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Supplementary 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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1. EXECUTIVE SUMMARY

The National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 should not be supported

The National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 (the Bill) imposes further cuts to expenditure to the Pharmaceutical Benefits Scheme (PBS) and will impact Australians' access to pharmaceuticals and damage a critical component of our leading manufactured goods export industry.

The Government claims that the Bill has the support of the industry. This is not the case. Suppliers of generic medicines strongly oppose the Bill. The Bill will enact a protection agreement by Government of the interests of one sector of the industry (suppliers of originator medicines) to the detriment of another (suppliers of generic medicines).

The Community Affairs Legislation Committee (the Committee) should request further scrutiny of the Bill. The Committee should be assured that:

1. The Bill will not result in cuts to the PBS that will cause irreparable harm to any sector of the medicines industry thus ensuring that the Government meets its obligation under the fourth objective of the National Medicines Policy of maintaining a responsible and viable medicines industry across all sectors of the medicines industry.
2. All savings to the PBS stemming from the Bill have been included in the forward estimates and if the Bill may possibly generate greater savings than anticipated, appropriate safeguards are put in place to ensure the viability of all sectors of the medicines industry.
3. The Bill will not result in reduced competitive effects in the market.

The Bill gives effect to damaging cuts to expenditure on the PBS

The PBS does not require "fixing"

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.

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. Of 24 reporting OECD nations, Australia has the third lowest spend on pharmaceutical sales as a percentage of GDP.

The cost of the PBS is not out of control

PBS cost as a percentage of GDP has been steady at 0.6 – 0.7 per cent, most recently reported at 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.

The Government is misinterpreting key PBS data

The Minister for Health and Ageing stated in Parliament on 2 June 2010 and again on 29 September 2010: "The PBS Reform Report estimates that PBS costs will reach $13 billion in 2018, compared to about $9 billion in 2010." The projected growth rate cited by the Minister represents an annual growth rate of 5.7 per cent, well below the historic average growth rate of the PBS of approximately 8 per cent. Clearly PBS growth is not out of control.

The PBS is sustainable

PBS costs are sustainable, especially as a result of the major 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. The further cuts to expenditure on the PBS proposed under the Bill layer more reform on a system still in the throes of reform, like building on a foundation of wet cement.

The Bill threatens Australians' access to essential medicines

High risk of short term stock shortages jeopardising supply of essential medicines to consumers

The Bill increases ten-fold (from 162 to over 1600) the number of medicines that will be subjected to repeated price reductions to pharmacists. The price changes will coincide with a high risk of stock shortages resulting in patients' inability to obtain prescription medicines as needed. Nobody has considered this.

Market rationalisation will jeopardise supply of medicines to consumers in medium term

Under price disclosure, the price of the medicine can drop below the cost of goods of some manufacturers, forcing the market exit of these suppliers. The capacity for the remaining suppliers to produce sufficient volumes to meet the whole supply of the market has not been assessed, jeopardising Australians' access to prescription medicine over the medium term.

Increased reliance on imported medicines will jeopardise ongoing supply of medicines to consumers

Diminished local manufacturing capability will mean the supply chain will become longer (overseas manufacturing) and responsiveness to shortages and disruptions will be delayed, again disrupting Australians' access to medicines.

Australia's ability to protect its population's health in the event of a pandemic is jeopardised

A domestic 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 a potential emergency manufacturing need, as generic medicine manufacturing is geared towards the production of multiple, different medicines. The proposed expenditure cuts to the PBS result in diminished local manufacturing capability, risking levels of assurance of continuity of supply and insurance in case of a potential pandemic requiring emergency manufacturing.

The Bill will cause serious detriment to the generic medicines sector

The generic medicines sector is an important contributor to the economy

Generic medicines lower the benchmark price of medicines on the PBS. Local challe nges of weak patents generate earlier market entry of generics and consequent savings to the PBS. Domestic manufacturing brings important health and economic benefits to the nation.

The introduction of generic medicines stimulates innovation by virtue of the reduced profitability of medicines after the period of market exclusivity. Generic medicines are essential in balancing reward for innovation against long term medicines affordability, and sustainability of the PBS.

The Bill threatens the viability of the generic medicines sector

The PBS is divided into two formularies, F1 and F2. F1 comprises originator medicines and F2 generic medicines. The proposed Bill will cut $1.9 billion from 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 and 2009/10 from $2.8 billion to $2.2 billion.

Australia's leading manufactured goods export industry will be damaged

Pharmaceuticals are Australia's leading manufactured goods export industry. Bringing in more than $4 billion a year in revenue to Australia, it is ahead of cars, wine and IT. The industry operates with long timelines that require significant investment in research, development, people, plant and equipment. Policy certainty is necessary for long term investment in Australia.

Repeated cuts to expenditure on the PBS are not sustainable

Repeated cuts to expenditure on the PBS that continually reduces the profitability of the sector is critically damaging. Already the 2007 reforms have cost a large number of jobs across the industry and there are examples of companies that have closed down R&D and manufacturing plants as a result of the reforms.

The Bill requires more informed policy analysis

The Bill does not target the source of growth in PBS expenditure

PBS data show that PBS growth is driven by growth of expenditure on F1. Contradictorily, the proposed cuts to expenditure on the PBS fall SOLELY on the suppliers of medicines in F2.

The cost of F2 fell by 21.4 per cent between 2005/06 and 2009/10 from $2.8 billion to $2.2 billion (Government contribution). Conversely, the Bill does not address the growth of F1 that has increased by 35.4 per cent (Government contribution) over the same period. Increasing costs of F1 will be the key growth driver to the PBS in the future.

The Bill will cause irreparable harm to the generic medicines sector

The Bill will result in cuts to the PBS that will cause irreparable harm to the generic medicines sector. This is contrary to the public's longer term interests. The Government's responsibility to protect the public's longer term interest is embedded in the fourth objective of the National Medicines Policy of maintaining a responsible and viable medicines industry across all sectors of the medicines industry.

The cuts to PBS expenditure fall most heavily on the suppliers of generic medicines

The reforms are weighted to older F2 medicines, the part of the F2 market predominantly supplied by members of GMiA. The reforms impact the core business of supplier s of generic medicines as compared to members of Medicines Australia whose core business is protected under the F1 formulary. Further scrutiny of the Bill will make this evident.

Short sighted savings to the PBS jeopardise the sustainability of the PBS

While greater savings can be seen as good for the public, greater savings that jeopardise any sector of the medicines industry are clearly short sighted and to be avoided. The presence of a generics sector has saved the PBS $1.4 billion (Government contribution) between 2005/06 and 2008/09. Appropriate safeguards must be put in place to ensure that cuts to PBS expenditure do not jeopardise the viability of all sectors of the medicines industry.

Expert advice on the impact of the competitive effects to the market of the Bill is needed

The Government claims that under the proposed reforms companies can continue to compete for market share. This conclusion has been reached by officers from the Department of Health and Ageing who do not have the economic expertise in complex competitive market analysis to determine accurately the likely effects of the key provisions of the Bill. These conclusions are driven more by wishful thinking than any skilled analysis of the market and likely competitive effects.

The Committee should direct the Australian Competition and Consumer Commission (ACCC), under the Trade Practices Act (Cwlth) 1974 (TPA), to prepare a report for the Committee on the likely competitive effects of the key provisions of the Bill on the interests of Aust ralian consumers. The ACCC has the expertise to prepare such a report for the Committee under subsection 28(1)(c) of the TPA and the Committee has the power to direct the ACCC to prepare such a report under subsection 29(3) of the TPA.

In summary

The National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 should not be supported

If the Bill is enacted it will fundamentally change the landscape of supply of generic medicines in Australia. At risk is:

- Surety of competition of multiple brands of generic medicines that keep prices affordable;
- Sustainability of lower pricing of generic medicines due to the paradoxical effects that emerge from restrictive pricing policies. In the prescription medicine market if some suppliers of generic medicines are forced to exit the market, the remaining players could increase prices;
- The stimulus to innovate, brought on by the inevitable reduced profitability of medicines when generics are introduced post the market exclusivity period ;
- Appropriate balancing of reward for innovation against long term medicines affordability, and sustainability of the PBS;
- Active challenge of potentially weak patents.

A weakened generic medicines sector is not in the public's best interest. The Bill does NOT bring stability to industry. Rather, the Bill jeopardises the ongoing viability of the generic medicines sector in Australia, which in turn substantially strengthens the commercial interests of the suppliers of originator medicines in Australia.

The Bill does NOT deliver longer term sustainability to the PBS nor does it ensure more affordable medicines for Australians in the long term.

2. THE GOVERNMENT CLAIMS THAT THE BILL IS NECESSARY TO ADDRESS UNSUSTAINABLE GROWTH OF THE PBS – THIS CONCLUSION IS ERRONEOUS AND BASED ON POOR ANALYSIS

The Minister for Health and Ageing stated in Parliament on 2 June 2010 and repeated again on 29 September 2010: "Since the previous major pricing reforms in 2007, the growth rate for PBS expenditure has increased from 4.3 per cent in 2006-07 to an estimated 10.5 per cent for the 2009-10 financial year." The Minister's statements are misleading.

The growth rate of PBS expenditure increases and decreases over time. To selectively choose two time points is misleading. The average growth rate of the PBS has been approximately 8 per cent over the past ten years. The growth rate of PBS expenditure regularly increases and decreases over time.

The Minister for Health and Ageing stated in Parliament on 2 June 2010 and again on 29 September 2010: "The PBS Reform Report estimates that PBS costs will reach $13 billion in 2018, compared to about $9 billion in 2010."

The projected growth rate cited by the Minister represents an annual growth rate of 5.7 per cent, below the historic average growth rate of 8 per cent of the PBS.

PBS cost as a percentage of GDP has been steady at 0.6 – 0.7 per cent, most recently reported at 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 on the PBS.

The growth of the PBS is manageable and there is no need for further cuts to expenditure on the PBS.

3. FUTURE GROWTH OF THE PBS WILL BE DRIVEN BY GROWTH OF THE F1 FORMULARY – THE BURDEN OF EXPENDITURE CUTS FALLS SOLELY ON THE SUPPLIERS OF MEDICINES IN THE F2 FORMULARY

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 the proposed cuts to expenditure on the PBS falls SOLELY on the suppliers of medicines in the F2 formulary.

The Bill will cut $1.9 billion out of the F2 formulary over 5 years. The cost to Government of the entire F2 formulary fell by 21.4 per cent between 2005/06 and 2009/10 from $2.8 billion to $2.2 billion. The proposed cuts represent a large proportion of the F2 formulary which will be challenging for suppliers to bear commercially.

Conversely, the Bill does not address the growth of the F1 formulary that has increased by 35.4 per cent from $2.8 billion to $4.8 billion (Government contribution) over the same period. Increasing costs of the F1 formulary will be the key growth driver of the PBS in the future.

Government expenditure by F1 and F2 formulary over the past five years is presented in table 1.

Table 1: 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.

4. THE PROPOSED REFORMS PROMOTE THE SECTIONAL INTERESTS OF MEMBERS OF MEDICINES AUSTRALIA

Members of GMiA support many of the objectives contained in the Memorandum of Understanding (MoU) underpinned by the Bill and through consultation wish to work with Government to achieve the same important public benefits.

Members of GMiA strongly oppose the clauses of the MoU that promote the sectional interests of members of Medicines Australia and simultaneously weaken the generic medicines sector, as a weakened generic medicines sector is not in the public's best interest.

Specifically

1. Clause 5: re-affirms the split in pricing of patented (originator) and generic medicines, resulting in Australians paying more per health outcome for originator medicines than generic medicines in some cases.
2. Clause 16: prohibits the Government from introducing therapeutic groups, an important policy tool that allows Government to set the price of medicines delivering the same health outcome at the same price.
3. Clause 20: prohibits the Government from introducing any measure to favour prescribing or dispensing of generic medicines without the agreement of Medicines Australia.

The MoU provides a significant windfall for suppliers of originator medicines at the cost of the generic medicines sector.

1. The price of single brand medicines is protected and the public cannot be assured that the price of single branded medicines will deliver the best value for money;

2. The generic medicines sector is significantly weakened and this will allow suppliers of originator medicines to retain market share of their brands that are subject to generic competition.

5. GMiA IS AN IMPORTANT STAKEHOLDER AND SHOULD BE PART OF THE CONSULTATION

The Government claims that this Bill has the support of the industry. This is not the case. Suppliers of generic medicines strongly oppose the Bill. The Bill will enact a protection agreement by Government of the interests of one sector of the industry (suppliers of originator medicines) to the detriment of another (suppliers of generic medicines).

The Government has negotiated the proposed reform of the PBS by exclusive MoU with just one sector of the industry (the companies represented by Medicines A ustralia supplying predominantly originator medicines).

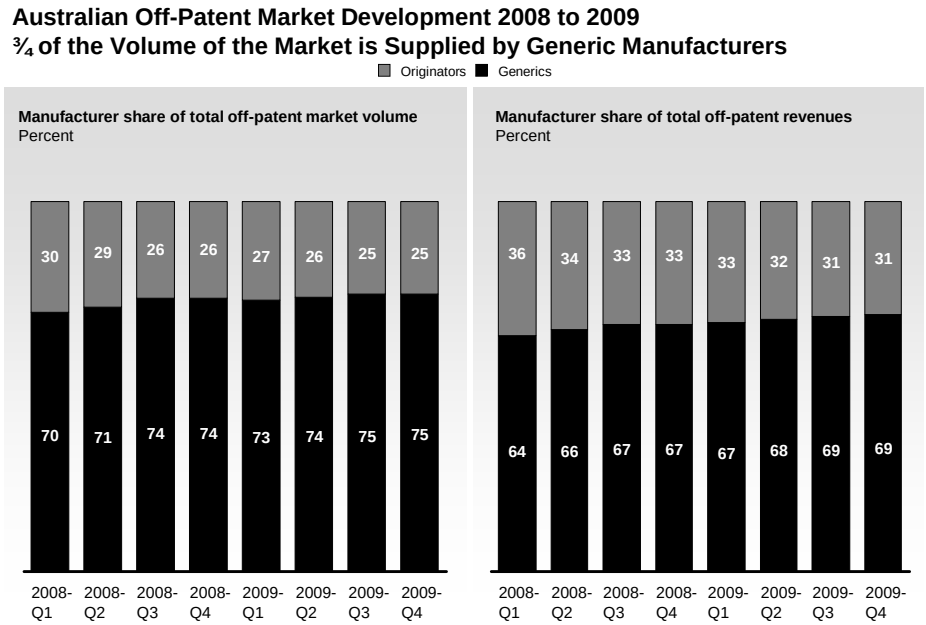
The sector most severely impacted by the reforms – the generic medicines sector - was excluded from the negotiations and will bear the brunt of the $1.9 billion projected savings to the PBS.

The Minister for Health and Ageing has stated this occurred because Medicines Australia companies supply more than 60 per cent of generic medicines to the Australian market , however the source of these data has not been disclosed.

Independent market research data commissioned by a member company of GMiA, show that members of GMiA supply about 70 per cent of the generic market on the PBS as presented in Table 2 below. This analysis includes all generic medicines supplied to the market, not just generic medicines costing more than the PBS co-payment. It is important to include generic medicines supplied to the PBS that are not captured by typical PBS data sets, as the PBS list price also affects the price of these medicines.

Irrespective of market share, suppliers of generic medicines are strategically important to the Government as it is the market entry and market competition by generic medicine s that trigger the important price reductions on the PBS, making medicines more affordable.

Table 2: Share of market supplied by the originator and generic medicines sectors



Source: Independent market research data commissioned by member company of GMiA

It is noteworthy that originator companies supply 25% of the volume at 31% of the cost. In contrast, companies that specialise in the supply of generic medicines supply 75% of the volume at 69% of the cost.

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:

- Expenditure cuts to the PBS formulary are heavily weighted towards the older F2 medicines, where typically the greater market share is held by members of GMiA. The cuts to expenditure 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 creation of the F1 and F2 formulary has resulted in the Government paying different prices for medicines delivering the same health benefit in some instances. For example, the following doses cholesterol lowering medicines provide the same health benefit, yet are priced at significantly different prices because of formulary status: rosuvastatin 20mg costs $96.43 (F1); atorvastatin 20mg costs $100.70 (F1) and simvastatin 80mg costs $59.42 (F2).

Without the insight and contribution of the generic medicines 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.

6. FURTHER SCRUTINY OF THE BILL IS PARAMOUNT

The Bill requires significant review and amendment. The Bill will result in cuts to the PBS that will cause irreparable harm to the generic medicines sector. This is contrary to the public's longer term interests. The Government's responsibility to protect the public's longer term interest is embedded in the fourth objective of the National Medicines Policy of maintaining a responsible and viable medicines industry across all sectors of the medicines industry.

Scrutiny of the Bill is required to ensure that the cuts to expenditure on the PBS and the other reform clauses contained the in the Bill and the MoU do not cause irreparable harm to the generic medicines sector. A full analysis of the impact of the Bill by industry sector is required.

Greater scrutiny of the Bill will reveal that the cuts to PBS expenditure fall most heavily on the suppliers of generic medicines. The reforms are weighted to older F2 medicines, the part of the F2 market predominantly supplied by members of GMiA. The reforms impact the core business of suppliers of generic medicines as compared to members of Medicines Australia whose core business is protected under the F1 formulary.

The savings to the PBS stemming from the Bill should be scrutinised. Appropriate safeguards should be put in place, in the event that the Bill delivers greater savings than anticipated, to ensure the viability of all sectors of the medicines industry.

At the time the 2007 reforms were announced, savings of $3 billion over ten years were projected. Only three years into those reforms, savings are already projected to be about double what was originally anticipated. While greater savings can be seen as good for the public, greater savings that jeopardise any sector of the medicines industry are clearly short sighted and to be avoided.

Members of GMiA are in a position to provide the Government with certainty of the savings stemming from the 2007 PBS reforms. It is expected that with greater certainty about future savings and the ability to include these savings into the forward estimates, it will be clear that the cuts to PBS expenditure under the Bill are not warranted.

The Government claims that under the proposed reforms companies can continue to compete for market share. This conclusion has been reached by officers from the Department of Health and Ageing who do not have the economic expertise in complex competitive market analysis to determine accurately the likely effects of the key provisions of the Bill. These conclusions are driven more by wishful thinking than any skilled analysis of the market and likely competitive effects.

The Committee should direct the ACCC, under the TPA, to prepare a report for the Committee on the likely competitive effects of the key provisions of the Bill on the interests of Australian consumers. The ACCC has the power to prepare such a report for the Committee under subsection 28(1)(c) of the TPA and the Committee has the power to direct the ACCC to prepare such a report under subsection 29(3) of the TPA.

7. THE BILL CONTAINS MANY ANOMALIES AND CANNOT BE IMPLEMENTED

The submission made by GMiA to the Senate Inquiry on 20 August 2010 provides a comprehensive overview of the flaws contained in the MoU (section 7) and methodological problems with the Bill as tabled in the Parliament on 2 June 2010 (section 8).

A major component of the reform under the Bill is the provision for an average price reduction of at least 23 per cent across the F2 formulary. Under the Bill three medicines with no generic competition (the brands Nexium, Pariet and Zanidip) are included in the F2 formulary. These brands cost the PBS approximately $250 million, are not subject to competition and are not discounted. This will erroneously influence the overall outcome, and is expected to result in an actual average price reduction of 27-30 per cent for generic medicines.

Members of GMiA had been advised that they would be part of a working group tasked with implementation of the Bill. This group met twice, on 18 June and 20 July 2010. GMiA was advised on 18 October that the regulations are now at an advanced stage, making it highly unlikely that members of GMiA will have any input into the implementation of the Bill.

GMiA notes that the Bill tabled in the Parliament on 29 September 2010 is generally unchanged from the Bill tabled on 2 June 2010. This means that the time for implementation of the Bill has been reduced from approximately three months to something more like three weeks. This is a ridiculous amount of time for an industry sector to make the necessary commercial adjustments to accommodate any policy change, let alone a policy change of the substantial size proposed under the current Bill.

APPENDIX

A1. THE MEMORANDUM OF UNDERSTANDING UNDERPINNED BY THE BILL WILL CAUSE SERIOUS DETRIMENT TO THE GENERIC MEDICINES SECTOR AND AUSTRALIANS' ACCESS TO MORE AFFORDABLE MEDICINES THROUGH A SUSTAINABLE PBS IS JEOPARDISED

The Government has relied upon advice that is based on a simplistic review of the PBS market and does not fully grasp the complexities of this constructed market.

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 Bill 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.

a. Restrictive medicines pricing policies 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.

A highly relevant case study that tracks the prices of generic medicines over time in Ontario province, Canada, is presented as Appendix 3 in the GMiA submission to the Senate Inquiry 20 August 2010. A 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 an average of 537% by 2001.

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.

b. The reforms do not provide pricing stability for the generic medicines sector

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 Bill perpetuates the failure of the 2007 reforms to book into the Budget estimates resulting savings.

Currently 162 items are under the price disclosure policy. The implementation of price disclosure on these 162 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.

The Bill proposes to increase the number of items subject to the price disclosure policy to more than 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 more than 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, creating substantial administrative burden over the traditional Australian holiday period. The claimed difficulties associated with making implemented price adjustments through the supply chain has led 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 represent the pharmaceutical wholesalers.

c. The policy removes the key market mechanism for suppliers to compete

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 Bill is designed to deliver the savings from competition to the Government, an objective strongly supported by members of GMiA. However, the Bill simultaneously takes away the ability of suppliers of generic medicines to compete.

The First Assistant Secretary of the Department of Health and Ageing stated at Senate Estimates on 2 June 2010 that the Bill 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.

Generic manufacturers 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.

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 PBS is a constructed market and market forces are not free to reliably deliver a true market price.

The price disclosure policy must be coupled with concomitant policy that provides a market incentive for the physician, pharmacist and consumer to choose a generic medicine. Price disclosure removes the market mechanism for suppliers of generic medicines to effectively compete for market share. This puts at risk the ongoing viability of suppliers of generic medicines and the ongoing supply of generic medicines to patients.

Clause 20 of the MoU expressly forbids the Government from introducing any policies that will encourage the use of generic medicines over more expensive originator brands and explicitly prevents the Government from introducing incentives to encourage doctors, pharmacists and patients to consider choosing a generic medicine.

d. 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 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 Bill will not decrease market entry of generic medicines as Government does, “not distinguish in the off patent market 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 have 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 encourage 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 MoU it underpins.

e. 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 highly skilled jobs within the Australian generic medicines sector.