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13 June 2007

Mr Elton Humphrey
Committee Secretary
Senate Community Affairs Committee
Parliament House
CANBERRA ACT 2600

Dear Mr Humphrey

Senate Inquiry: National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007

The Generic Medicines Industry Association (GMiA) welcomes the establishment of the Senate Inquiry into the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007 and is pleased to have the opportunity to make a submission to the Inquiry.

Background to generic medicines listed on the PBS

When a medicine is first developed, the pharmaceutical company discovering the product and bringing it to the market for the first time is granted a period of patent protection on that medicine. When the patent expires, typically after 20 years, other pharmaceutical companies can then seek approval from the Therapeutic Goods Administration (TGA) to market an equivalent product namely, a "generic" product. GMiA is the industry association representing the manufacturers of prescription generic medicines listed on the PBS.

Prior to listing on the PBS, a generic medicine must demonstrate "essential similarity" to the existing formulation of the active ingredient (originator brand). This is achieved by submitting chemistry and clinical data to the therapeutic Goods Administration (TGA) that demonstrates that the generic brand is of high quality, and delivers the active ingredient into the blood stream at the same rate and extent to the originator brand.

Since 1995 when the brand substitution policy was introduced, generic medicines have saved the PBS more than $2.8 billion. This has been achieved mainly

through reference pricing and more recently additional savings have been achieved through the mandatory 12.5% reduction when a new generic medicine is listed on the PBS. It must be noted that the company that owns the patent can also launch a copy of their own product, but these 'off-patent' originators only offer their copy brand to maintain market share under pressure from generics entering the market.

Under the current reference pricing policy, generics would have resulted in PBS savings of approximately $8 billion by 2010 due to the many anticipated patent expiries between 2005 and 2010. We attach for the Committee's information a report prepared by Econtech on behalf of the GMiA – *An Analysis of the Importance of the Current Reference Pricing System* – dated 17 May 2005 (Attachment 1) which outlines these savings and thereby highlighting the importance reference pricing and of a viable generic sector to the future sustainability of the PBS.

GMiA members are concerned that the proposed changes to the PBS undermine reference pricing and the generic sector in Australia, putting at risk future price reductions and a sustainable PBS which jeopardises consumers' continued access to affordable medicines.

This is a major change to the fundamentals of the PBS.

The uptake of generics is still low in Australia compared to other countries -28% of prescriptions whereas in the United Kingdom generics are approximately 75% of prescriptions and in the United States they are around half of all prescriptions. The Government's generic awareness campaign is welcomed by the GMiA and will contribute greatly to the community's understanding of generics. We also welcome the payment of $1.50 to pharmacists for dispensing benchmark-priced medicines but we believe this should be restricted to "true" generics. However, we believe there should be some mechanism that specifically rewards consumers for choosing generics such as reduced co-payments for generics thus rewarding them for contributing to the sustainability of the PBS.

Detailed below are our concerns about the Bill.

The impact of changes to the fundamentals of the PBS

The existing key tenets of the PBS are equity of access, affordability, sustainability and cost. The PBS is not about medicines, it is about health outcomes. Current arrangements enable the Government to obtain value for money when purchasing health outcomes. The centrepiece of those arrangements is reference pricing between medicines that deliver the same health outcomes.

This Bill dismantles reference pricing and instead classifies medicines into different formularies based on whether or not there are other brands of the same medicine. As a result the community will pay different prices for the same health outcomes.

The Bill therefore confuses the patentability of medicines with cost effectiveness. Cost effectiveness is satisfied by a new medicine if it delivers a quantifiable improvement in health outcome, compared to existing therapies. On the other hand patentability relies simply on whether a new medicine is sufficiently different, usually in chemical structure, to satisfy the test of "inventiveness".

Up to now, the PBS has recognised this difference through the publication of Therapeutic Relativity Sheets, and the establishment of Therapeutic Groups.

An example of this distinction may be provided in the ATC C09 therapeutic relativity sheet for agents acting on the renin-angiotensin system (Attachment 2). While individual active ingredient patents covered the eight ACE inhibitor medicines listed on the PBS, all are considered to provide similar safety and efficacy outcomes, and are priced on an average daily dose comparison. Their cost effectiveness is the same.

This illustration provides a practical example of the mechanism that has underpinned the PBS process since 1993, when an amendment to the National Health Act required the PBAC to consider both the cost and effectiveness of medicines prior to recommending any new listing on the schedule.

In practical terms, the PBAC makes this assessment by considering how much it would cost to achieve the health outcomes with a new medicine, compared with existing therapies that it would replace. Consequently, a price premium over an existing medicine can only be achieved if it is supported by a quantifiable improvement in effectiveness which translates into a better health outcome.

If no improvement in effectiveness can be demonstrated in a comparative clinical trial, the price of the new medicine remains around the level already paid for by the comparator.

The proposed amendment to the Act, appears to be risking the efficiency of this process, by protecting price based on whether the medicine has an active patent, rather than whether the medicine offers a true improvement in health outcomes.

Using the ACE inhibitor example, the proposed amendment will protect the price of each member of the class until their individual patents expire, rather than when generic competition provides equal effectiveness at the time of first in class patent expiry.

Consequently, the PBS will no longer be paying for improved health outcomes, but rather patent protection.

Interestingly, applying the same criteria to the statin medicines listed on the PBS, demonstrates that the dose response curves are parallel, indicating that they could also be priced on an average daily dose comparison. (Attachment 3)

As outlined above, it is generics that trigger savings to the PBS thereby creating headroom for the listing of newer and more expensive medicines. Generics are the sustainers of the PBS. However, these amendments along with existing pricing arrangements have the potential to drive down generic prices to a level that could make it uneconomical for companies to continue to market their products in Australia. Should this happen, future governments may not be able to guarantee continued and affordable access to new and expensive medicines for future generations.

In his second reading speech the Minister said that these changes attacked "a problem that has arisen in the current system of PBS pricing, where the price of single brand and multiple brand medicines that provide similar health outcomes has been linked" i.e. reference pricing.

By attempting to correct this "problem" the Government has changed the fundamentals of the PBS.

Cost to individual consumers

Affordable access to medicines, as mentioned above, is one of the tenets of the PBS. However, these amendments do not guarantee this. In fact, there is a possibility that many consumers could pay more for their medicines after 1 August 2008 as a result of these changes. Currently, 80% of scripts are dispensed for concession cardholders and attract a co-payment of $4.70. The changes in the Bill will likely drive the cost of medicines up for many of these consumers as originator companies will determine what consumers pay by virtue of the quantum of their premiums. Whilst the Bill determines that all premiums will be reduced by the same percentage as the Government subsidy and at the same time, originator companies will, however, be able to increase their premiums four months later which is the time of the next round of price adjustments.

As well as increased premiums, the cost of more for the 2,651 medicines listed on the PBS could also increase for many, especially those low-income working families who do not qualify for the healthcare concession card.

This is because there are no publicly announced proposals by Government to monitor the cost of these medicines including the estimated 400 which will fall below the general co-payment of $30.70 as a result of the proposed new pricing arrangements. As part of the compensation package offered to pharmacy, the agreed mark-up for many of these medicines will increase from 10% to 15%. Whilst competition between pharmacies could see some control on prices, it is not easy for unwell consumers to do price comparisons between pharmacies on the high street, especially if those pharmacies do not display their prices for below co-payment PBS listed medicines.

5.

Uncertainty for industry

a) Impact on industry of ad hoc price reductions in the context of PBS changes

In addition to the mandated price reductions – 12.5%, 3x2% and one-off 25% - companies are also able to continue to offer Government ad hoc price reductions. To overcome the initial impact on companies of the already announced price reductions, the GMiA proposes that the mandatory price reductions detailed in this legislation should apply to the prices existing on the 1 December 2006, the first listing date following the announcement of the changes to the PBS on 16 November 2006.

This would ensure that any ad hoc price reductions accepted and implemented by the Government between the 16 November 2006 and 1 August 2008 will be part of those mandated price reductions, not in addition to them.

Without certainty about future prices, it is almost impossible for industry to invest in Australia whether it is the development of new medicines or new brands of existing medicines or in manufacturing activities including the manufacture of medicines for export. Currently generic companies manufacture in Australia over 80% of all generics dispenses and export medicines to Asia, Europe, Canada, USA and New Zealand.

b) Impact of proposed disclosure arrangements on industry's ability to plan for the future

Although details of how the disclosure arrangements will operate are not detailed in the legislation, the disclosure policy is included and therefore the GMiA would like to bring to the attention of the Committee their concerns about the impact its implementation will have on the industry.

The price reductions will be relatively unpredictable in timing in that there will only be 6 months forewarning and the reductions could be much greater than 10%. Reduced predictability of future revenue from products in the F2A formulary to 31 December 2010 and F2 on or after 1 January 2011 for all products will lead to not only reduced investment by the pharmaceutical industry in Australia but must question viability of existing business to operate in such uncertain environment.

The GMiA's concern on procedural aspects of disclosure is driven by the lack of transparency of the methodology and process proposed and has been outlined to the Department. Summary of our comments on this matter is attached (Attachment 4).

The real concern here is the ability for generics industry to operate in an environment where conditions oppose investment. These reforms fail the test on providing certainty against key indicators driving investment decision as

highlighted in the "Australia Your Competitive Edge, The Facts" published by Invest Australia, 2006 such as stable regulatory environment, effective implementation of government decision, transparency in government policy thereby providing predictability and certainty for business planning, management of shareholder value.

Evergreening

The GMiA is concerned that these changes to the PBS will encourage the practice of "evergreening" of patents. In order to stave off mandatory price reductions and generic competition, originator companies will seek to extend patents so as to remain in the F1 formulary.

The delay of generic entry weakens the single, most effective brake on PBS growth - generic price pressure. As detailed earlier in the submission, generics have saved the PBS approximately $2.8 billion since 1995. Savings to the PBS would be greater by now except for the changes to patent law in 1998, which allow patents to be extended by up to five years.

Whilst the GMiA supports Australia's strong and effective patent regime, members nevertheless believe that once a molecule patent expires, competition should be allowed to begin. The legislation has the potential to stop this.

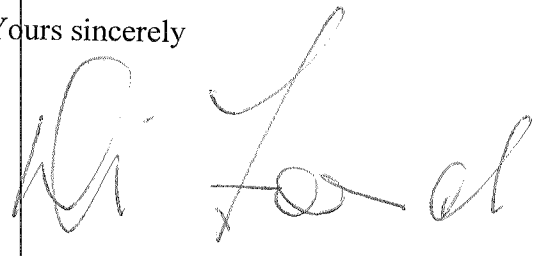
Lack of appeal process included in the Bill

Attached is legal advice from Norton White regarding the lack of any review process included in the Bill. (Attachment 5) As advised, the PBS and the commercial environment for the pharmaceutical industry will be very much dependent on determinations made by the Minister of the day. Many such determinations will be unreviewable by the courts and tribunals.

GMiA members request that the Committee give consideration to the points raised in the advice including the constitutional issues referred to and suggest that the legislation be amended to ensure appeal processes are included.

We look forward to discussing this submission further with the Committee.

Yours sincerely



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