



## POSITION STATEMENT

### Supply and Storage of Medicines

#### Position

The Pharmacy Guild of Australia supports *The National Medicines Policy* and *The National Strategy for Quality Use of Medicines* (QUM). Consistent with these, the Guild maintains that the supply and storage of medicines from and in a community pharmacy should be in accordance with the Quality Care Community Pharmacy Standard,<sup>i</sup> relevant professional practice standards<sup>ii</sup> and Pharmacy Board of Australia guidelines<sup>iii</sup>.

The Guild supports a consistent, national approach in regulating the supply and storage of scheduled medicines and promotes the supply and storage of medicines according to relevant state, territory and Commonwealth legislation.

#### Storage of Medicines

The Guild maintains that pharmacy is the appropriate location for people to access medicines to ensure the safe and optimal use of the medicine with access to professional advice from a pharmacist when required. Community pharmacies are set up to manage the safety and quality aspects for the supply and storage of all scheduled medicines, and particularly for temperature-sensitive medicines, including cold-chain products such as vaccines. Community pharmacy staff are trained to meet the legal requirements of ordering, receiving and storing medicines in line with national quality and professional practice standards and patient expectations. Pharmacists have a responsibility to consider the ambient temperature within the pharmacy and any other storage location, particularly after-hours, and make necessary arrangements to ensure the storage of all medicines, including temperature sensitive medicines, is within the recommended temperature range.

Patients should have access to information about the safe and appropriate storage of their medicines by clear label instructions on the pack and by receiving any specific advice as part of the professional counselling and advice from pharmacists and pharmacy staff as well as written options where practicable (e.g. via pack labelling, ancillary labels or CMI).

Pharmacists have a responsibility to ensure patients are informed on how to manage the storage and transport of temperature sensitive medicines after dispensing. Foil bags or eskies should be used as appropriate depending on the stability of the product and the time before the patient expects to return home for the optimal storage of their medicine.

Patients should be informed on how to manage the storage and transport of temperature sensitive injectable medicines being administered outside of the pharmacy (e.g. at a general practice clinic).

Patients should be aware that another clinic may refuse to dispense a temperature sensitive medicine if concerned that the medicine has not been stored under controlled conditions, such as at the patient's home or in a hot car for an extended time. If the medicine cannot be administered at the pharmacy, patients should have the option to collect a temperature sensitive injectable immediately before use or

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deliver it directly to the clinic. Consideration should be given also to the proximity of the clinic as to how the patient is best to transport the cold-chain injectable. Pharmacists may also offer a delivery service to the clinic, noting that discretionary fees may also apply. The Guild believes the best solution for the benefit of the patient is for pharmacists to be enabled through regulation and remuneration to administer a prescribed injectable at the pharmacy at the time of dispensing. This would require communication from the prescriber if the time for administration is not immediate.

### **Supply of Medicines**

Community pharmacy's strength is vested in the professional support associated with the supply of medicines consistent with QUM principles. Access by the patient to either the pharmacist, or other trained pharmacy staff, in order to support the proper, optimal, safe and effective use of the product, is paramount.

Pharmacy staff must be accessible and approachable to assist in offering patients advice to promote the safe and appropriate use of all medicines supplied through pharmacies. The Guild supports Quality Care Community Pharmacy Standard requirements for a Professional Services Area to facilitate consistent application of professional standards and supply protocols in the supply of medicines.

The Guild supports the use of professional supply protocols within a quality assured framework to assist pharmacists and pharmacy assistants with the supply of medicines in line with QUM principles, with referral to other health professionals as appropriate.

### **Pharmacy Depots**

The Guild recognises that patients in remote and some rural areas do not have the same level of access to health care as in metropolitan areas. The Guild supports the operation of pharmacy depots in rural and remote areas where an approved community pharmacy<sup>iv</sup> is unavailable or access is limited. The operation of a pharmacy depot must be consistent with Commonwealth and state and territory legislation and processes must be in place to optimise patient safety by ensuring patients have access to counselling and advice from a pharmacist.

### **Telepharmacy and Distant Supply**

While the Guild recognises that telepharmacy arrangements involving video or phone consultations can be of value for remote patients with access issues, the Guild believes such arrangements should not be regarded as a routine substitute for direct face-to-face services. The standard of care provided in telepharmacy consultations may be limited by the lack of direct interaction between the pharmacist and the patient. Distant supply arrangements without direct face-to-face contact with a pharmacist does not diminish the professional obligations associated with the dispensing and/or supply of medicines. If anything, the Guild believes pharmacists should have strict clinical governance and quality controls and follow more stringent procedures to ensure quality use of medicines and optimise patient safety and health outcomes. Noting the Medical Board of Australia has developed *Guidelines for telehealth consultations with patients*<sup>v</sup> the Guild believes that the increasing incidence of telehealth clinics requires the Australian Health Practitioner Regulation Agency (Ahpra) to develop equivalent guidance applicable to all health practitioners.

The Guild believes that the PBS is underpinned by patient choice in how they access and receive their healthcare. With the rise in digital health solutions, it is critical that patients retain the ability to choose where they have their PBS medicines dispensed. Channelling of prescriptions to particular pharmacies removes patient choice and prevents patients from accessing their preferred pharmacy. It is the position of the Guild that instances of prescription channelling should be investigated as a priority and strict sanctions should be applied if patient choice has been violated.

The Guild holds concerns around the vertical integrated operational model between medicinal cannabis clinics and their associated pharmacies. It is the Guild's position that medical, nursing and pharmacy clinicians should always retain professional autonomy for the holistic management of their patients. The Guild does not support any ownership model whereby the commercial interests of the corporate entity has influence over the administration and clinical operation of either or both the medical clinic and the affiliated pharmacy.

### ***Licence Holder System***

The Guild supports a Poisons Licence Holder system for the supply of Schedule 2 (Pharmacy Only Medicine) in the following circumstances:

- licences are limited to outlets which are located further than a legislated limit from the nearest pharmacy
- a reduced list of Pharmacy Only Medicines is available, determined in consultation with relevant jurisdictional health professional organisations
- such licences only being granted for outlets based in a community setting, and not for large detached grocery outlets on major highways
- the licence is rescinded should a pharmacy open within the legislated limit of the outlet.

### ***Distribution and Delivery of Pharmaceutical Benefits***

The Guild believes that the best channel for distribution of all pharmaceutical benefits listed on the Pharmaceutical Benefits Scheme (PBS) and the Repatriation Pharmaceutical Benefits Scheme (RPBS) is through full line CSO (Community Service Obligation) compliant distributors (CSO Wholesalers) that the whole community pharmacy network can readily access. Where medicine companies believe they can provide a more effective and efficient service through direct supply, in the interests of patient care this should be in addition to supply through CSO Wholesalers.

The Guild also believes that the distribution and delivery of pharmaceutical benefits should be supported by service and delivery standards predicated on the right of all Australians to readily access any pharmaceutical benefit (in accordance with relevant eligibility restrictions) and to commence treatment as soon as possible. These standards must reflect the criticality for access to their medicine by patient groups such as those with an urgent need to commence a new treatment or maintain treatment continuity such as when travelling.

It should be a condition of listing on the PBS or RPBS that in addition to meeting the requirements of the current Australian code of good wholesaling practice for medicines<sup>vi</sup> and relevant federal, state and territory laws, the distribution and delivery of a pharmaceutical benefit must be compliant with standards that enforce the following service and delivery requirements:

- **Guaranteed Delivery Time** – Delivery of medicines within one working day, noting that for some remote locations this is not always possible and that reasonable efforts are made to ensure delivery is made within a timeframe not exceeding three working days
- **Order Quantities** – No minimum order quantities with pharmacies able to order single items if needed to meet a patient's prescription needs
- **Urgent supplies** – A system in place to ensure community pharmacies have urgent access to medicines in cases of emergency
- **Expiry Dates** – no short-dated stock (less than 3 months expiry) should be supplied to a pharmacy without the pharmacy's confirmation that this is acceptable.
- **Price Change Policies** – Arrangements should be in place for community pharmacies to access PBS medicines subject to a price reduction at the reduced price prior to implementation to guarantee continuity of treatment for patients. The Guild believes pharmacists should be able to purchase PBS medicines at the reduced price at least a week ahead of the scheduled change as a minimum.
- **Additional fees** – Prohibiting distributors from imposing any additional fees such as an administrative surcharge or delivery fee, unless these fees are able to be passed on to the patient at the discretion of the pharmacist

- **Independent Oversight** – An independent authority must be responsible for managing and enforcing compliance with these standards
- **Removal of delivery containers** – Prompt collection and removal of delivery containers (including those used for cold chain delivery) so pharmacies can maintain a hazard free working area
- **Guaranteed Price** – In addition to meeting all of the above requirements, there must be a guarantee that the delivery of any pharmaceutical benefit to the community pharmacy is at no more than the approved Price to Pharmacists<sup>vii</sup>

In order to achieve these service and delivery standards, there must be appropriate remuneration for the distribution of pharmaceutical benefits which also recognises the additional administrative, handling and security arrangements associated with the distribution of medicines such as those requiring cold chain management, cytotoxic medicines, Controlled Drugs and other medicines subject to diversion as well as high-cost medicines. The Guild believes the CSO Funding Pool arrangements is a cost-effective and efficient means of ensuring compliance with service and delivery standards for the distribution of pharmaceutical benefits.

The Guild supports the CSO funding pool being limited to full line distributors, but for this to be effective, arrangements should be in place to enable full line distributors to distribute the whole range of pharmaceutical benefits, including those on the General Schedule as well as Section 100 medicines. Remuneration for dispensing Section 100 medicines should match that of the General Schedule to minimise the financial barriers for pharmacies ordering and stocking Section 100 medicines.

The Guild also supports improving ordering efficiency within community pharmacy so that the distribution of PBS medicines is efficient and cost-effective, however this should be achieved through incentivising efficient pharmacy ordering practices (e.g. via trading terms), rather than permitting the application of penalty surcharges such as delivery fees for multiple orders, as the latter is a disincentive for pharmacists to meet urgent patient needs.

#### ***Exclusive Direct-Supply***

The Guild believes exclusive direct supply arrangements in which pharmaceutical benefits are supplied directly to community pharmacy by only one distributor undermine the principle of the National Medicines Policy and puts the profits of medicine companies ahead of patient-centric healthcare. Companies that engage in exclusive direct supply are not held to the service and delivery standards implemented through the CSO and there is no oversight by an independent industry authority. Such arrangements also undermine the PBS remuneration system which allocates a wholesale mark-up for pharmaceutical benefits listed on the General Schedule.

Under no circumstances should direct to patient supply occur. It is critical that patients have direct contact with their pharmacy and GP to ensure QUM and safe use of medicines, which is completely undermined by direct to patient supply.

#### **Supply Disruptions of Prescription Medicines**

Hindering or delaying a person's access to their medicine can affect the continuity of their treatment and result in negative health outcomes. The Guild supports measures that minimise the risk of disrupting the availability and supply of prescription medicines and does not negatively impact the cost of a pharmaceutical benefit for patients. As a general principle, the Guild believes:

- Arrangements that support the local manufacture of prescription medicines should be encouraged and prioritised by all levels of government
- Pharmacists should be enabled by legislation, policy and programs to substitute therapeutically equivalent alternatives consistent with contemporary therapeutic protocols and guides to manage a supply disruption

- PBS Brand premiums must be promptly removed when supply of base-priced brands of pharmaceutical benefits is disrupted

The Guild also believes it is incumbent on the Government to thoroughly assess any policy changes that could affect the availability and supply of PBS medicines in consultation with the PBS supply chain, including the Guild as the representative body for community pharmacy.

### ***Emergency Restrictions***

It is critical for the Government to work with medicine companies, wholesalers and the Guild to implement emergency restrictions when needed to manage significant supply disruptions, such as experienced with prescription and over-the-counter medicines during the SARS-CoV-2 pandemic in 2020<sup>viii</sup>. Such arrangements require exemptions to CSO requirements for PBS medicines and must ensure equity in access by pharmacies and pharmacy groups, and particularly recognise the needs of rural and remote communities with fewer health care services available.

### **Transfer of Medicines**

State and Territory legislation must allow the exchange of stock between pharmacies or between a pharmacy and a hospital to assist with urgent patient care if a particular medicine is unavailable in a pharmacy. Pharmacies must also be allowed to transfer stock with short expiry to a dispensary that can use the product to minimise wastage and financial loss. Such transfers should not be regarded as wholesaling and pharmacists with their expert knowledge can be expected to ensure the proper storage and safety requirements are met as part of the transfer arrangements.

### **Return of Expired and Unwanted Medicines**

The Guild recognises that the accumulation of expired and unwanted medicines in households poses a safety risk for household members, particularly those at risk of accidental poisoning. The Guild also recognises that the disposal of expired and unwanted medicines as part of a household's domestic waste poses a safety and environmental risk for the community. The Guild therefore supports the Return of Unwanted Medicines (RUM) Project<sup>ix</sup> for households to return expired and unwanted medicines to their local community pharmacy for safe collection and disposal. This does not include the collection and disposal of vaping device, which are not medicines and pose additional safety concerns associated with disposal of lithium-ion batteries, such as fires and burns due to exploding devices.

While community pharmacies provide this as a 'free community service', the service comes at a cost to the pharmacy. Managing a medicine disposal service for expired and unwanted medicines still requires administrative functions by pharmacy staff as well as an allocation of space for the safe storage and collection of disposal bins. Arrangements must continue to ensure the supply and collection of bins does not occur as either a financial or administrative impost for participating pharmacies.

The Guild supports the implementation of a national program for the safe and environmentally-responsible disposal of expired or unwanted dangerous medicines and medicine-related products, such as cytotoxic medicines, needles and other sharps which are excluded from the RUM Project.

The Guild believes that the disposal of expired and unwanted medicines and medicine-related products is part of the stewardship responsibility of medicine companies/sponsors. The Guild believes this responsibility should be addressed as part of the listing negotiations between the government and companies for pharmaceutical benefits to support the costs of collection and disposal projects such as RUM.

Except in situations where a medicine is faulty or subject to a recall, the public should be aware that medicines cannot be returned to a pharmacy for refund as pharmacists generally cannot guarantee the conditions of storage once the medicine has left the pharmacy premises. The Guild encourages all

community pharmacies to have a store policy on public display regarding the return of medicines, refunds and indicating where medicines not returned to saleable stock are quarantined for safe disposal.

## Medicine Recalls

The Guild acknowledges that an effective and efficient medicine recall process aligns with the National Medicine Policy,<sup>x</sup> with medicines needing to meet appropriate standards of quality, safety and efficacy and therefore supports the timely removal of recalled medicines and the role of community pharmacy in this process. The role for community pharmacy in medicine recalls should be clearly defined in policies, standards and procedures covering the pharmacy sector. The Guild encourages the development of standards for medicine recalls that reflect a defined role for pharmacies and provide a series of actions at the community pharmacy level that are predictable and able to be monitored. A uniform process to be followed for medicine recalls would maximise efficiency and ensure recall-related tasks were commensurate with any remuneration provided.

The Guild supports the following as general principles for the recall of medicines:

- The responsibility of medicine recalls rests with the product manufacturer/sponsor and the Therapeutic Goods Administration
- People affected by a recall requiring a refund must return the product to the place of purchase; a pharmacy is not responsible for refunding products purchased at another pharmacy unless there in an arrangement in place within a banner group
- Pharmacies can only replace recalled prescription medicines in accordance with state and territory legislation, noting that the covering prescription is with the pharmacy in which the medicine was originally dispensed
- A system of payment to community pharmacies should be in place for participation in medicines recalls that recognises the administrative and financial burden to a pharmacy to ensure a company can meet its obligations, patient safety is optimised, and ongoing patient care is appropriately managed. This may be via:
  - payment of an agreed fee by sponsors, based upon volumes of recalled products; or
  - a single annual up-front payment financed by sponsors for participation in recalls by community pharmacies.

## Background

The various provisions in state and territory poisons legislation are designed to ensure that pharmacists are responsible for providing facilities and procedures that ensure the safe and proper storage and lawful supply of medicines, including taking measures to prevent the diversion of any medicines onto the illicit market.

The Board also specifies particular provisions affecting the sale or supply of medicines by pharmacists relating to professional behaviour, while pharmacy authorities within state and territory Health Departments address specific jurisdictional responsibilities.

## Pharmacy Depots

The [\*National Health Legislation Amendment \(Conditions of Approval for Approved Pharmacists\) Instrument 2023\*](#) implemented under the National Health Act 1953 expressly prohibits an unapproved pharmacy<sup>xi</sup> from acting as a depot for the collection of pharmaceutical benefits.

South Australia and Victoria restricts the operation of a depot to a pharmacist. In other jurisdictions, a depot is typically a non-pharmacy outlet in remote locations that acts as an intermediary for the collection of medicines and other pharmacy goods that have been dispensed by and/or supplied from a pharmacy.



## Telepharmacy

Telepharmacy refers to the use of technology to conduct a consultation or counselling service with a pharmacist as an alternative to a direct face-to-face service. It can include telephone, video or online communications, transmission of digital images and/or data, and distant dispensing and/or supply of medicines.<sup>xii</sup>

## Community Service Obligation

The CSO Funding Pool<sup>xiii</sup> was introduced in the Fourth Community Pharmacy Agreement (4CPA) in July 2006 in recognition of the additional costs faced by some pharmaceutical wholesalers in providing the full range of PBS medicines to pharmacies. The aim of the CSO Funding Pool is to ensure there are arrangements in place for all Australians to have access to the full range of PBS medicines, via their community pharmacy, regardless of where they live and usually within 24 hours.

## Prescription Medicine Supply Guarantee

The Guarantee of Supply requirements and sanctions for failing to comply with the requirements are set out in Division 3C of Part VII of the *National Health Act 1953*. New arrangements to increase the local stockholding capacity of essential pharmaceutical benefits came into effect from 1 July 2023.

## Policy Change Assessment and Consultation

In 2018, the Pharmaceutical Benefits Advisory Committee (PBAC) first considered a proposal from the Government to increase the PBS quantity for 143 medicines (348 PBS item codes).<sup>xiv</sup> In 2022 the PBAC reviewed this list and expanded it to 304 medicines<sup>xv</sup>. In both cases, there was no public consultation and recommendations were made without the input of supply chain expertise. The policy was then announced by Government without proper understanding or consideration of the potential impact on the supply chain.

## Medicine Recalls

The TGA regulates the recall requirements for therapeutic goods and provides guidance and resources to manage recalls, including a *Uniform recall procedure for therapeutic goods*.<sup>xvi</sup> The TGA also monitors overseas recalls to assess whether there may be any impact on Australia and manages a recall database. The recall of medicines and medicine-related products is managed by the responsible company/sponsor under consultation with the TGA.

## Related Statements

In-person supply of medicines; June 2023

## Authority

### Endorsed

National Council – July 2024

### Reviewed

Practice, Policy and Regulatory Sub-committee – May 2024

## References

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<sup>i</sup> Australian Standard 85000:2017; Quality Care Community Pharmacy Standard; [www.qcpp.com](http://www.qcpp.com)

<sup>ii</sup> [Professional Practice Standards | Pharmaceutical Society of Australia \(psa.org.au\)](https://www.psa.org.au)

<sup>iii</sup> [www.pharmacyboard.gov.au](http://www.pharmacyboard.gov.au)

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- <sup>iv</sup> Approved pharmacist under Section 90 of the *National Health Act 1953* to dispense and supply pharmaceutical benefits
- <sup>v</sup> [Medical Board of Australia - Telehealth consultations with patients](#) (Sep 2023)
- <sup>vi</sup> Australian Code of good wholesaling practice for medicines in schedules 2, 3, 4 & 8; <https://www.tga.gov.au/publication/australian-code-good-wholesaling-practice-medicines-schedules-2-3-4-8>
- <sup>vii</sup> Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2015; <https://www.legislation.gov.au/Details/F2017C00523>
- <sup>viii</sup> [Limits on dispensing and sales of prescription and over-the-counter medicines | Therapeutic Goods Administration \(TGA\)](#)
- <sup>ix</sup> [About the RUM Project | Return of Unwanted Medicine \(returnmed.com.au\)](#)
- <sup>x</sup> <http://www.health.gov.au/internet/main/publishing.nsf/Content/National+Medicines+Policy-2>
- <sup>xi</sup> Unapproved pharmacy: a pharmacy not approved under Section 90 of the National Health Act 1953 to dispense and supply pharmaceutical benefits
- <sup>xii</sup> With reference to Medical Board Guidelines: Telehealth consultations with patients, 1 Sep 2023
- <sup>xiii</sup> <http://www.health.gov.au/internet/main/publishing.nsf/Content/community-service-obligation-funding-pool>
- <sup>xiv</sup> [Pharmaceutical Benefits Scheme \(PBS\) | Recommendations made by the PBAC - August 2018](#)
- <sup>xv</sup> [Increased-Dispensing-Quantities-List-of-Medicines.pdf \(pbs.gov.au\)](#)
- <sup>xvi</sup> [Product recalls | Therapeutic Goods Administration \(TGA\)](#)