specified. Until such rudimentary requirements are known, suppliers of generic medicines are unable to make any substantial start on development of automated internal reporting systems.

8.5 The Bill proposes a significant shortening, from twelve months to six months, from end of reporting period to effective price adjustment

The Bill proposes a significant shortening, from twelve months to six months, from end of reporting period to effective price adjustment. Six steps must occur in this process being:

i. Sponsor must await data availability from reporting period end to collect, collate, analyse, calculate and prepare the necessary price disclosure reporting data

ii. Third party must analyse reporting data and calculate effective price adjustments

iii. The Department of Health and Ageing must prepare and publish the proposed price adjustments

iv. Sponsors may have a period of time to review and validate price adjustments and to raise concerns about the proposed price adjustments including providing an opportunity to resolve any potential disputes

v. The Department of Health and Ageing must transfer and publish the final price adjustments

vi. The new price becomes effective six months after the end of the reporting period

Members of GMiA have genuine concerns that the proposed six month period provides insufficient time to complete the above steps.

8.6 The Bill is likely to result in wide stock outs, compromising patient access to medicines

A major consequence of the Bill is that 1600 products will be subject to an average of 23 per cent price reduction on 1 April 2012. This will result in wholesalers and pharmacists destocking ahead of the price change. As a result, about seven weeks of normal sales will be lost from the supply chain. It will be impossible to fill this gap on 1 April 2012. It is not clear how major stock out and disruption of supply of essential medicines will be avoided. It is likely that there will be some instances in which patients may be unable to access important medications.

9. The Bill jeopardises the ongoing supply of generic medicines

In 2007, the Australian Government, with the support of the Parliament, passed th e most comprehensive package of changes to the PBS since its inception in 1948. The reforms created structural changes to the PBS intended for its long term sustainability and a clear statement of intent was provided by Government to industry that these re forms would deliver policy stability over the next ten years. The 2007 reform resulted in one member of GMiA laying off 18% of the workforce and closing its R&D facility. Proposed further reforms, only three years after the introduction of major reforms that have not yet played out, causes continued significant commercial instability for suppliers of generic medicines.

The First Assistant Secretary for the Department of Health and Ageing stated at Senate Estimates on 2 June 2010 that the Department of Health and Ageing believes that the impact of the proposed 2010 PBS reforms on the investment and jobs of the generic medicines sector would be low. This statement is not correct.

The impact of the Bill is far greater to the generics sector as compared to other parts of the medicines sector. Pharmaceuticals are the leading transformed goods export industry in Australia – greater than cars and wine – and bring in more than $4 billion a year in export sales. Members of GMiA contribute significantly to total pharmaceutical exports. This legislation puts in jeopardy the generics sector, the very sector of the industry that triggers PBS savings.

The appropriate sector of Government to fully assess the likely impact of reforms is the Department of Innovation, Industry, Science and Resource. Senator Carr stated at Senate Estimates on 31 May that, “this Department was not involved in the negotiations concerning the construction of that MoU”. That is, there was no assessment of the impact of the reforms on the generic medicines industry sector.

9.1 Restrictive medicines pricing policy can lead to increased prices over time

Restrictive prescription medicine pricing policy can result in the exit of major generic players, reduced competition in the market place and eventual increased prices of generic medicines over time.

Appendix 3 provides a highly relevant case study that tracks the prices of generic medicines over time in Ontario province, Canada. Restrictive prescription medicine pricing policy imposed by the

Ontario government in 1993 triggered a cascade of events that resulted in the market exit of a major generic player, reduced competition in the marketplace and ultimately increased prices of generic medicines by 2001.

In the face of inflation and a weakening dollar, one major generic player was forced to exit the market, denying patients access to a range of prescription medicines manufactured by this company.

Unable to endure the reality of selling goods at below cost, the remaining player was able to re-establish business viability only by increasing prices by an average of 537% across the portfolio – a move that placed further pressure on the government subsidy for many prescription medicines.

The Ontario case study provides clear evidence of the paradoxical effects that emerge from restrictive pricing policy in the prescription medicine market – that is, increased drug prices across a reduced portfolio of medicines.

Companies unable to compete on price are paralysed against fluctuating market forces such as inflation and exchange rates. As business becomes unviable, major players are forced to exit, further weakening competition in the marketplace.

Those companies that manage to outlast their fallen rivals are left with one option – to considerably increase prices. In the absence of competition, these price increases are no longer susceptible to the economic paradigm of supply and demand, and are potentially allowed to grow without limitation.

9.2 The reforms do not provide pricing stability for suppliers of generic medicines

On 2 June 2010, in the second reading speech of the Bill, the Minister for Health and Ageing stated in Parliament, “Under the MOU, the Government will provide the industry with pricing certainty over the next four years”. For the suppliers of generic medicine the exact opposite is true. The PBS reforms create unnecessary and avoidable administrative burden on both Government and industry.

Cost and time resources associated with the collection and analysis of data to support the price disclosure policy are significant. Price disclosure creates significant uncertainty for the Government and industry as future cost savings to the PBS cannot be easily predicted. Thus, the 2010 reforms perpetuate the failure of the 2007 reforms to book into the Budget estimates resulting savings.

Currently 160 items are under the price disclosure policy. The implementation of these 160 items has been subject to significant administrative difficulties and the subject of legal challenge. The first price adjustments from price disclosure were considerably delayed. The eventual price adjustments stemming from the initial price disclosure policy were highly variable.

Table 9.1 presents the set of price adjustments that have been implemented under the price disclosure policy. The extent of price reductions varies considerably - from 0% to 71.8%. The large variation in the extent of the price reductions across items is not well understood. In the instances where big price adjustments are made, it is commercially very difficult to absorb these price shocks.

Table 9.1: Items subject to price disclosure policy and resultant price reduction after 1st year of review

Round 1		Round 2		Round 3	
Doxorubicin IV *	63.54%	Fluconazole ^	55.26%	Carvedilol ^	27.29%
Mitozantrone *	34.42%	Vancomycin ^	71.80%	Sumatriptan	0%
Ondansetron *	15.37%	Alendronic	0%	Enalapril	0%
Meloxicam#	0%	Ceftriaxone	0%	Irinotecan	0%
Amisulpride	0%	Naltrexone	0%		
Fosinopril	0%	Octreotide	0%		
Oxybutiynin	0%				
Perindopril	0%				
Valproic	0%				

* Voluntary price reductions implemented 1 December 2009
# Price disclosure reduction of 22.46% revised to 14.57% and remains under discussion
^ Implemented 1 April 2010
Source: Commonwealth of Australia, *The impact of PBS reform: report to the Parliament on the National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007*, Commonwealth of Australia, Canberra, February 2010, pp. 8–9, http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs-reform-report

The Bill proposes to increase the number of items subject to the price disclosure policy to 1600 items. This is administratively unachievable. The first price reductions are scheduled for 1 April 2012 when the Government expects the market to accommodate, overnight, a minimum average price reduction of 23 per cent across 1600 items. There will inevitably be serious market disruptions, including a high likelihood of stock outs of essential items leaving patients without access to their medicines.

The Bill proposes a set of statutory price cuts to the entire F2 formulary effective 1 February 2011. In practice, this would require implementation of the statutory price cuts over the Christmas period, risking creating confusion in the market. The claimed difficulties associated with making implemented price adjustments through the supply chain has lead to an Australian practice where prices are typically changed at only two or three time points during the year, 1 April, 1 August and 1 December.

These issues should have and could have been addressed had there been broader consultation with stakeholders including members of GMiA who supply the vast majority of these 1600 items and with members of the National Pharmaceutical Services Association who represents the pharmaceutical wholesalers.

9.3 The policy removes the key market mechanism for suppliers to compete

The First Assistant Secretary of the Department of Health and Ageing stated at Senate Estimates on 2 June 2010 that the reforms will not take cuts out of the earnings of pharmaceutical companies. This statement is erroneous and demonstrates a major deficiency in the Department's understanding of the market dynamics of generic medicines. For this statement to be realised, suppliers of generic medicines must be able to stop providing discounts to the pharmacist. This effectively removes the key market mechanism available to suppliers of generic medicines to compete in the market.

It is worth reiterating that the generic manufacturer cannot compete on quality, safety or efficacy differences between their product, and those produced by originator companies: these parameters must be identical if TGA approval to market is to be secured. Similarly, the generic manufacturer cannot compete on price to the consumer: price discounting cannot be offered to the consumer, either directly or through differential co-payments.

Members of GMiA strongly support the principle that the Government and public should derive the benefit from reduced prices of medicines stemming from generic competition. The proposed 2010 reform is designed to deliver the savings from competition to the Government but in the process takes away the ability of suppliers of generic medicines to compete.

The suggestion that price disclosure sets price reflective of market forces, that is, Government is a price taker of generic medicines, is simplistic and overlooks the complex market dynamics present in the pharmaceutical market. The 2007 reforms rely on the premise that the price disclosure policy will deliver the true price based on market forces. However, in a Government constructed market, like the PBS, market forces are not free to reliably deliver a true market price.

Wholesalers face a parallel predicament to the suppliers of generic medicines, in that price discounts to pharmacists is also the key market mechanism available to wholesalers to grow business. Similarly, the advent of price disclosure removes this key market mechanism . In the 2007, wholesalers received compensation via the introduction of a community service obligation. No parallel compensation was provided in the proposed 2010 reforms. In an editorial in the Australian Journal of Pharmacy (Vol 91, Jul 2010), Stephen Greenwood, former executive director of the Pharmacy Guild (1992 – 2006) notes that the wholesalers expect to be able to pass onto the pharmacists the income cuts from the 2010 reforms. Greenwood observes that commercially this will not be easy to achieve.

It is clear that the representatives in the Pharmacy Guild believe that it will be commercially very difficult for the supply chain to claw back savings by reducing the level of discounting.

The price disclosure policy, without concomitant policy that prov ides a market incentive for the physician, pharmacist and consumer to choose a generic medicine and a market mechanism for suppliers of generic medicines to effectively compete for market share profitably puts at risk the ongoing viability of suppliers of generic medicines and the ongoing supply of generic medicines to patients.

9.4 Market entry is determined by market profitability not market size

The First Assistant Secretary of the Department of Health and Ageing stated at Senate Estimates on 2 June 2010 that there is very significant growth for generic medicines in Australia. He noted that about nineteen medicines that currently cost the PBS about $2.3 billion dollars are coming off patent in the next few years.

Suppliers of generic medicines will make commercial decisions about market entry on more than just the market size. Clearly low prices and limited market incentives to choose a generic medicine make a market commercially unattractive. Overseas experience suggests that markets with low priced generic medicines and limited market incentives to choose a generic medicine are typically supplied by imported medicines with minimal domestic operations.

The Memorandum of Understanding underpinning the Bill expressly forbids the Government from introducing any policies that will encourage the use of generic medicines over mo re

expensive originator brands and explicitly prevents the Government from introducing incentives to encourage doctors, pharmacists and patients to consider choosing a generic medicine.

The Deputy Secretary of the Department of Health and Ageing stated at Senate Estimates on 2 June 2010 that the Department is very confident that the reforms will not decrease market entry of generic medicines as Government does, "not distinguish in the off patent between generic and originator patent in the commodity market".

In a constructed pharmaceutical market such as the Australian pharmaceutical market, the viability of the generic medicines sector is reliant upon Government to ensure that there is a mechanism to provide an incentive for the market to choose a generic medicine. Current Government policy does not provide an effective incentive for the market to choose a generic medicine.

This is reflected by the low market penetration of generic branded medicines in Australia. The Deputy Secretary of the Department of Health and Ageing at Senate Estimates stated at Senate Estimates on 2 June 2010 that medicines supplied by members of GMiA has grown from 27 per cent in 2005/06 to just over 33 per cent in 2008/09 of the total available PBS generic market by volume. This market share is well below the levels seen in overseas markets where IMS reports that generic branded market share is as high as 89 per cent in the US market, 81 per cent in Canada and 75 per cent in Germany by volume.

In Australia, generic medicine policy is focused on reducing the price to Government, a principle strongly supported by the members of GMiA. However, more competitive prices can only be achieved with concomitant policies that incentivise the use of generic medicines. Yet, the lack of a volume driver is not only absent in generic medicine policy in Australia, a volume driver is clearly blocked by the Bill and the Memorandum of Understanding underpinning the Bill.

9.5 The generic medicines sector makes an important contribution to the economy

Generic pharmaceuticals are strategically a very important sector.

The Secretary of the Department of Health and Ageing at Senate Estimates on 2 June stated that, "The bottom line is that the generic market is a global market, and we have historically paid too much for those products". This statement grossly under-values the contribution made by the suppliers of generic medicines and the strategic importance of the generic medicines sector to the Australian economy.

A viable generic medicines sector brings important benefits to the Australian economy including:

i. Patent challenges of potentially weak patents provide for earlier market entry of generic medicines and generate earlier savings to the PBS.

   The Secretary of the Department of Health and Ageing at Senate Estimates on 2 June stated that the decision of the supplier of a generic medicine of, "whether or not you are going to challenge a patent is one you do in terms of a global market".

   The decision to develop a generic version of a molecule is a global decision, however the decision to challenge a patent must be made on a market by market basis. This reflects the different judicial systems, the different patent specifications and different patent expiry dates across markets.

ii. Introduction of competition for the majority of medicines upon expiry of valid patents, not just medicines of high commercial value. As the profitability of a market declines, so does the number of introductions of new generic medicines. The market entry of generic

competition for the low value molecules that in aggregate represent substantial potential savings to the PBS is jeopardised. GMiA estimates that of the $3 billion market value expected to be genericised over the next 5 years, the ten largest molecules represent 55 per cent of the market value.

iii. Continuity of stock in the event of manufacturing disruptions. Despite best efforts by any manufacturer, manufacturing disruptions can and do occur, particularly when manufacturers are subject to high levels of competition and are under pressure to keep costs as low as possible.

A viable domestic generic medicines sector provides a significantly higher level of assurances of ongoing supply of medicines.

iv. A pharmaceutical manufacturing base provides an important public health benefit in the event of a potential pandemic. Suppliers of generic medicines are particularly well positioned to meet potential emergency manufacturing needs, as generic medicine manufacturing is geared towards the production of multiple different medicines.

Should the Bill be enacted, it will fundamentally change the landscape of the supply of generic medicines in Australia. Over time, current suppliers will find many products to be no longer commercially viable. These products are at risk of being withdrawn from the Australian market as current processes for price reviews are inadequate.

Existing suppliers of generic medicines that currently provide important benefits of strong patient support services, pharmacovigilance monitoring, local manufacturing and employment are at risk of being replaced with small distributors sourcing medicines from the lowest cost manufacturing countries. Responsible strategic policy planning by Government concerning the funding of medicines on the PBS is imperative to ensure the longevity of local manufacturing and the current employment of 5,000 highly skilled jobs within the Australian generic medicines sector.

Appendix 1: Retrospective analysis of PBS expenditure

GMiA has analysed PBS expenditure from April 2005 to April 2009. GMiA used the PBS dataset compiled by Medicare Australia that is available to the general public. The dataset was copied into a database and the analysis was performed using MS Excel and MS Access.

The savings to Government stemming from the presence of a generics sector has been calculated by year and by specific policy and is presented in Table A.1.1. At a minimum, **the presence of a generics sector has saved the PBS $1.4 billion (Government contribution) over this 4 year time period.**

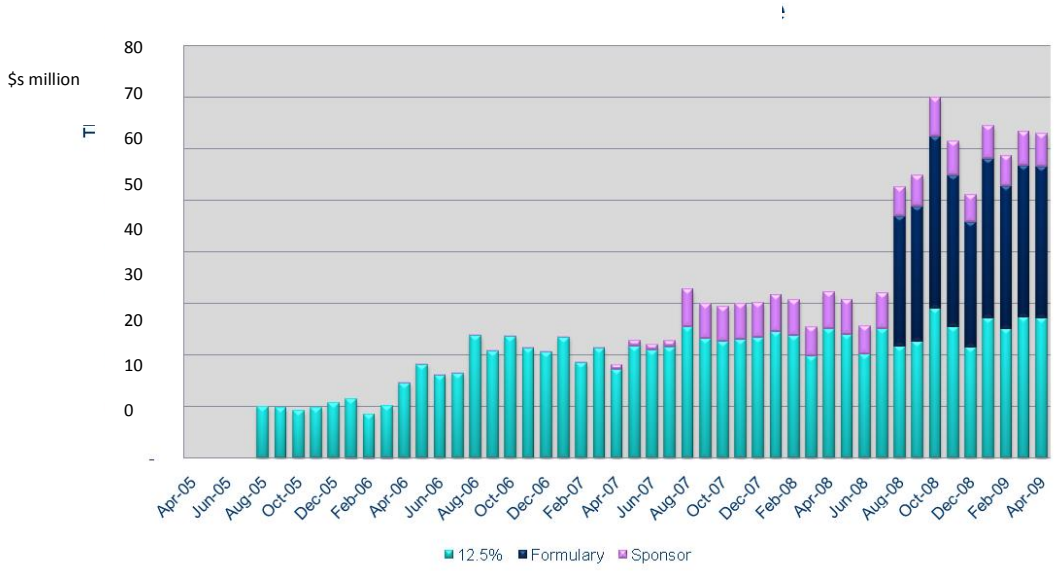
Savings to the PBS stemming from the automatic price reductions of 12.5% upon PBS listing of the second brand have netted $952 million (Government contribution) over four years. Savings to the PBS stemming from the price reductions applicable to the F2A formulary have netted almost $10 million (Government contribution) over four years. Savings to the PBS stemming from the price reductions applicable to the F2T formulary have saved $299 million (Government contribution) over four years. Savings stemming from voluntary price reductions initiated by the Sponsor have saved the PBS $154 million (Government contribution) over four years.

These savings are also presented by bar chart by month in Table A.1.2. **Savings stemming from the presence of the generic medicines sector are growing over time.**

Table A.1.1: Savings to Government stemming from the presence of the generic medicine sector (Government contribution) ($ million)

	12.5%	F2A	F2T	Sponsor	Total
F2006	127.8	-	-	0.3	128.1
F2007	249.1	-	-	4.4	253.5
F2008	276.0	-	-	75.3	351.4
F2009	299.3	9.6	298.7	74.0	681.7
Total	952.4	9.6	298.7	154.1	1,414.8

Table A.1.2: Savings to Government stemming from the presence of the generic medicines sector presented by bar chart by month (Government contribution) ($ million)



The proportion of PBS expenditure flowing to the F1 versus the F2 formulary over time was analysed by both services and benefits as presented in Tables A.1.3 and A.1.4. **The share of PBS receipts to the F2 formulary has declined by 17.7%, in contrast the share of PBS receipts to the F1 formulary has increased by 35.4% (Government contribution).**

The number of services in the F2 formulary has been relatively stable, declining marginally on average 1.2% per annum from 122 million services to 116 million services and the cost to the PBS of the F2 formulary has declined on average 4.5% per annum from $2.8 billion to $2.32 billion (Government contribution) from April 2005 to April 2009 (MAT).

In contrast, the number of F1 PBS services has grown on average 5.8% per annum from 47 million services to 58 million services from April 2005 to April 2009 (MAT), however the growth of the total cost of PBS benefits on the F1 formulary has been considerable, increasing on average 13.8% per annum from $2.68 billion to $4.15 billion (Government contribution) over this same period.

Table A.1.3: PBS expenditure by formulary (Government contribution) (million)

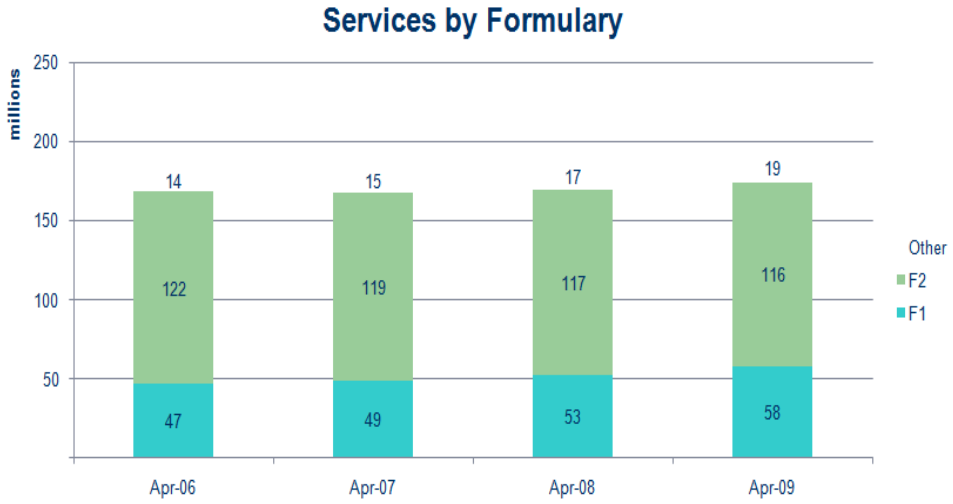
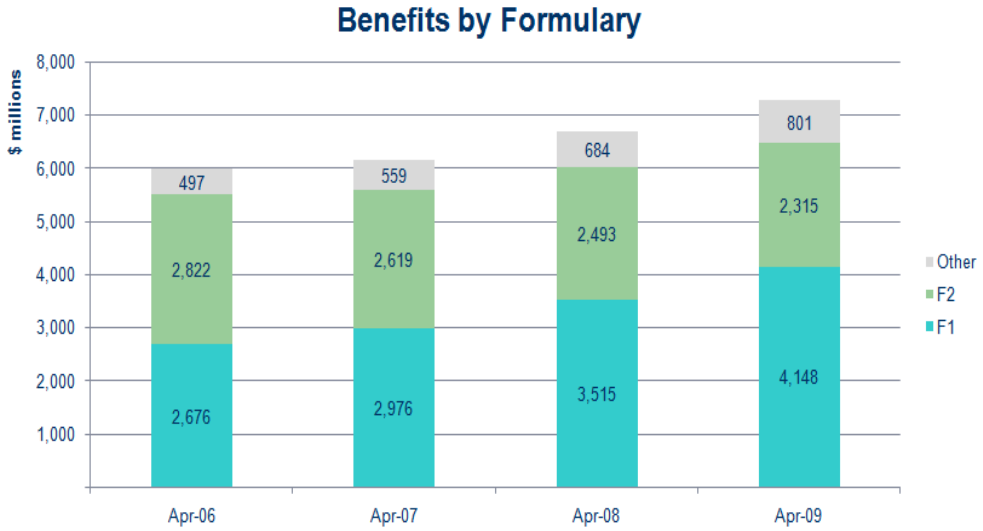


Table A.1.4: PBS expenditure by formulary (Government contribution) ($ million)



GMiA analysis found that the proportion of PBS expenditure distributed among the supply chain has changed from 1 April 2005 to 1 April 2009 as presented in Tables A.1.5 and A.1.6. The Community Service Obligation additional funding of $69 million over three years to compensate distributors is not included in the GMiA analysis.

PBS receipts to the pharmacist and the F1 manufacturer have increased from 1 April 2005 to 1 April 2009. In contrast, PBS receipts to the F2 manufacturer and the distributor have declined over the same period.

- The pharmacist has received an increase in PBS receipts from $1.24 billion to $1.56 billion (pharmacy mark up plus dispensing fee); or from 20% to 22% of the total PBS spend.

- The F1 manufacturer has received an increase in PBS receipts from $2.13 billion to $3.39 billion (price to wholesaler); or from 35% to 48% of the total PBS spend.
- The F2 manufacturer has experienced a decrease in PBS receipts of $2.25 billion to $1.74 billion (price to wholesaler); or from 37% to 25% of the total PBS spend.
- The distributor has experienced a decrease in PBS receipts from $0.49 billion to $0.39 billion (wholesaler mark up); or from 8% to 6% of the total PBS spend.

Table A.1.5: Proportion of PBS expenditure by supply chain (dispensed price) ($ million)

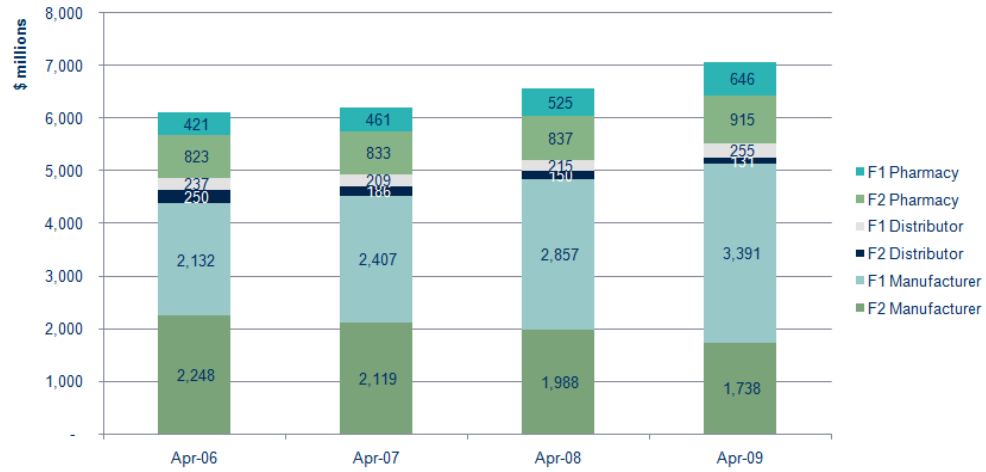
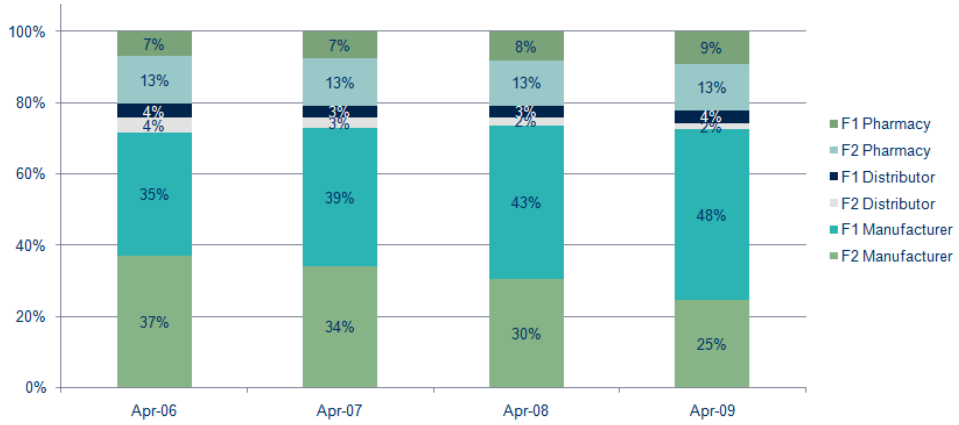


Table A.1.6: Proportion of PBS expenditure by supply chain (dispensed price) (%)

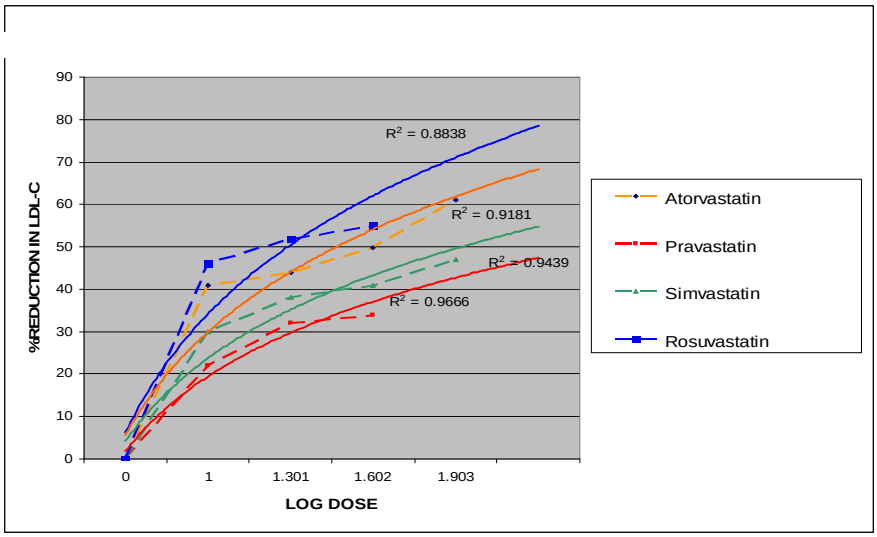


Appendix 2: Case study - Inclusion of rosuvastatin and atorvastatin in cholesterol lowering therapeutic group

It is an established fact that all statins lower LDL cholesterol, the marker for statin efficacy. The magnitude of cholesterol lowering correlates with the dosage used and is comparable for all the statins, as evidenced by the parallel dose response curves.

The parallel dose response curves can be used to compare the cost of using different statins to reduce LDL cholesterol by a specified amount. The approximate dose of each statin required to achieve a similar outcome of 50% reduction in LDL-C has been estimated from these fitted curves (see table A.2.1). It can be seen that a 20mg dose of rosuvastatin, 30mg dose of atorvastatin and 80mg dose of simvastatin all produce the target LDL-C reduction.

Table A.2.1: Statin dose response curves



So, for example, if we examine the cost of lowering LDL cholesterol by 50% in a patient, we can see that compared to using simvastatin, using atorvastatin costs the government 62% more and using rosuvastatin costs 69% more (see table A.2.2).

Table A.2.2: Cost of each dose of statin on the PBS (DPMQ: 30 tablets)

	Rosuvastatin 20mg	Atorvastatin 20mg & 10mg	Simvastatin 80mg
COST	$96.43	$100.70	$59.42
% increase cost over simvastatin equivalent	62	69	-

An analysis of the statin market in Australia shows that since the introduction of PBS reforms on 1 August 2008, the usage of atorvastatin has increased by 2.1 million prescriptions, or 21 per cent, and

the usage of rosuvastatin has increased by 1.5 million prescriptions, or 100 per cent. These figures are all the more notable because total statins usage increased by 3.3 million prescriptions. Correspondingly, the usage of generic statins, for example simvastatin and pravastatin, fell.

The bewildering aspect of this issue is that recent government policy changes have caused the cost blow-out by preventing the application of reference pricing and thwarting the policy of the PBS to pay for outcomes rather than molecules.

In July 2005, the then Health Minister, removed atorvastatin from the lipid lowering therapeutic group, granting atorvastatin a price rise and quarantining it from price reductions subsequent to generic entry of simvastatin. Atorvastatin was then categorised as an F1 drug as part of PBS reforms in 2007. The Government and taxpayers have been denied substantial savings pursuant to the 25 per cent price cut applied to the other statins in the F2T category.

The new therapeutic group for atorvastatin and rosuvastatin, announced in this year's Budget, will generate savings for the Government and taxpayers when the patent on atorvastatin expires in 2012. While some savings will be generated through this measure, they are very small compared to the savings that would have been generated had atorvastatin not been removed from the lipid lowering therapeutic group in 2005.

The foundation of the PBS is that pharmaceuticals are subsidised on the basis of health outcome and not on the basis of patent status or molecular structure. Drugs producing similar outcomes should be linked in price. Subsidy and access processes are about optimising health outcomes and obtaining good value for money. Reference pricing has ensured the government did not pay more for a medicine than was warranted by the health outcome it provided.

Appendix 3: Case study - Restrictive medicines pricing policy in the Canadian pharmaceutical market

A.3.1 Background

Canada does not have a national drug scheme, however public coverage is provided to about half of the population through provincial drug schemes.

The focus of this case study is Ontario, the largest province in Canada, where changes to drug prices were seen as a result of products falling below manufacturer's cost on the Ontario Drug Benefit (ODB) Formulary.

A.3.1.1 Ontario Drug Benefit (ODB) Program

Through the Ontario Drug Benefit (ODB) Program, the Ministry of Health and Long-Term Care, covers most of the cost of prescription drug products listed in the Ontario Drug Benefit (ODB) Formulary, as well as some exceptional cases.

Source: http://www.health.gov.on.ca/english/public/pub/drugs/odb.html

A.3.1.2 Canadian Generic Drug Manufacturers 2000-2001

There has been a highly competitive drug industry in Canada for over thirty five years. Ten years ago there were at least eight generic companies operating in Canada.

- Apotex
- Novopharm (now Teva)
- Pharmascience
- Genpharm (now Mylan)
- Ratiopharm
- Nupharm
- Altimed
- Linson

A.3.2 Ontario Market – 30th March 2001

The Ontario government implemented a reimbursement price freeze on all drugs in 1993. Since that time, inflation ran at 2 ½ to 3% per year for a total of over 20% by 2001.

In addition, during that same time period, the Canadian dollar fell about 20% relative to the US dollar, the currency used by Apotex to purchase some of its raw materials. The end result was that many of the drugs listed on the Ontario Drug Benefit (ODB) Formulary fell below manufacturing or product cost.

This in turn resulted in Novopharm (now Teva) taking the decision to discontinue manufacture and supply on many low price products (delisting a number of their brands from the ODB Formulary and exiting from the market), leaving Apotex as the sole generic supplier for public coverage across a range of products – complete list in Appendix 1. At that time, no other generic companies were marketing these products.

A.3.3 Ontario Market – 30th June 2001

Following several years of failed negotiation attempts with the Ontario Drug Benefit Program to increase the cost of many molecules to above manufacturer cost, Apotex unilaterally increased its prices anywhere between 30% to over 1400%, with a 537% average increase. It was no longer viable for Apotex to continue to sell these products at below cost being the only player left to supply the market.

The price increase, instigated by Apotex, occurred on 1st July 2001 – see Appendix 2.

A.3.3.1 "Cost to Operator" approach

Although the reimbursement amount listed in the ODB Formulary did not increase, the "Cost to Operator" approach available in Ontario provided pharmacists with the ability to claim reimbursement from the Government for the cost of a product over and above the price listed in the ODB Formulary.

A.3.4 Ontario Market – 30th January 2002

Apotex further increased their prices in 2002 by an average of 38%

A.3.4.1 Ontario Drug Price Examples

Example 1 – Amitriptyline

			Apotex Pricing			
PRODUCT	Increase Jan 02 to current	Increase Jun 01 to Jan 02	Jan 2002 Price Increase	Jul 2001 Price Increase	Jun 2001 Prices	1998 Prices
			Price/Tab	Price/Tab	Price/Tab	
Only Other Generic Discontinued March 30, 2001						
APO-AMITRIPTYLINE 10 MG	53%	637%	$ 0.0435	$ 0.0150	$ 0.0059	$ 0.0059
APO-AMITRIPTYLINE 25 MG	46%	949%	$ 0.0829	$ 0.0250	$ 0.0079	$ 0.0079
APO-AMITRIPTYLINE 50 MG	52%	811%	$ 0.1540	$ 0.0450	$ 0.0169	$ 0.0169

Price Increases

Price increase in July 2001

- 637% to 949% across the three strengths
- Average price increase of 799%

Price increase in January 2002

- 46% to 53% across the three strengths
- Average price increase of 50%

Example 2 – Trifluoperazine

		Apotex Pricing				
PRODUCT	Increase Jan 02 to current	Increase Jun 01 to Jan 02	Jan 2002 Price Increase	Jul 2001 Price Increase	Jun 2001 Prices	1998 Prices
			Price/Tab	Price/Tab	Price/Tab	
Only Other Generic Discontinued March 30, 2001						
APO-TRIFLUOPERAZINE 1 MG	58%	399%	$ 0.0846	$ 0.0275	$ 0.0170	$ 0.0065
APO-TRIFLUOPERAZINE 2 MG	58%	1442%	$ 0.1110	$ 0.0575	$ 0.0072	$ 0.0072
APO-TRIFLUOPERAZINE 5 MG	58%	1334%	$ 0.1470	$ 0.0875	$ 0.0103	$ 0.0103
APO-TRIFLUOPERAZINE 10 MG	58%	930%	$ 0.1762	$ 0.0375	$ 0.0171	$ 0.0171

Price Increases

Price increase in July 2001

- 399% to 1442% across the three strengths
- Average price increase of 1026%

Price increase in January 2002

- 58% across the three strengths

Example 3 – Diazepam

		Apotex Pricing				
PRODUCT	Increase Jan 02 to current	Increase Jun 01 to Jan 02	Jan 2002 Price Increase	Jul 2001 Price Increase	Jun 2001 Prices	1998 Prices
			Price/Tab	Price/Tab	Price/Tab	
Only Other Generic Discontinued March 30, 2001						
APO-DIAZEPAM 2 MG	0%	824%	$ 0.0508	$ 0.0175	$ 0.0055	$ 0.0055
APO-DIAZEPAM 5 MG	0%	1130%	$ 0.0750	$ 0.0275	$ 0.0061	$ 0.0061
APO-DIAZEPAM 10 MG	0%	1157%	$ 0.0867	$ 0.0375	$ 0.0069	$ 0.0069

Price Increases

Price increase in July 2001

- 824% to 1157% across the three strengths
- Average price increase of 1037%

**further examples available on request from Apotex*

A.3.5 Novopharm Discontinued Product List, effective 30th March 2001

Novopharm Discontinued Product List

Effective March 30, 2001

Discontinued Products	Apotex Equivalent
Novo-Ampicillin (susp. Only) 125/5 mg/mL, 250/5 mg/mL	Apo-Ampi
Novo-Baclofen 10, 20 mg	Apo-Baclofen
Novo-Butamide 500mg	Apo-Tolbutamide
Novo-Butazone 100mg	Apo-Phenylbutazone
Novo-Cromolyn Nebulizer 1%	Apo-Cromolyn nasal solution
Novo-Dipam 2, 5, 10 mg	Apo-Diazepam
Novo-Doparil 15, 25 mg	Apo-Methazide
Novo-Ferrosulfate FCT 300mg	Apo-Ferrous Sulfate
Novo-Flunisolide 0.25%	Apo-Flunisolide
Novo-Flupam 15mg	Apo-Flurazepam
Novo-Folacid 5mg	Apo-Folic
Novo-Furan 50, 100mg susp 25/5 mg/mL	Apo-Nitrofurantoin
Novo-Hexidyl 2, 5 mg	Apo-Trihex
Novo-Medopa 125, 250, 500mg	Apo-Methyldopa
Novo-Mepro 400mg	Apo-Meprobamate
Novoxapam 10, 15, 30 mg	Apo-Oxazepam
Novo-Poxide 5, 10, 25 mg	Apo-Chlordiazepoxide
Novo-Pramine 10, 25, 50 mg	Apo-Imipramine
Novo-Profen SC 300, 400mg	Apo-Ibuprofen
Novo-Pyrazone 100, 200 mg	Apo-Sulfinpyrazone
Novo-Quinidin 200mg	Apo-Quinidine
Novo-Ridazine 10, 25, 50, 100, 200mg, susp. 2mg/mL	Apo-Thioridazine
Novo-Rythro Encap 250mg	Apo-Erythro-EC
Novo-Terfenadine 60mg	Apo-Terfinadine
Novo-Tetra 250mg	Apo-Tetra
Novo-Thalidone 50, 100mg	Apo-Chlorthalidone
Novo-Triedapin 10, 25, 50, 75, 100mg	Apo-Doxepin
Novo-Trifluzine 2, 5, 10 mg	Apo-Trifluoperazine
Novo-Triphyl 200mg	Apo-Oxytriphylline
Novo-Triptyn 10, 25, 50mg	Apo-Amitrityline
Novo-Zolamide 250mg	Apo-Acetazolamide

A.3.6 Apotex Price Increase Letter, 13th June 2001

June 13, 2001

Dear Valued Customer:

Re: Price Increases

As you know, the Ontario government implemented a price freeze in 1993 – seven years ago.

In the past seven years, inflation has been running at 2 ½ to 3% per year for a total of over 20%. Also, the Canadian dollar has fallen about 20% relative to the U.S. dollar, in which raw materials are purchased.

We have been negotiating with the Ontario Drug Benefit Program over the past three years in an effort to obtain price increases for older products which we are currently selling below cost. The Program has been unresponsive.

We thus have no alternative but to proceed with price increases unilaterally.

Commencing July 1st, 2001, price increases will be in effect for the attached products.

We realize that this may create additional paper work for you; however, we believe that long term this is in our mutual best interest, as we cannot continue to sell at below cost. As you are aware there are several hundred drugs listed in the Ontario Drug Benefit that cannot be purchased at the Best Available Price (BAP).

Our understanding is that the current Pharmacy Computer Systems have a program to manage ODB cost to operator claims with minimal extra work.

For third party prescriptions, we have been advised by BCE Emergis and ESI that the new prices will be reimbursed on the effective date. Greenshield is reviewing their policies and expect to have procedures in place by July 1st .

Your continued support is greatly appreciated.

Please do not hesitate contacting me directly at 416-401-7323 if you require any further clarification.

Yours very truly,

APOTEX INC.

Jack M. Kay
President and C.O.O.

JMK/jm

Attachment