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Generic Medicines Industry Association

Submission to Senate Community Affairs References Committee

Inquiry into consumer access to pharmaceutical benefits

Responding to the National Health Amendment (PBS) Bill 2010 the MOU and other budget announcements

18 June 2010

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1. Executive Summary

Issue:

The Government is seeking to introduce a Bill that is underpinned by a Memorandum of Understanding between Government and the suppliers of patented medicines. The Bill promotes the sectional interests of the suppliers of patented medicines to the detriment of the sup pliers of generic medicines, the very sector that the Government relies upon to trigger the price reductions necessary to sustain the PBS.

The Bill has not been subject to proper scrutiny and due process. The procedural unfairness of the policy's development needs to be examined closely and not just passed unchallenged by the Senate.

Background:

The Government claims that the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 will amend the *National Health Act 1953* (the Act) 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.

These reforms were announced as part of the Federal Budget on 11 May 2010 and introd uced in the House of Representatives on 2 June 2010. The reforms are underpinned by a Memorandum of Understanding (MoU) between the Government and Medicines Australia who represent the suppliers of patented medicines.

Recommendation:

The Bill must be subjected to the scrutiny of a Senate Committee to expose its flawed, dangerous and biased nature that has resulted from the unusual and unfair policy development procedure.

A revised Bill should be prepared with the benefit of proper, industry-wide consultation that responsibly meets the claimed objectives of the current Bill. The generic medicines sector strongly supports the principle that Australia should have access to more affordable medicines due to competition from generic medicines.

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 sect or.

2. Introduction

This submission, prepared by the Generic Medicines Industry Association (GMiA), responds to a request received from the Community Affairs References Committee on 1 June 2010 to provide further information to the Committee's inquiry into consumer access to pharmaceutical benefits.

The Committee asks that GMiA includes comment on to what extent the Memorandum of Understanding (MoU) between Government and the suppliers of patented medicines, represented by Medicines Australia, has addressed concerns of members of the GMiA raised earlier during the inquiry and / or whether the members of GMiA have ongoing or outstanding concerns relevant to the terms of reference for the inquiry.

This submission discusses the serious concerns held by members of the GMiA concerning the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 will amend the *National Health Act 1953* (the Act) and the underpinning MoU between Government and Medicines Australia.

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.

3. Growth of the PBS is already projected to reduce as a result of the 2007 reforms to the PBS

The Minister for Health and Ageing stated in Parliament on 2 June 2010 that the proposed new PBS pricing arrangements are, "aimed at reducing growth in PBS expenditure, ensuring access to quality medicines at lower cost to the taxpayer, and providing certainty to the pharmaceutical industry in relation to PBS pricing policy." Growth of the PBS is already projected to decrease as a result of the 2007 reforms to the PBS.

In 2007, the Government implemented the most major reform to the PBS since its inception in 1948. The reforms were to play out over a decade and save $3 billion. Two years into the 10 -year reform process, three separate analyses have projected the 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 2007 reforms feature a price disclosure saving mechanism that is retrospective and claws back discounts given to pharmacists. The bigger the discounts given to pharmacists, the bigger the amount clawed back by the Government. Therefore the exact size of the savings cannot be forecast with certainty and the savings cannot be included in the forward Budget estimates. The reforms introduced in 2007 will generate significant savings to Government, however its retrospective nature means the savings cannot be included in the Government's forward budget estimates.

Members of GMiA are mobilised to work with the Department of Health and Ageing to propose ways that these savings can be included into the forward Budget estimates so that the Commonwealth Budget can accurately project future Government expenditure and savings.

4. The growth of the PBS is manageable

The Minister for Health and Ageing stated in Parliament on 2 June 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 statement is misleading.

Average growth of the PBS has been 8.9 per cent over the past 10 years. 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.

The Minister for Health and Ageing also 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 rate cited by the Minister represents an annual growth rate of 5.7 per cent, below the historic average growth rate of 8.9 per cent of the PBS.

Further, since 1993, every single medicine that has been listed on the PBS has had to undergo rigorous health economic assessment and be proven to be cost effective. Every dollar spent on medicines on the PBS is proven to be cost effective and providing good value for money by delivering demonstrated health benefits. Growth of spending on the PBS is therefore a good thing and certainly expected when the population is growing.

5. Flaws in the MoU underpinning the Bill

Members of GMiA note the below flaws in the MoU underpinning the Bill:

i. There is no public transparency to the stated saving of $1.9 billion dollars over five years. The PBS reforms from 2007 will generate savings to the PBS and it will not be possible to disaggregate savings between the 2007 and 2010 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.

ii. 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.

iii. 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 merits 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.

iv. The MoU provides for the Access to Medicines Working Group (AMWG) to monitor: PBS expenditure trends; implementation and progress of the MoU; horizon scanning; 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.

v. 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 directly to the patient, they cannot advertise to the patient and they cannot discount to the patient.

   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.

vi. The Bill provides for an average price reduction of at least 23 per cent across the F2 formulary and includes three medicines that are not subject to generic competition. This will erroneously influence the overall outcome, and is expected to result in an actual average price reduction of 30 per cent for generic medicines.

vii. The MoU indicates that 1600 new 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. This will result in a loss of around 7 weeks of normal sales out of 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. In some circumstances patients unable to get medication could be dangerous or life threatening.

6. Current generic medicine policy lacks of volume driver

The Deputy Secretary of the Department of Health and Ageing at Senate Estimates on 2 June stated 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". Further, the MoU expressly forbids the Government from introducing any policies that will encourage the use of generic medicines over more expensive originator brands.

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 on 2 June stated 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, it is blocked by the Bill and the MoU.

That is, the MoU explicitly prevents the Government from introducing incentives to encourage doctors, pharmacists and patients to consider choosing a generic medicine.

7. The Bill jeopardises the ongoing viability of the generic medicines sector

The First Assistant Secretary for the Department of Health and Ageing stated at Senate Estimates on 2 June 2010 that the Department believes that the impact of the proposed 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 about $4 billion a year in export sales. Members of GMiA contribute approximately 12 per cent 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 for 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.

The First Assistant Secretary provided three reasons to support the above statement. None of these statements capture the full complexity of the issue.

First, the reforms offer a stable pricing policy for four years. 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.

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 Bill proposes to increase the number of items under the price disclosure 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.

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.

Secondly, the First Assistant Secretary stated that the reforms will not take cuts out of the earnings of pharmaceutical companies. For this statement to be realised, suppliers of generic medicines must be able to cease providing discounts to the pharmacist. This effectively removes the key market mechanism available to suppliers of generic medicines to compete in the market.

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 current 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 regulatory system ensures that generic medicines are bioequivalent to the originator medic ines so there is little ability for the supplier of generic medicines to differentiate the product. Suppliers of medicines are not allowed to advertise to the public, they are not allowed to sell directly to the public and they are not allowed to provide cheaper medicines to the patient. The only mechanism available to suppliers of generic medicines is to offer discounts to pharmacists. This mechanism is removed with the advent of price disclosure.

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.

Thirdly, the First Assistant Secretary stated 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.

8. Pharmaceuticals and generic pharmaceuticals are strategically an 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 economic 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 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.

9. GMiA was not consulted on the MoU despite repeated requests to be involved in policy reform

The Deputy Secretary of the Department of Health and Ageing at Senate Estimates on 2 June stated that discussions relating to the MoU were had between Government and Medicines Australia as this was considered, “the appropriate venue and way in which to conduct that discussion and to reach agreement with the industry”. Policy making and attempts to pass legislation that promote sectional interests should not be tolerated.

There was no consultation, negotiation or agreement about an MoU with the GMiA. Members of GMiA supply approximately 70% of the volume of generic products. Therefore the MoU lacks balance and details 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 ind ustry.

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

10. A generic awareness campaign is unlikely to make a difference

Senator Boyce asked officials from the Department of Health Ageing at Senate Estimates on 2 June if there are, “any plans to use tools other than the current query from the pharmacist t o encourage consumers to ask for generics?”

The First Assistant Secretary of the Department of Health and Ageing replied, “A part of the Budget announcement was for a new generic medicines campaign, which is going to be rolled out through the National Prescribing Service at a cost of $10 million over four years, basically pointing out to consumers that generic medicines are an equal choice”.

The PBS reform package announced in November 2006 provided $20 million for a generic awareness campaign. This amount was reduced to $5.1 million in the 2008/09 Federal Budget. The campaign was delivered by the National Prescribing Service between June 2008 and July 2009.

The campaign was called, "Generic medicines are an equal choice campaign." The objective of the campaign was to increase confidence of understanding of the safety and efficacy of prescription generic medicines to a sub-group of the community. Prior to the campaign, 72 per cent of consumers reported feeling confident using generic medicines. At the end of the campaign, this per cent was increased to 77 per cent.

The National Prescribing Service completed a self-evaluation of the 2008/09 Generic Awareness Campaign in July 2009. At the time of the Public Hearing of the Community Affairs Senate Committee on 7 May 2010, GMiA had not been able to obtain a copy of this evaluation report. A copy of this report has since been provided to GMiA. The report details that the campaign comprised a total budget of $4.4 million and an actual cost of $4.16 million, considerably below the initial allocation of $20 million and even below the eventual allocation of $5.1 million.

While the campaign proposed in the 2010 Budget cannot hurt, members of GMiA have absolutely no confidence that another generic awareness campaign delivered by the National Prescribing Service will encourage consumers to choose a generic medicine.