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 80% of the 5,350 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.

Background

The Guild welcomes the opportunity to comment on the Terms of Reference for the *Post-Market Review of Authority Required PBS Listings* and commends the Minister for Health, The Hon Peter Dutton's commitment to reducing unnecessary red tape and paperwork for health professionals when they prescribe and dispense medicines.

The Guild agrees that there needs to be restrictions for some Pharmaceutical Benefit Scheme (PBS) items to ensure that medicines are prescribed in accordance with the recommendations of the Pharmaceutical Benefits Advisory Committee (PBAC). However, to ensure that these restrictions continue to be relevant and necessary, listings should be regularly reviewed to ensure that the restrictions continue to be consistent with the policy intent of the PBS and appropriate to current clinical practice.

The Guild notes that when generic versions of a medicine enter the market there is a mandatory price reduction on the molecule and it is also subject to the Price Disclosure mechanism which may lead to further price reductions. Taking these factors and the product life cycle of medicines into account, any economic basis for the PBAC's recommendation to list a medicine as an Authority Required or an Authority Required (STREAMLINED) may change over time.

The Guild does not believe that the prescriber or the pharmacist should be burdened with unnecessary administrative tasks, with no public benefit, when prescribing or dispensing pharmaceutical benefits. PBS items should not be Authority Required or Authority Required (STREAMLINED) unless there are sound clinical or economic reasons. The Guild agrees that there are important reasons to collect drug utilisation data on PBS items. This has been further enhanced by the Fifth Community Pharmacy Agreement (5CPA) which enabled the electronic collection of under co-payment data. However, the input and collection of administrative data should only occur when necessary. A current example where it is not necessary is the collection of data for Authority Required (STREAMLINED) benefits where there is only one indication. This is an unnecessary administrative burden and not an effective use of the time of prescribers and pharmacists. The Guild believes that it is important that these administrative efficiency issues should be part of the current review.

As noted in the *Schedule of Pharmaceutical Benefits* explanatory notes, items are listed in the following broad categories:

- **Unrestricted benefits** - have no restrictions on their therapeutic uses for the purposes of subsidy
- **Restricted benefits** - can only be prescribed and dispensed for specific therapeutic uses listed in the Schedule
- **Authority Required (STREAMLINED) -** are restricted but do not require prior approval from DHS-Medicare or the DVA and can only be prescribed and dispensed for the indication listed in the Schedule.
    - The prescriber must include the 4 digit STREAMLINED authority code in order to validate the prescription as a pharmaceutical benefit
    - A pharmacist must record the STREAMLINED authority code in order to supply the item as a pharmaceutical benefit
    - The pharmacist must include the Authority Form Serial Number (usually in the top right hand corner of the form) in order to process and claim the item as a pharmaceutical benefit
- **Authority Required -** can only be prescribed with prior approval from DHS-Medicare or the Australian Government Department of Veterans' Affairs (DVA)
    - The prescriber must include the phone or written authority code in order to validate the prescription as a pharmaceutical benefit
    - A pharmacist must ensure that the phone or written authority code has been included in order to supply the item as a pharmaceutical benefit
    - The pharmacist must include the Authority Form Serial Number (usually in the top right hand corner of the form) in order to process and claim the item as a pharmaceutical benefit

The *Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (PBAC) – June 2013 (Version 4.4)*[1] state that a drug or drug form is considered for Restricted Benefit or Authority Required listing for the following reasons:

- to limit PBS usage so that this is in accordance with the approval and registration granted by the Therapeutic Goods Administration (TGA)
- to allow the controlled introduction of a drug in a new therapeutic class
- to limit PBS usage to the indications, conditions or settings seen as being appropriate for clinical, cost-effectiveness, or other reasons
- to alleviate concerns about adverse reactions, possible misuse, overuse or abuse.

As part of the PBS Reforms announced by the Minister for Health and Ageing in November 2006, a new streamlined authority process was instituted from 1 July 2007 for almost half of the medicines then listed as Authority Required. The aim was to reduce the administrative burden for prescribers, providing them with more time to devote to patient care without compromising the integrity of the authority system.

On 1 July 2007 new Streamlined Authority codes were introduced. These codes align with specific indications. There are three steps to be completed when prescribing an Authority Required (STREAMLINED) item:

- the patient must meet the PBS restriction criteria for the item
- the prescription must be written on an authority prescription form

[1] http://www.pbac.pbs.gov.au/content/information/printable-files/pbacg-book.pdf

- the prescription must include the streamlined authority code corresponding to the PBS restriction that the patient meets.

Terms of Reference

The Guild notes the Terms of Reference (ToR) as follows:

1. Review the criteria used by the PBAC to determine if a medicine should be recommended as Authority Required or Authority Required (STREAMLINED) on the PBS.
2. Systematically review the current Authority Required listings according to the proposed criteria to ensure this is applied consistently to all PBS Authority listed medicines.

Comments on TOR

The Guild agrees that the two points contained in the current ToR are appropriate. However the Guild suggests that the ToR should additionally include consideration of the following:

(a) *how often the PBAC is required to review PBS listings.*

The Guild notes in the *Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee (PBAC)* under Box 1.1 Roles of the PBAC it states that the Committee "Regularly reviews the list of PBS items". The Guild is unaware of the last review by the PBAC and notes that it is still yet to receive a response to its submission on Streamlined Authorities to the March 2012 PBAC meeting (attached as Appendix 1). If the listings were regularly reviewed it would ensure they were up-to-date, relevant to current clinical practice and the product life cycle of the medicines.

(b) *criteria used by the PBAC to determine if a medicine should be included in the Section 100 Highly Specialised Drugs (HSD) category or Section 85, noting the complex and duplicative arrangements for Section 100 HSD.*

With HSD items, prescriptions written in a public hospital (HSD Public) are Authority Required (STREAMLINED) items and must be dispensed and claimed from a public hospital. The same medicine can only be prescribed in a private hospital as an Authority Required item. These prescriptions however are able to be dispensed and claimed from either private hospital or community pharmacies. The Guild is aware of access problems for patients requiring HSD Public medicines and suggests that it would be opportune for the Post Market Review to consider the Section 100 HSD criteria at the same time.

(c) *administrative efficiency issues related to Authority Required (STREAMLINED) and Authority Required items.*

Some of these issues include:

- the need for Authority Required (STREAMLINED) items to be written on a special triplicate form. Given that the streamlined code is the number of interest and is collected for statistical purposes it is unnecessary for the Authority Form Serial Number to be collected as it is unknown to DHS-Medicare and serves no purpose.
- Telephone approvals for controlled drugs are limited to one month's therapy. When prescribers wish to prescribe a controlled drug for a period in excess of one month, the prescription must be posted to Medicare and posted back to either the patient or prescriber, taking up to 2 weeks. Patients requiring these prescriptions are often very ill and they and/or their carers should not need to manage this administrative complexity to obtain the medicines they require.

Chemotherapy treatments

As stated in the Post-Market Review of Authority Required PBS Listings "Next Steps" the Committee will also give immediate consideration to the existing variations to authority requirements for oncology treatment in public and private hospitals.

The Guild agrees with the recommendations made in the *Review of Funding Arrangements for Chemotherapy Services* that the need for prior authority approval for medicines listed in the Efficient Funding of Chemotherapy (EFC) when prescribed in a private hospital is unnecessary. The Guild believes that all items in the EFC list should be Authority Required (STREAMLINED) as is the case for most EFC medicines in the public hospital setting.

In addition the Guild supports the initiative in the 2014-15 Commonwealth Budget to enable dispensing and claiming from standardised electronic medication charts in public and private hospitals and notes that this should also be able to be used for the dispensing of chemotherapy medicines by community pharmacies. This paperless claiming model for EFC medicines would be similar to the 5CPA Initiative *"Supply and PBS Claiming from a Medication Chart in RACFs"* where the medication chart acts as the single source of information for prescribing, dispensing and claiming functions.

General Comments

As previously noted, while not objecting to the concept of restrictions for PBS items to ensure that medicines are prescribed in accordance with the PBAC recommendations, the Guild believes the Restricted Benefit category is underutilised and should be the primary means for applying restrictions. This system can be enhanced with robust prescribing

systems and electronic auditing to ensure prescribers are aware of and accept responsibility for prescribing Restricted Benefit items in accordance with their listing.

The Guild proposes the following criteria for PBS restrictions:

A medicine or medicinal form is considered for **Restricted Benefit** for the following reasons:

- To limit PBS usage so that it is used in accordance with the approval and registration granted by the TGA.
- For items previously listed as STREAMLINED where there is only one indication or where usage data is considered unnecessary or not useful.

A medicine or medicinal form is considered for **Authority Required** listing for the following reasons:

- Instances where the prescriber is seeking an increase above the maximum quantity, and/or an increased number of repeats.
- To allow the controlled introduction of a medicine in a new therapeutic class if there is a need to limit PBS usage to those patient groups where it is found to be cost-effective.
- To allow for the listing of medicines where a prior written approval for authority to prescribe is required e.g. S100 HSD Complex Authority Required items.
- To limit PBS usage so that this is in accordance with the approval and registration granted by the TGA e.g. quinine for use in malaria as opposed to nocturnal leg cramps.
- To alleviate concerns about adverse reactions, possible misuse, overuse or abuse e.g. temazepam capsules where there was a risk of injection.

A medicine or medicinal form is considered for **Authority Required (STREAMLINED)** for the following reasons:

- After the controlled introduction of a medicine in a new therapeutic class and/or there is no longer a need to limit PBS usage and there are multiple restrictions for which usage data is considered necessary.
- To allow for treatment in patients groups of a drug in a Therapeutic Group with a Therapeutic Group Premium (TGP) where adverse effects occurring with all of the base-priced drugs, drug interactions occur or are expected to occur with all the base-priced drugs or transfer to a base-priced drug would cause patient confusion resulting in problems with compliance.
- To allow for differential increased maximum quantities or increased repeats for special patient groups (e.g. oxazepam for use in patients who are receiving long-term nursing care on account of age, infirmity ...)

Other considerations

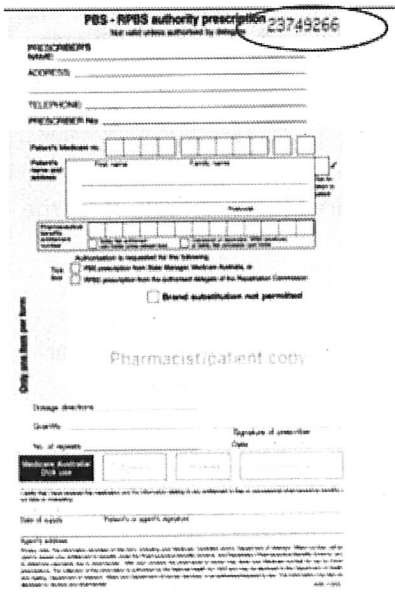
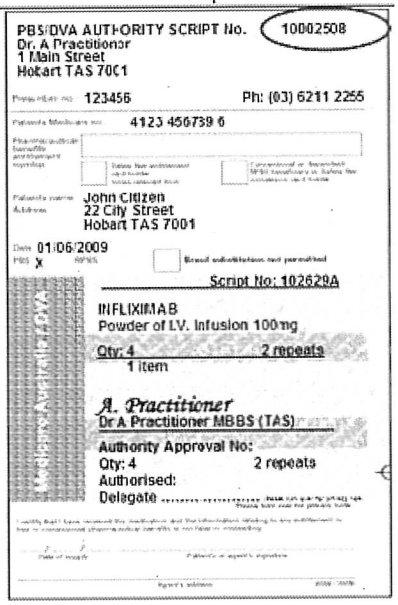
Medication Charts

The Guild notes that legislation changes are being made at Commonwealth and State and Territory level to enable the dispensing of PBS medicines from medication charts. In the case of using medication charts in a residential facility, the National Health Determination[2] allows a Restricted Benefit or Streamlined Authority medicine to be written, dispensed and claimed from a compliant medication chart. However, in the case of Authority Required items, a separate prescription is needed. Utilising the Restricted Benefit and Authority Required (STREAMLINED) categories would simplify prescribing and dispensing in situations where a medication chart is being used for supply and claiming purposes.

Authority Prescription Serial Number

The Guild believes that the PBAC should also consider other matters relating to Authority Required/Streamlined when it is considering the issue at its July 2014 meeting

If items are recommended by the PBAC as needing an Authority Required (STREAMLINED) listing the Guild would question the necessity of recording the Authority Prescription Serial Number i.e. the number in the top right hand corner circled in the example below:

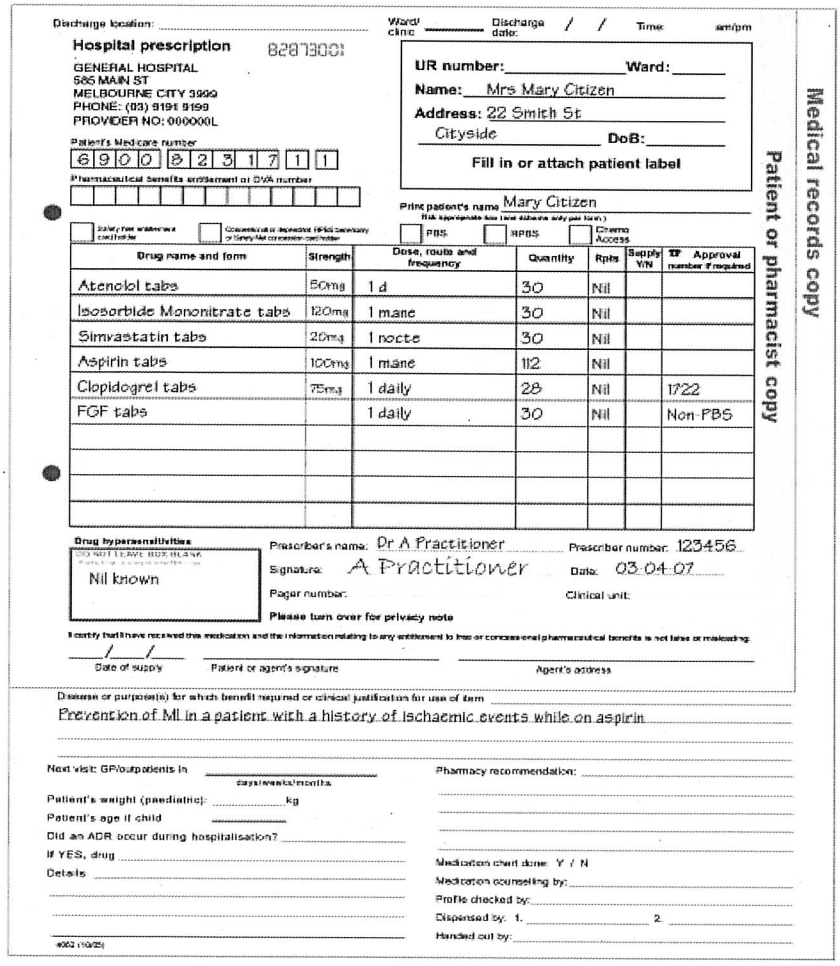
Authority Prescription	Computer Generated Authority Prescription
	

For a regular Authority Required prescription the 8 digit Authority Form Serial Number is quoted to the Medicare operator when the prescriber phones for approval. This number is

[2] National Health (Residential Medication Chart) Determination 2012; http://www.comlaw.gov.au/Details/F2014C00765

then presumably used to track the prescription. However, when a prescriber writes an Authority Required (STREAMLINED) prescription this number is not quoted to the Medicare operator and cannot therefore be used to track the prescription. As this number has no purpose for Authority Required (STREAMLINED) in this situation the Guild believes it is an unnecessary administrative burden to community pharmacists when dispensing the original Authority Required (STREAMLINED) and all subsequent repeats.

Further to the above, the Guild questions the need to use a special Authority Prescription form when a regular prescription form could be used and the STREAMLINED code included next to the prescription. This would save on paper and would only entail a simple software change in prescribing and dispensing software. This is consistent with public hospital prescriptions (see example below) and with the Residential Aged Care Medication Charts initiative where the STREAMLINED code is written on the Residential Medication Chart.



Discharge location: ..... Ward/clinic ..... Discharge date: / / Time: am/pm

Hospital prescription 8287300I

GENERAL HOSPITAL
585 MAIN ST
MELBOURNE CITY 3999
PHONE: (03) 9191 9199
PROVIDER NO: 000000L

Patient's Medicare number: 6900 8231 7 1 1

Pharmaceutical benefits entitlement or DVA number:

UR number: ..... **Ward:** .....
Name: Mrs Mary Citizen
Address: 22 Smith St
Cityside **DoB:** .....
Fill in or attach patient label

Print patient's name: Mary Citizen

Safety net entitlement card holder | Concessional or dependent (PBS beneficiary or Safety Net concession card holder) | PBS | RPBS | Chemo Access

Drug name and form	Strength	Dose, route and frequency	Quantity	Rpts	Supply Y/N	TP Approval number if required
Atenolol tabs	50mg	1 d	30	Nil		
Isosorbide Mononitrate tabs	120mg	1 mane	30	Nil		
Simvastatin tabs	20mg	1 nocte	30	Nil		
Aspirin tabs	100mg	1 mane	112	Nil		
Clopidogrel tabs	75mg	1 daily	28	Nil		1722
FGF tabs		1 daily	30	Nil		Non-PBS

Drug hypersensitivities (DO NOT LEAVE BOX BLANK)
Nil known

Prescriber's name: Dr A Practitioner Prescriber number: 123456
Signature: A Practitioner Date: 03 04 07
Pager number: Clinical unit:

Please turn over for privacy note

I certify that I have received this medication and the information relating to any entitlement to free or concessional pharmaceutical benefits is not false or misleading.

/ / Date of supply ..... Patient or agent's signature ..... Agent's address

Patient or pharmacist copy

Medical records copy

Disease or purpose(s) for which benefit required or clinical justification for use of item:
Prevention of MI in a patient with a history of ischaemic events while on aspirin

Next visit: GP/outpatients in ..... days/weeks/months

Patient's weight (paediatric): ..... kg
Patient's age if child .....
Did an ADR occur during hospitalisation? .....
If YES, drug .....
Details .....

Pharmacy recommendation: .....

Medication chart done: Y / N
Medication counselling by: .....
Profile checked by: .....
Dispensed by: 1. ..... 2. .....
Handed out by: .....

Image from www.medicareaustralia.gov.au