The Pharmacy Guild of Australia

10 November 2010

Senator Claire Moore
Chair, Community Affairs Legislation Committee
The Senate
Parliament House
CANBERRA ACT 2600

Dear Senator Moore

I am writing to provide further information and clarification on evidence provided by the Guild and other witnesses at the Committee hearing on 9 November. I wish to reiterate the Guild's support for the Bill. The following clarifications focus on the Guild's proposal that the 1 December date for changes to price disclosure be delayed until 1 February 2011.

1 - Responses to Department of Health and Ageing evidence

Mr Learmonth stated at the hearing that "the Guild were under the impression that disclosure would start much earlier than it would".

This is not true. The Guild has made it very clear through submissions and our evidence that we understand, based on the current Bill, that the changes to price disclosure would take effect from 1 December. We have always been fully aware that the 11 October date in the Bill is unrelated to price disclosure. I quote the Guild's supplementary submission (pages 1 and 2):

"It appears that the new Bill was written with the expectation that it would be passed at the September sittings. This is evident by the use of 11 October 2010 as the reference point for deciding which drugs will be subject to price reductions on 1 February 2011."

Between the June 2010 version of this Bill and the current version, this date was changed from 30 September to 11 October. In the absence of any other explanation, the Guild believes that this was to allow for the passing of the Bill in September and subsequent Royal Assent (which, according to the Office of Parliamentary Counsel takes between 7 and 10 working days). Our conclusion from this was that the Bill was drafted on the basis of expecting Royal Assent in early October. This would have allowed for a period of two months official notice to all parties before the changes to price disclosure were implemented on 1 December.

Even if there is another explanation for the selection of the unusual 11 October date, it does not diminish our concerns regarding the implementation of price disclosure changes on 1 December. The 1 December data allows for no official notice period following passing of the Bill.

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2 – Clarification of number of new products entering price disclosure

The Guild has major concerns about the integrity and accuracy of the price disclosure data that will be compiled by manufacturers during December 2010 and January 2011 if our proposal is not accepted. Ms Riley stated that the top four GMIA members will have approximately 975 products entering price disclosure. The GMIA submission (page 9) states that "this reform increases the number of brands subject to price disclosure from 160 items to 1,600 items". The discrepancy between 975 and 1,600 was questioned by Senator Boyce at the hearing.

The GMIA figure (1,600) relates to all brands of all drugs entering price disclosure. The Guild figure (975) only related to the top four GMIA members – Alphapharm, Sigma, Apotex and Ascent. In addition to these four manufacturers, there are dozens of other generic and originator manufacturers impacted by the price disclosure changes. These manufacturer's products were included in the GMIA figure but not in the Guild's figure, but all 1,600 products will be affected by the changes.

The Guild used the top 4 GMIA members to draw a direct contrast with the top 4 Medicines Australia members. The top 4 Medicines Australia members will have a total of 218 products being added to price disclosure. As opposed to GMIA members who sell directly to thousands of pharmacies, Medicines Australia members sell only to wholesalers and a very small number of other accounts. Due to the combination of having more products affected and many more customers, the top 4 GMIA members' increase in data management will be at least 100 times as large as the top 4 Medicines Australia members. It is not surprising, therefore, that Medicines Australia do not view this issue as significant while others, such as GMIA members, Spirit Pharmaceuticals, NPSA and the Guild do consider it to be a very significant transition issue, given the time of year and the absence of an official notice period.

3 – Clarification of the increase in workload and risk to integrity and accuracy of data

GMIA and NPSA witnesses indicated support for the Guild's proposal. To quote Mr Davies:
"My knowledge of the industry is that that [1 December] would be a dangerous time to bring in implementation. I support the Guild's position on the revised timing for that."

I also wish to elaborate on the Guild's assertion that manufacturers will be subject to an unprecedented increase in data management. Even where systems are in place, rushing this expansion in December is likely to cause problems for these companies and, ultimately, for PBS pricing and our members.

As an example, consider the following progression for Alphapharm, the largest generics company in Australia. The table below shows the number of new drugs that have been added to price disclosure in each month since the start of the price disclosure arrangements in August 2007.

Month	**Number of Alphapharm products added to Price Disclosure**
August 2007	2
November 2007	1
April 2008	1
August 2008	1
December 2008	5
August 2009	3
September 2009	2
October 2009	6
December 2009	2

April 2010	5
June 2010	8
August 2010	4
December 2010 (proposed)	**246**

As shown above, up to now Alphapharm and its systems, staff and quality assurance processes have had to deal with no more than 8 products being added to price disclosure at any one time. On 1 December 2010, several days after the expected passing of the Bill and at the most difficult time of the year, they will be required to immediately add 246 products. By any measure, this will not be an easy task. All other generic manufacturers, large and small, will also be affected.

Mr Learmonth from the Department of Health and Ageing conceded that there was a burden on manufacturers from the current price disclosure system, by saying the following:

"We have been looking at ways to streamline the current system by reducing the amount of reporting to accommodate the various systems that they themselves use to track through inventories and prices and to generally ease the burden as much as possible..."

The Guild's proposal ensures that the extra burden will not occur immediately after the Bill is passed and will not occur at the worst time of year. This will minimise the risk of our members being affected by PBS price changes on 1 April 2010 that do not accurately reflect the pricing in the market.

4 – Example of supply problems from offshore manufacturers

During the hearing, Senator Boyce requested an example of past problems with medicines supply from overseas manufacturers.

Ranbaxy, an Indian generics company, was added as a manufacturer on 1 August 2006, listing brands of aciclovir (Ozvir), cefaclor (Ozcef), cephalexin (Rancef) and ranitidine hydrochloride (Ulcaid) on the PBS. Despite the listing, Ulcaid was unavailable to be supplied by the company. As a result it was deleted from the PBS on 1 December 2006 and then re-added on 1 February 2007.

Another example involved Ranbaxy's brand of diazepam, Ranzepam. Ranbaxy listed both the 2 mg and 5 mg strength tablets on 1 August 2008. The 2 mg strength was never available and was deleted from the PBS on 1 September 2008, and it has never returned.

The problems with Ranbaxy's brands resulted in guarantee of supply provisions (sections 99AE to 99AEL) being added to the National Health Act 1953 as part of the original PBS reforms legislation. The Guild supported these additions.

Yours Sincerely,

Kos Sclavos
National President
The Pharmacy Guild of Australia

ATTACHMENT 1

Guild Opening Statement at 9 November 2010 hearing

In the interest of time, Ms Riley delivered a shortened version of the Guild's opening statement at the hearing. Below is the full statement.

This Bill contains major amendments to the National Health Act that will achieve more than $1.86 billion in savings over the next four years. Although these amendments will have a significant impact on the future profitability of community pharmacies, the Guild supports the Bill, in the interest of industry certainty and value for taxpayers, and because the further reforms were negotiated in parallel with the Fifth Community Pharmacy Agreement. The PBS has been a world leading scheme for 60 years and these further reforms ensure that it will remain sustainable for future decades. The PBS as a proportion of GDP will be lower in 2013 than it was in 2001, 12 years earlier, and there is a permanent mechanism to ensure that the price competition on off-patent medicines flows through to taxpayers.

The Guild is seeking small but important changes to the current Bill to ensure a smooth transition to the new arrangements. The Guild's proposed changes would have no effect on the level of savings or the timing of those savings.

This Bill was originally introduced to Parliament in June 2010. Its passage was delayed by the first referral to this Committee and then by the election. The original Bill contained a start date of 1 October 2010 for changes to PBS Price Disclosure. The Bill is designed to significantly expand the scope of Price Disclosure, to include all drugs for which there is more than one brand available on the PBS.

Sensibly, the version of the Bill introduced to the new Parliament on 29 September had been amended, compared with the June version, to delay the 1 October 2010 change to price disclosure until 1 December 2010. It appears that the new Bill was written with the expectation that it would be passed at the September sittings. This is evident by the use of 11 October 2010 as the reference point for deciding which drugs will be subject to price reductions on 1 February 2011. Had the Bill been passed in the September sitting it would have allowed for a two months notice period to the industry, which would have been adequate to allow for necessary communications and market adjustment, and to minimise the possibility of errors in procedures and data collection.

The reporting date for this Inquiry is 16 November 2010. This means that the Bill will now not be considered until one of the late November sittings of Parliament. In recognition of this, it is important that the Bill be further amended. The Guild proposes the following changes:

- Firstly, that the proposed 1 December 2010 start date for price disclosure be delayed until 1 February 2011.
- Secondly, to ensure that the level and timing of government savings are not affected by the first change, that the duration of the data period for this 1 February 2011 round of price disclosure be further reduced, from 10 months to 8 months. This will allow price reductions to occur on 1 April 2012 as planned.

These changes would have no impact on the savings that have been booked in the forward estimates. The 1 February 2011 price reductions would occur as scheduled on the same range of drugs. The price reductions on 1 April are guaranteed by this Bill to average at least 23% and the timing and scope of those would not be affected.

The Guild's proposal addresses serious risks that exist in relation to the expansion of price disclosure. The first risk relates to the preparedness of manufacturers, particularly generic manufacturers, for the very large increase in data management brought about by the changes. The top 4 members of GMIA will be required to start disclosing on approximately 975 individual products as a result of this Bill. Under the conservative assumption that each of the companies have accounts with 1,500 pharmacies that order once per month, this represents close to one and a half million pieces of sales information each month that need to be managed and reported on by these four companies alone. That is before accounting for extra complexities such as product returns, bonus stock and bundled deals, all of which must be included in the reported figures.

If the Bill is passed without change in the late November sittings, these companies will need to have systems, procedures and staff in place to manage this workload, within a few days of the official notification, in the lead-up to a Christmas and New Year holiday period. This would be fraught with danger and would inevitably lead to mistakes in data and, ultimately, calculations that do not correctly match the market situation.

This has not been a high profile issue for GMIA, as they have been fighting a broader argument. The fact that GMIA members and other generics companies have been arguing against the Bill further raises the concern that these companies will not be ready to implement the change if there is not sufficient notice. This transition issue is raised in the GMIA submission and also in the submission from Spirit Pharmaceuticals, a small Australian generics company that is not a member of GMIA. Spirit's submission states the following, which highlights the practical problems and risks:

<quote> *our data collection systems are manual, the pricing structures complex and the collection and reporting of data represents a disproportionately high administrative burden related to the value of the product reported. We are reliant on timely, and correct, reporting from third parties in many instances and the rapid expansion of this requirement will undoubtedly lead to reduced reliability in the data.*<end quote>

The second problem addressed by the Guild's proposal is the risk of disruptions to supply, particularly over the Christmas and New Year period. We expect that the Bill will result in a rethink amongst generic companies of marketing strategies and offers to pharmacies. Community pharmacies owners and managers will potentially be faced with a rapidly changing purchasing environment and may face sudden deterioration in margins if they do not react immediately. This may involve purchases being delayed or switched to different suppliers. Putting this kind of market upheaval on pharmacies at their busiest period of the year would create significant transition risks, and is not necessary to meet the objectives of the reforms. Our members at all times endeavour to meet patient demand for the full range of PBS medicines, without the patient being required to pay more than their co-payment if a generic is available. However that will be a difficult task during December and January if the Guild's proposed change is not acted upon.

It is understandable that Medicines Australia do not view the Guild's proposed changes as necessary. In contrast to the one and a half million pieces of complex sales data that will need to be managed by the top 4 GMIA member companies, the top 4 Medicines Australia members, including their generics subsidiaries, will need to cope with little more than 5 or 10 thousand. This is because they each have a much smaller range of products affected and significantly fewer customers because most of their sales go through three major wholesalers. As they do not offer trading terms to pharmacies, the data they will need to handle is far less complex than for GMIA members and they will not be as exposed to the short term supply chain upheaval.

Medicines Australia have suggested that reducing the data period from 10 months to 8 months "will impede the ability to obtain the necessary amount of data for a full, market-based assessment of what discounting is occurring". This concern is unfounded. There are two groups of drugs being brought into price disclosure for this round. The first group are 99 drugs for which there has been a highly competitive generics market since before October 2006. This is clearly a stable market and 10 months versus 8 months will not make any difference. The second group are drugs which had two or more manufacturers before August 2007 but have not had any new manufacturers list new brands since then. These drugs obviously also have a stable market, so shortening the period will not make any difference to them either.

It would create far greater uncertainty to collect data during December and January when the market is likely to be temporarily unstable following the passing of the Bill, and companies may be ill-prepared for the change in processes and workload.

A longer data period is only necessary for drugs that have just opened up to generic competition, in which case the market will take up to 12 months to establish and settle down. No drugs that fit this description will fall into this price disclosure cycle.

The Guild supports the reforms included in the Bill and the MOU. We request your consideration of these simple, savings-neutral changes to the Bill to ensure a smooth transition to the new arrangements and the accuracy and integrity of the data that will be provided to the Department of Health and Ageing.