promoting excellence in medicines management

ABN 54 004 553 806

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PBSpostmarket@health.gov.au

Re: Post-market review of Authority Required PBS listings

The Society of Hospital Pharmacists of Australia (SHPA) is the national professional organisation for over 3,000 pharmacists, pharmacists in training, pharmacy technicians and associates working across Australia's health system. SHPA is the only professional pharmacy organisation with a core base of members practising in public and private hospitals and other health service facilities.

SHPA is committed to facilitating the safe and effective use of medicines, which is the core business of pharmacists, especially in hospitals. SHPA supports pharmacists to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved for Australians, as individuals, for the community as a whole and for healthcare facilities within our systems of healthcare.

SHPA welcomes this review of the criteria used by the PBAC to determine when and how access to medicines is managed through an authority system as part of the PBS.

The current plethora of funding mechanisms and rules for medicines cause confusion, increase the risk of medication error and diverts prescribers and pharmacists away from direct patient care.

The administrative burden for pharmacists is onerous, particularly hospital pharmacists, and the number of funding mechanisms and categories has continued to expand in recent decades.

Further problems have been created when new government policy is developed that entrench and promulgate the old problems. Layer upon layer of waste-causing activities have compounded and accumulated until a high proportion of what is done to provide medicines is non-value adding.

In addition, there has been a failure to take advantage of new technologies that could be used to streamline most processes, improve information sharing between health care professionals and the data available to the Department and the PBAC through the DUSC.

In compiling this submission SHPA began with the following assumptions:

- **that medicines should only be restricted through an authority system where there is a significant risk of diversion to an unapproved indication, or where there are inherent risks to the consumer – cost alone is not a sufficient reason for restricting access to a medicine through the PBS**
- that the administrative burden for both prescribers and pharmacists should be minimised
- that there was no obligation to retain any feature of the current range of authority categories and approval processes
- that the system should be supported by automated and electronic / web-based tools as much as possible and that paper-based and verbal approval processes should be used only when no automated alternative was feasible

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- that the new system should be 'future proof'; that is it would be able to be applied to new medicines, including personalised medicines, and be equally applicable to all prescribers including non-medical prescribers
- that the new system could encompass the approval process for medicines that would currently be listed in Section 100 highly specialised drugs which in practice may remove the need for this separate category
- that a 'learning' system is developed with inbuilt review periods. In particular the impact of accelerated price disclosure should anticipated; where price is the primary reason for restricting access to a medicines the restriction should be automatically removed when the price falls below a pre-determined threshold
- the remuneration for pharmacists related to the supply of the medicine would be separate and that the structure for remuneration is not necessarily linked to authority categories

SHPA has assumed the following processes and additional reforms:

- that there would be one 'authority system' but that medicines may be listed within this system for numerous reasons
- that quality use of medicines principles are paramount and should be the major determinants for restricting access to medicines through the PBS
- a move from paper-based and verbal approval systems to electronic and automated approval and claiming systems which would enable prescribers to seek and confirm approval prior to prescribing the medicine
- electronic algorithms accessed through a web-based system would be used to confirm eligibility (including general eligibility for services through the PBS) and enable prospective data collection such as indication and specific consumer information (e.g. specified scans or test results) at the time of prescribing and when the medicine is supplied.

  This would: streamline all processes for prescribers, pharmacists and the Department, reduce the cost of managing the approval process, ensure that pharmacists can confirm the consumer's eligibility prior to supplying the medicine and support prospective and post-market reviews ultilisation and benefits / risk reviews
- that the electronic approval system will record the approval of prescriber's to prescribe specific medicines and record all approvals for specific consumers through a consumer specific approval number. Both pharmacists and prescribers would need to be able to access approval information
- that where appropriate, the approval system will support collaborative prescribing models; for example the current system enables medicines to be commenced by a medical specialist in a hospital setting and ordered on discharge from the hospital by the resident medical officer
- that the revised system will ensure medicines are prescribed according to any restrictions rather than relying on pharmacists to enforce restrictions in order to receive payment i.e. prescriptions should only be written when approval is confirmed and that approval information included in the prescription and is therefore available to the pharmacist supplying the medicine
- that there is a robust prospective audit system
- that when the PBAC identifies the need to restrict access to a medicine that the period for review of the listing is identified as part of that decision and where appropriate the PBAC identifies a predetermined period for post-market review of stated anticipated utilisation, benefits and risks
- that restrictions are applied consistently to all dose forms, strengths, pack sizes and brands of the same medicine and biosimilar products

- that the pack sizes and number of repeats available should reflect the conditions placed on access to the medicine. For example, if the medicine is restricted to approved prescribers and the outcome of treatment should be assessed after 4 months, then the pack size and number of repeats should enable the consumer to access 4 months supply of the medicine using the prescription from the approved prescriber
- that the proposed system will be equally applicable to new medicines and new medicine categories
- that the Life Saving Drugs Programme would continue to support access to medicines used to treat very rare life-threatening conditions

In principle, SHPA believes that the PBAC should consider restricting access to medicines with only the following attributes and proposes a mechanism for managing the access to these medicines.

Attributes	**Potential means of restricting access**
Medicines that have an inherent high-risk if used inappropriately These medicines may require specific expertise to prescribe or monitor (e.g. intravenous chemotherapy medicines, clozapine)	Prescriber is 'approved' based on credentialing information embedded into their prescriber number or, if this is impractical, prescriber seeks approval to prescribe each of these medicines to their patient cohort. If required, prescriber provides proof of monitoring / clinical parameters to enable further supply.
Medicines that have specific anticipated outcomes that should be measured and considered prior to treatment being continued These medicines may be started by approved prescribers but should only be continued after review of outcomes (cholinesterase inhibitors to treat the symptoms of Alzheimer's disease)	Prescriber seeks initial approval to prescribe this medicine for an individual consumer AND provides proof of outcome to seek approval for further supply
There are specific public health issues (e.g. pandemic management) or specific quality use of medicine issues (e.g. antimicrobial stewardship) that require that the use of the medicine should be controlled / monitored across the whole population (e.g. some antibiotics or antivirals)	Prescriber is 'approved' based on credentialing information embedded into their prescriber number or, if this is impractical, prescriber seeks approval to prescribe this medicine based on electronic algorithm
Medicines that are targeted to specific patient cohorts based on pharamacogenomics or are personalised for an individual consumer based on pharamacogenomics or pharmacometrics	Prescriber is 'approved' based on credentialing information embedded into their prescriber number or, if this is impractical, prescriber seeks approval to prescribe each of these medicines to their patient cohort AND prescriber seeks approval to prescribe this medicine based on electronic algorithm
New medicines that may present a risk to individual consumers or groups of consumers if not used appropriately It may be deemed prudent to restrict access for a predetermined period to enable post-market review of stated anticipated benefits and risks.	Prescriber is 'approved' based on credentialing information embedded into their prescriber number or, if this is impractical, prescriber seeks approval to prescribe each of these medicines to their patient cohort

SHPA believes that this approach would 'future proof' the system for the coming decade, enable a consistent approach between medicines listed under Section 85 and Section 100, and address the following problems with the current system that has evolved over the last 70 years:

- a complicated and confusing system of eight separate categories with differing systems for approval which results in considerable red tape and makes meaningful post-market and utilisation reviews difficult
- differing authority indications / numbers for the same medicines which cause confusion and lead to treatment delays
- lack of consistency between multiple authority categories and the highly specialised drug programme
- a mismatch between the pack sizes and number of repeats with dosage required for specific diseases / conditions
- lack of transparent and consistent approval process across and within authority categories
- the perception that categorising a medicine with an authority listing is based on cost alone
- inability to link approval information with a consumer's shared health record
- that consumers cannot always access the quantity of medicines that they require for the management of chronic conditions and disease
- the need for a review process based on quality use of medicines principles similar to the drug utilisation evaluation systems used in the hospital sector
- the mismatch between the information available in 'real time' to prescribers and pharmacists and between clinicians based in the community and hospital sectors
- pharmacists acting as gatekeepers and pharmacies bearing the financial risk of supplying authority medicines
- limited range of data being available to the DUSC

Please contact myself or Karen O'Leary (shpa@shpa.org.au) if you require any further information about how SHPA may assist with review PBS authority system.

Yours sincerely,

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(BPharm,DipHospPharmAdmin,GDipQIHCare,FSHP,AICD)