The Pharmacy Guild of Australia

POSITION STATEMENT

Medicines Access Programs

Position

The Pharmacy Guild of Australia (Guild) strongly supports the rights of patients to have any prescription dispensed from their community pharmacy of choice. The Guild also acknowledges innovation within Australian pharmacy practice in response to evolving technology, medicines and health policy. The Guild welcomes such innovation, however is strongly opposed to the implementation of business practices that direct patients away from their regular, local community pharmacy, including prescription channelling.

Timely access to medicines that are affordable to individuals and the community is one of the four pillars of the National Medicines Policy, and the Guild believes that to appropriately deliver against this pillar, patients should have timely access to any pharmaceutical benefit when required from their approved[1] community pharmacy of choice. This is of particular importance as electronic prescriptions, telehealth prescribing and online and digital platforms for medicine ordering and prescription management evolve.

Specialised Pharmaceutical Benefits

The Pharmaceutical Benefits Scheme (PBS) provides Australians with affordable access to essential medicines subsidised by the Australian Government. In addition to the General Schedule which covers the majority of the PBS supplied primarily through community pharmacies, there are a range of Section 100 programs[2] subsidised under *Section 100 of the National Health Act 1953* which covers more specialised medicines. In particular, the Highly Specialised Drugs (HSD) program lists specialised PBS medicines for the treatment of chronic conditions which are restricted to being prescribed in public and private hospitals with appropriate specialist facilities. Of the three HSD program categories (Public, Private and Community Access), Public category HSD prescriptions cannot be dispensed from a community pharmacy. The unfortunate consequence of this is that public hospital patients have poorer access to their HSD medicines. This is of particular concern to patients in rural and remote areas who are treated in a public hospital but for convenience prefer to have their medicines dispensed in a community pharmacy closer to home. It is also a concern for patients with limited mobility who cannot easily travel to a public hospital to access their medicines. Health care and pharmacy practice has evolved since this program was set up. While treatments may still be initiated in hospitals or specialist clinics, PBS laws and program rules should enable patients to always have the ability to use their preferred community pharmacy to access any HSD prescription.

Prescription Supply

The Guild's position on Prescription Supply is as follows:

- The following conditions must apply to all entities with authorisation to supply pharmaceutical benefits and the Department of Health and Aged Care (DoHAC) must be vigilant in investigating potential breaches and applying strict sanctions:
  - claims for dispensing Pharmaceutical Benefits must continue to be on the condition that the medicine has been stocked, dispensed and supplied from the claiming community pharmacy, or other authorised entity[3]

- prescribers should not have stock of medicines for use in their clinic that is 'replenished' by a community pharmacy dispensing a pharmaceutical benefit after use

- Medicine companies or other entities should not be able to enter exclusive dispensing arrangements with select pharmacies or pharmacy groups.
- Business models that encompass innovation and expansion into the supply of specialised pharmaceutical benefits from community pharmacies and are not based on exclusive dispensing arrangements should be supported and encouraged.
- Education and business support should be available for all pharmacists to ensure familiarity regarding supply and remuneration arrangements for specialised pharmaceutical benefits.
- Prescription channelling from prescribers, clinic staff or hospitals should be prohibited. While clinicians may advise patients of available services from individual pharmacies, patients should not be actively encouraged or otherwise coerced by clinical staff to transfer their pharmacy business to any individual pharmacy.
- Patient choice of any health care provider should be a fundamental principle enshrined in policy and law and where appropriate, enforced and monitored by the DoHAC, the Australian Competition & Consumer Commission (ACCC) and other relevant regulatory bodies.
- Prescriptions, medication charts and electronic prescription tokens are a means of communication between a prescriber and pharmacist and should not be used as a means to promote or divert patients to particular providers.
- Hardcopy and electronic prescriptions (including electronic prescription tokens and medication charts), should not be altered in any way, including to promote or divert patients to particular providers.
- With any digital health innovation or advancement, appropriate consideration should be given to any possible implications that may impact the patient's right to have their medicine prescribed or dispensed from their prescriber or community pharmacy of choice respectively.
- Community pharmacy must be appropriately remunerated for provision of pharmacy services associated with the dispensing and supply of medicines. This includes covering the requisite administrative and business costs with medicine supply (e.g. ordering, storage, claiming, insurance) as well as the clinical costs to ensure the safe and optimal use of a medicine by a patient.

Selective Prescription Supply

The Guild recognises that special arrangements may be required in some circumstances for some very low volume specialised pharmaceutical benefits to meet patient and prescriber needs but believes these should be the exception.

Importantly, pharmacists setting up selective dispensing arrangements for specialised medicines, should be aware of potential compliance issues and ensure all processes such as clinic imprest or supply arrangements are compliant with all relevant Commonwealth and state or territory legislation. Selective dispensing arrangements, and particularly those involving indirect (i.e. non face-to-face) supply to patients, must ensure appropriate clinical governance controls are in place and the dispensing and medicine supply processes comply with relevant practice and quality standards and are consistent with contemporary professional guidelines.

Medicines Access Programs (MAP)

The Guild supports early access to life saving medicines for all Australians and believes that this should be provided in accordance with all relevant policies, procedures, and codes of conduct outlined by regulatory bodies such as the DoHAC and the Therapeutic Goods Administration (TGA).

Noting the PBS is the means of providing affordable access to life saving medicines in primary care, medicine companies sometimes implement an early access program while applying for PBS listing. The

Guild recognises that availability of these early access programs such as MAP provide a mechanism for patients with a clinical need to access medicines that might otherwise be out of their financial reach because the medicines are not yet listed on the PBS. In these circumstances, the Guild believes that the principles of patient-directed care and patient choice in preferred pharmacy must be embedded in the program, and holds the following positions:

Patient and prescriber involvement

- The prescriber should only prescribe those medicines for which there is an approved clinical indication.
- If an application for PBS listing has been made then the medicine should only be prescribed as part of the MAP, consistent with the requested PBS restriction.
- Patients should only be commenced if there is a guarantee by the sponsor that supply of medicine will continue until it is subsidised by the PBS or arrangements are in place for managing patients if the PBS application is unsuccessful. The patient should not be put at risk if the program is ceased or PBS-listing does not eventuate. This is consistent with Council of Australian Therapeutic Advisory Groups guidelines.[4]
- Patients and carers should be provided with all the necessary and relevant information about the medicine and the program, including costs, and provide informed consent for preferred pharmacy for dispensing.
- Once the item is successfully listed on the PBS, patients must have the option to return to their regular pharmacy for ongoing PBS dispensing.

Community pharmacy involvement in MAP

- Any community pharmacy should have the option of participating in a MAP.
- Pharmacies should have all the program details to assist in deciding whether to participate and should also have the right to decline involvement if providing the service is administratively burdensome and/or comes at a financial loss.
- Pharmacies should be provided with all the necessary information about the medicine so that they can provide appropriate counselling to the patient and assist in pharmacovigilance, and monitoring any side effects or interactions.
- Where a community pharmacy is involved in a MAP it should store, manage, dispense and maintain records for these medicines as they would any other medicines.
- Community pharmacies should be appropriately remunerated for the work involved, whether by the company or as a patient co-payment. Patient co-payments should be equivalent to that of the PBS as a minimum, noting that there may be exceptions where a larger co-payment is agreed.
- Where select pharmacies are involved in a MAP for specialised medicines, the pharmacy must comply with all relevant laws and standards and be consistent with professional and clinical guidelines for dispensing and supply. These select pharmacies must also ensure patients have the option to return to their regular pharmacy for PBS dispensing once the product is successfully listed on the PBS.
- An agreement should be formed between the sponsor and the Guild for community pharmacy involvement in MAP to determine community pharmacy supply and remuneration arrangements and a standardised process for monitoring pharmacovigilance and recording.

Background

Section 100 Highly Specialised Drugs

The categories and rules for HSD program are complex and continue to expand, diverting doctors and pharmacists' time away from direct patient care, causing confusion and increasing the risk of error. The rules vary according to where the patient is treated (community, hospital outpatient, same-day hospital patient, hospital in the home, overnight patient), if they are being treated for an acute or chronic condition, what type of facility is providing the treatment (hospital, sub-acute or non-acute facility, Aboriginal Health

Service), the ownership of the facility (private hospital, public hospital, private practice clinic) and the type of pharmacy dispensing the medicine (public hospital pharmacy, private hospital pharmacy, community pharmacy).

Prescription Channelling

Although prescription channelling is in itself not an illegal practice, under section 47 of the *Competition and Consumer Act*[5] exclusive dealing is against the law if it substantially lessens competition. Exclusive dealing is defined by the ACCC as "one person trading with another imposing puts conditions on the other's freedom to choose what it buys or sells, who it does business with, or where it trades."[6]

Patients will continue to be able to choose their preferred prescriber and community pharmacy with electronic prescriptions.[7]

Supply only from approved premises

The *National Health (Pharmaceutical Benefits)(Conditions of approval for approved pharmacists) Determination 2017*[8] requires approved pharmacists to only claim from the Commonwealth for supply of a pharmaceutical benefit for a product that was supplied at or from the approved premises and that a claim should never be made if the pharmaceutical benefit was never at the approved premises.

Medicines Access Programs

MAPs can go by a number of different names such as compassionate use, expanded access, product familiarisation, cost-share, early access programs but all have the same principle that patients can get access to a medicine that is subsidised by the sponsor when there is no suitable equivalent or tolerated therapeutic alternative available for the patient.

These programs provide patients with access to medicines that may not yet be registered in Australia or may be registered with the TGA but not yet subsidised under the PBS. MAPs allow patients to access the medicine before registration or subsidy and differ from the Special Access Scheme (SAS).

Related Policies

- *In-person Supply of Medicines*
- *Digital Health*
- *Patient Health Care*

Authority

Endorsed

National Council – December 2023

Reviewed

Practice, Policy and Regulation sub-committee – July 2023

References

[1] A Community Pharmacy that is owned by a pharmacist approved under Section 90 of the *National Healthy Act 1953*
[2] Pharmaceutical Benefits Scheme (PBS) | Section 100
[3] A medical practitioner or a hospital authority authorised under Sections 92 and 94 respectively of the *National Health Act 1953*
[4] Managing Medicines Access Programs - Council of Australian Therapeutic Advisory Groups (CATAG)
[5] https://www.accc.gov.au/business/anti-competitive-behaviour/exclusive-dealing

[6] Australian Competition & Consumer Commission, *Exclusive Dealing*, https://www.accc.gov.au/business/anti-competitive-behaviour/exclusive-dealing

[7] Electronic prescriptions for dispensers (digitalhealth.gov.au)

[8] https://www.legislation.gov.au/Series/F2017L01297