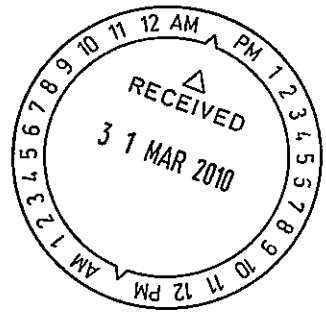
The Pharmacy
Guild of Australia



Ref: POLGOV CCB-SEN

31 March 2010

Inquiry into Consumer Access to Pharmaceutical Benefits
Department of the Senate
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Sir/Madam,

Consumer access to pharmaceutical benefits and the creation of new therapeutic groups through the Pharmaceutical Benefits Scheme (PBS)

Please find attached a submission from The Pharmacy Guild of Australia (the Guild). Thank you for the opportunity to make a submission to the Senate Inquiry into Consumer Access to Pharmaceutical Benefits.

Whilst the Guild accepts that the main purpose of therapeutic groups is to achieve government savings, it is essential that the creation of new therapeutic groups has a sound clinical basis and the Guild would support more information being made public regarding the process and the basis for the formation of new groups.

The Guild also believes that it is essential that there are adequate safeguards for patients through a mechanism for doctors to prescribe medicines in a therapeutic group without the requirement to pay the Therapeutic Group Premium (TGP) when the prescriber believes that a patient is unable to take the base priced medicine.

Yours sincerely

Wendy Phillips

Wendy Phillips
Executive Director

Encl.

National Secretariat
Level 2, 15 National Circuit, Barton, ACT 2600 Australia
PO Box 7036, Canberra Business Centre, ACT 2610 Australia
Telephone: + 61 2 6270 1888 · Facsimile: + 61 2 6270 1800
Email: guild.nat@guild.org.au · Internet: www.guild.org.au

The Pharmacy Guild of Australia

Submission

to

Senate

Community Affairs Committee

in response to the

Inquiry into Consumer Access to Pharmaceutical Benefits

31 March 2010

Contact Officer :
Dr Michael Tatchell
Director Health Economics
The Pharmacy Guild of Australia
National Secretariat
Level 2, 15 National Circuit, Barton, ACT 2600 Australia
PO Box 7036 Canberra Business Centre, ACT 2610 Australia

About The Pharmacy Guild of Australia

The Pharmacy Guild of Australia (the Guild) was established in 1928, and is registered under the federal Workplace Relations Act 1996 as an employers' organisation. The Guild's members are the owners of approximately 4,300 of the 5,050 community pharmacies in Australia. The Guild aims to promote, maintain and support community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of medicines, medicines management and related services.

Summary

Pharmaceutical Benefits Scheme (PBS) therapeutic groups were first introduced in 1997. The Guild regards therapeutic groups as an effective way for the government to achieve value from the PBS without affecting patient outcomes. In combination with the major PBS Reforms that took effect in 2007-08, and are predicted to save $7.4 billion over ten years, the appropriate use of therapeutic groups ensures that the PBS is sustainable for future generations, and allows headroom for the listing of new drugs.

While the main purpose of therapeutic groups is to achieve government savings, it is essential that the creation of new therapeutic groups has a sound clinical basis. The Guild has no reason to believe that this has not been the case for all therapeutic groups that have been created or are currently proposed. However, the Guild would support more information being made public regarding the process and the basis for the formation of new groups.

It is also essential that there are adequate safeguards for patients through a mechanism for doctors to prescribe medicines in a therapeutic group without the requirement to pay the Therapeutic Group Premium (TGP) when the prescriber believes that a patient cannot take the base priced medicine. The Guild believes that the current exemption mechanism is appropriate, and should be applied to all new therapeutic groups. However, to avoid confusion or the application of inappropriate patient contributions, prescribers must be given adequate notice of the creation of new therapeutic groups, and provided with appropriate information regarding the exemption mechanism in each case.

Guild Submission

On 25 November 2009 the Senate referred the matter of Therapeutic Groups and consumer access to pharmaceutical benefits to the Community Affairs Committee for inquiry. The Guild welcomes the opportunity to provide this written submission. This submission addresses in turn the Terms of Reference as published on the Committee website.

Consumer access to pharmaceutical benefits and the creation of new therapeutic groups through the Pharmaceutical Benefits Scheme (PBS), including:

a. the impact of new therapeutic groups on consumer access to existing PBS drugs, vaccines and future drugs, particularly high cost drugs;

With the introduction of a new therapeutic group to the PBS, consumers still have access to the existing PBS medicines. If a sponsor of a drug in a therapeutic group elects not to have a Therapeutic Group Premium applied to the listing of its medicine then the consumer will pay no more for their medicines than the relevant patient co-payment.

Should the sponsor request a Therapeutic Group Premium (TGP) then the consumer must pay this premium unless their prescriber believes they are entitled to an exemption. In this case the prescriber can apply to Medicare Australia for an "Authority Required" prescription allowing the consumer to be exempt from the premium. A current example is lercanidipine which includes a standard "Authority Required" restriction for TGP exemption as follows:

> *Adverse effects occurring with all of the base-priced drugs;*
> *Drug interactions occurring with all of the base-priced drugs;*
> *Drug interactions expected to occur with all of the base-priced drugs;*
> *Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance*

Future drugs and vaccines

The Guild presumes that the policy would be the same for future medicines listed on the PBS. If a new medicine under consideration for PBS-listing delivers the same outcome as an already listed medicine then the Commonwealth should pay no more for this new medicine than the currently listed medicine. This is the basis of the price reference system that ensures the taxpayer pays no more for medicines that produce the same clinical outcome.

High Cost Drugs

Regardless of the cost of a drug the same cost-effectiveness requirements are applied by the Pharmaceutical Benefits Advisory Committee (PBAC) when it considers applications for the listing of new drugs on the PBS. This means that every new medicine recommended by the PBAC has passed stringent cost-effectiveness tests and is therefore considered good value for money.

The patient copayment remains the same regardless of the drug price. The level of the TGP applied is a matter for the manufacturer. Currently, the TGPs for items on the PBS currently vary between $1.52 and $4.66, which for a concessional patient can almost double the cost of a medicine unless an exemption is allowed.

The Guild believes it is important to ensure that high cost drugs are listed on the PBS at a price that both the Government and the community can afford as they can represent a high proportion of the PBS cost. This ensures the sustainability of the PBS so Australians can continue to access cost-effective medicines in the future.

b. the criteria and clinical evidence used to qualify drugs as interchangeable at a patient level;

The Guild notes that the PBAC is the independent statutory body of experts established on 12 May 1954 under section 101 of the National Health Act 1953 to make recommendations and give advice to the Minister about which drugs and medicinal preparations should be made available as pharmaceutical benefits. The Committee is required by the Act to consider the effectiveness and cost of a proposed benefit compared to alternative therapies. In making its recommendations the Committee, on the basis of community usage, recommends maximum quantities and repeats and may also recommend restrictions as to the indications where PBS subsidy is available. When recommending listings, the Committee provides advice to the Pharmaceutical Benefits Pricing Authority (PBPA) regarding comparison with alternatives or their cost effectiveness.

The Guild believes the PBAC is the appropriate expert body to provide the Minister with advice as to which groups of drugs qualify for a therapeutic group. The Guild expects that the clinical evidence used is of similar rigor or in fact the same clinical evidence used to evaluate medicines for registration by the Australian Drug Evaluation Committee (ADEC) of the Therapeutic Goods Administration.

The Guild believes that the criteria used by the PBAC and the clinical evidence evaluated by the Committee in making such recommendations to the Minister should be published on the Department's website to ensure transparency and accountability of the process. This could be done by publishing the complete minutes of all PBAC deliberations on the DoHA website. This would also address any doubts on behalf of prescribers, patients and pharmacists about the therapeutic equivalence of medicines in particular therapeutic groups.

c. the effect of new therapeutic groups on the number and size of patient contributions;

The PBS covers all Australian residents when they have a prescription dispensed for a medicine prescribed under the PBS. From 1 January 2010, a general patient pays up to $33.30 for a medicine listed on the PBS and for patients with a concession card the co-payment is $5.40. These payments are adjusted in line with movements in the Consumer Price Index on 1 January each year.

Within the PBS there are specifically defined groups of drugs which have similar safety and health outcomes. The prices for all medicines in a group are based on the lowest priced drug. If a sponsor of a medicine is unwilling to market the medicine at the lowest price, they may request that patients pay extra for their medicine by the application of a TGP which is paid by the patient and does not count towards the Safety Net threshold.

As there is always at least one medicine within each group of medicines available without a TGP a patient can avoid the premium by asking their prescriber to change their medication to the medicine without the TGP. If, however, the prescriber believes that the patient is unable to take the lowest priced medicine in a group, the prescriber can request an exemption from Medicare Australia as per the example given in (a) above for lercanidpine.

The Guild accepts that with the creation of new therapeutic groups there may be more TGPs for patients to pay. As long as there are mechanisms to ensure that patients are no worse off if they are only able to take a medicine that has a TGP. There should be no impediment to patient access to pharmaceutical benefits that have a TGP.

The Guild points out that patients and prescribers are not always aware of these mechanisms and this may sometimes lead to unnecessary confusion or patients paying the TGP when they may not need to do so.

There is often confusion amongst stakeholders between the TGP and the Brand Price Premium. The PBS subsidises all brands of the same drug up to the cost of the lowest priced brand. When a sponsor is unwilling to market their brand at the lowest price it can apply for a Brand Price Premium that patients must pay if they elect to get that brand. This Brand Price Premium does not count towards the Safety Net threshold and the prescriber cannot apply for an 'Authority Required' prescription to exempt the patient from paying this premium. In the past there have even been brands with both a Therapeutic Group Premium and a Brand Price Premium.

With the advent of more therapeutic groups and therefore the possibility for more TGPs, the opportunities for patient confusion are increased. It would be unfortunate if, as a result, pharmacists are required to spend more time explaining the intricacies of a medicine's price, rather than counselling the patient on the more important clinical aspects of a their medicines regimen.

d. consultation undertaken in the development of new therapeutic groups;

As mentioned in section *(b) regarding the criteria and clinical evidence used to qualify drugs as interchangeable at the patient level*, the Guild believes the process for determining therapeutic groups is far from clear. For example, there appear to be no published guidelines or criteria that the PBAC use when determining the medicines that are to be eligible for creation of a therapeutic group.

The Guild notes that other agenda items considered by the PBAC are provided on the Department's website 6 weeks prior to each meeting. There is no such publication of agenda items relating to the creation of therapeutic groups and therefore this does not allow for stakeholder consultation in their development. Early public notice of PBAC consideration of new therapeutic groups should be introduced as soon as possible.

The Guild also suggests that the unabridged Minutes of all PBAC meetings be published to ensure complete transparency. As previously mentioned, the creation of a therapeutic group and the scientific data and clinical justification of which medicines are included in each should be available to all stakeholders. The ready availability of this information would help to improve confidence in the Government's therapeutic group policy.

The PBS provides reliable, timely and affordable access to a wide range of medicines for all Australians and the Guild believes it is only reasonable to expect complete transparency and accountability in the expenditure funds used to improve the health outcomes for the Australian community.

e. the impact of new therapeutic groups on the classification of medicines in F1 and F2 formularies;

With the introduction of the new formularies (F1 and F2) in 2007, there has been no price referencing between drugs in F1 and drugs in F2.

The creation of a new therapeutic group would only impact on the formulary classification of a medicine if the group contained a mix of drugs from F1 and F2. If this was the case, the F1 drugs would be moved to F2. However, if any drug in the group was subsequently subjected to a price reduction as a result of price disclosure, this drug would be removed from the therapeutic group and the reduction would not flow on to the other drugs in the group.

The Guild believes this is a fair and appropriate system, as the price disclosure policy is driven by market competition, whereas the therapeutic group policy is driven by patient outcomes.

The following extracts from the Pharmaceutical Benefits Pricing Authority's *Policies, Procedures and Methods Used in the Recommendations for Pricing of Pharmaceutical Products 2009* summarise the relationship between the F1 and F2 formularies and Therapeutic Groups.

> "Since 1 August 2007, price links exist between:
>
> a) drugs in F1 where the drugs are in the same Reference Pricing Group or Therapeutic Group;
> b) drugs in F2 that are members of a Therapeutic Group;
> c) drugs listed on the Combination Drugs List and the individually listed component drugs (which may be in F1 or F2)"
>
> "Drugs in a Therapeutic Group are grouped together on the same formulary and their prices remain linked (even if they are in F2) until a reduction arising from price disclosure applies to a brand of a drug in the Therapeutic Group. At this point, the drug affected by the reduction is removed from the Therapeutic Group so that the price reduction does not flow on to the drugs remaining in the Therapeutic Group."

Reference: http://www.nhhrc.org.au/internet/main/publishing.nsf/Content/health-pbs-pbpa-pricing-policiesdoc~attachF-further

f. the delay to price reductions associated with the price disclosure provisions due to take effect on 1 August 2009 and the reasons for the delay;

The Guild is aware that due to problems with the manner in which sponsors were informed of the price changes, some initial price disclosure reductions were delayed.

It is important to the Guild that sponsors are satisfied with the transparency of the price disclosure arrangements. The Guild is aware of some dissatisfaction from sponsors who are unsure how the data they provide are being used, or they have been unable to reconcile the announced price reductions with their expected results. In at least one case, a sponsor has successfully challenged the basis for a price disclosure calculation.

The Guild supports the sponsors in seeking greater transparency and accountability in the expenditure of PBS funds used to improve the health outcomes for the Australian community.

g. the process and timing of consideration by Cabinet of high cost drugs and vaccines; and

The Guild understands that when a medicine or vaccine has been recommended for listing on the PBS by the PBAC, and the estimated net cost of the medicine or vaccine to the PBS is $10 million or more in any of the first four years of listing, Cabinet must consider these listing recommendations.

Whilst the Guild has no objection to the principle that Cabinet consider the listing of high cost medicines with a large impact on the PBS, we note this process may cause delays in the listing of new medicines or vaccines for certain diseases, or groups of patients, for which there are few treatment alternatives.

Any measures that would streamline the Cabinet approval process to ensure the timely availability of necessary medicines to the Australian community would seem reasonable. It may well be that the $10 million limit could to be re-considered given the number of new high cost medicines being recommended for listing by the PBAC.

h. any other related matters.

The Guild would like to take the opportunity to highlight other related matters with respect to consumer access to pharmaceutical benefits.

"a" flagging of interchangeable brands

The Guild is concerned that the Department of Health and Ageing does not appear to have a consistent, transparent and publicly available policy with respect to the brand equivalence marking of pharmaceutical benefits. This lack of policy would appear to have caused difficulties for consumer access to pharmaceutical benefits and the Guild raises the recent lansoprazole listing as an example to illustrate these difficulties.

Lansoprazole, a 'proton pump inhibitor' used for treatment of peptic ulcers, was originally listed on the PBS on 1 August 1994 with a maximum quantity of 28 with 5 repeats. The maximum quantity was changed from 28 to 30 on 1 August 1999.

At the PBAC meeting held in March 2009 the Committee recommended the listing of lansoprazole *oro-dispersible tablet* 30 mg with a maximum quantity of 28 (previously 30) to replace lansoprazole *capsules*. The new formulation of lansoprazole was listed on the PBS on 1 September 2009. It was not 'a' flagged to the capsule formulation ie to indicate that a pharmacist could substitute another brand. This was despite the Media Release of 1 September 2009 from the Minister for Health and Ageing stated the new formulation was *'equivalent to lansoprazole capsules and would replace these when they are removed from the Australian market'*.

An advance notice of the deletion of lansoprazole capsules on 1 November 2009 was only published in the October 2009 Schedule of Pharmaceutical Benefits.

On 10 September 2009 lansoprazole capsules 30 mg were reported to be 'out-of-stock' at all three wholesalers. Pharmacists presented with an original prescription or a repeat authorisation for lansoprazole capsule 30 mg were not able to dispense the new oro-dispersible tablet as they were not 'a' flagged in the Schedule of Pharmaceutical Benefits. This was despite the sponsor's advertising material and the Minister's Media Release claiming the two products were equivalent.

The Department of Health and Ageing's position was that patients who needed to continue lansoprazole therapy had to obtain a new prescription for tablets from their doctor. This was not only an inconvenience to the patient and an imposition on the prescriber's valuable time but an added cost to both the patient and to Medicare.

It would appear, based on correspondence to the Guild from the Department of Health and Ageing, that there is no document which encompasses all aspects of the Department's policy on brand equivalence marking. This would suggest that the Department does not have a policy for equivalence marking which leads to situations such as the lansoprazole debacle described above. The Guild would suggest that a definitive policy document be created involving input from all stakeholders so that situations such as occurred with lansoprazole are not repeated.

It should be noted that a generic brand of lansoprazole capsules has been listed on the PBS from 1 April 2010 with maximum quantity of only 28, whereas other proton pump inhibitors are listed on the PBS with a maximum quantity of 30. If the Department had a policy for equivalence marking, sponsors would not be able to use the excuse of 'pack size' to dictate the 'maximum quantity' in an effort to evergreen products. The Guild suggests that the maximum quantity of PBS items should be dictated by community usage rather than the 'available' pack size.

Brand Price Premiums and stock shortages of base priced brand

The PBS subsidises all brands of the same drug to the same amount; that is, up to the cost of the lowest priced brand. When a sponsor is unwilling to market their brand at the lowest price they will request a Brand Price Premium to be applied to their brand which patients must pay and which does not count towards the patient's Safety Net threshold. There will always be at least one brand without a brand premium.

The Guild has no objection to the Brand Price Premium policy as the patient can always get at least one brand without a Brand Price Premium. However, the Guild is concerned about the repeated shortages of supplies of the base priced brand as the patient is then compelled to pay the Brand Price Premium.

A recent example is where Tricortone®, the based-price brand of triamcinelone cream (a corticosteroid cream for the treatment of dermatoses) was unavailable. The only alternative brand was Aristocort® but it was listed with a Brand Price Premium of $3.48 for the PBS maximum quantity of 2x100g tubes. Although both brands are manufactured by the same sponsor, Tricortone was unavailable for long periods during 2009 due to production problems; therefore patients were compelled to pay the premium of $3.48 to access this medicine.

As this is not an isolated case, the Guild questions whether effective Departmental policies and procedures are in place to deal with situations such as these. At present it can take some time before the Department recognizes that a shortage exists and waives the Brand Price Premium. Until this occurs patients are left with no choice but to pay the Brand Price Premium. This process has to be executed in a more timely fashion to ensure patients continue to have access to the medicines they require without having to pay a premium due to shortages of the base priced brand.