

19 December 2025

PHARMAC PO Box 10254 The Terrace Wellington 6143

Sent via email to: <u>consult@pharmac.govt.nz</u>

Dear Sir/Madam.

Re: Consultation on improving access to treatments in the community for trauma and medical emergencies, and ketamine for palliative care

The Pharmacy Guild of New Zealand (Inc.) (the Guild) is a national membership organisation and the largest representative of community pharmacy owners in New Zealand. We provide leadership on all issues affecting the sector and advocate for the business and professional interests of community pharmacy.

This submission focuses on Guild members' concerns around general economic, funding, access and supply issues. Guild submissions should not be taken as any endorsement of, or any attempt to comment on, medicine safety, efficacy, or appropriateness for individual patients.

We have focused on the practical, operational, and system-level considerations required to ensure these proposals are implemented in a safe, equitable, and sustainable manner, without creating unintended burden or risk within the medicines supply chain.

1. Do you support the proposals? Why or why not?

We support the overall intent to improve equitable and timely access to essential treatments in community settings, particularly for people living in rural and remote communities experiencing trauma and medical emergencies, women giving birth at home, or individuals receiving palliative care outside of hospital settings.

Our support is, however, contingent on several critical considerations to ensure safe, sustainable and effective implementation:

- Clear definition of scope and limits of PSO supply for PRIME practices, LMCs, and palliative care services, including clarity around which practitioners can access which products, approved clinical indications, and appropriate maximum quantities aligned with clinical need.
- Robust traceability and monitoring mechanisms for medicines supplied under PSO to support clinical auditability, promote patient safety, and provide accurate national utilisation data for oversight and quality improvement purposes.
- Assurance that increased access via PSO does not unintentionally displace clinical or administrative workload or cost transfer to community pharmacies, ensuring that stock sourcing challenges, cold chain management, reconciliation requirements, and other administrative responsibilities do not impose unfunded burdens.
- Confirmation that funding for these medicines covers all relevant costs, and community pharmacies are not left carrying unreimbursed handling, storage, or dispensing costs associated with supplying these medicines via PSO.

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2. What do you think the impact of these proposals would be?

2.1. Positive impacts

- Improved safety and clinical outcomes for rural and remote patients, through earlier administration of emergency treatments already standard within ambulance services and hospital emergency departments, will support faster intervention at the point of care, reducing delays that can worsen clinical outcomes.
- Enabling PRIME providers to access a funded suite of emergency medicines will enhance response capability in community settings.
- Better clinical continuity and consistency and medicine availability between ambulance, hospital and community-based emergency responses, will reduce treatment gaps and support smoother handover when patients are transferred between services.
- Funded access to intravenous TXA for LMCs will have a meaningful impact on maternal safety,
 as TXA is internationally recognised as a lifesaving medicine for PPH, where early
 administration is vital and strongly associated with reduced morbidity and mortality. Providing
 funded access to intravenous TXA via PSO will support LMCs to manage obstetric emergencies
 promptly in home birth settings.
- This advances equity for women choosing home births, ensuring they have access to the same standard of emergency haemorrhage management available in primary birthing units and hospitals, and aligning with national objectives to support choice in maternity care while maintaining safety.
- Better access to ketamine for people receiving palliative care in the community has the potential to reduce unnecessary hospital admissions for symptom control, supporting care closer to home, and improving quality of life at the end of life.

2.2 Potential negative or unintended impacts

- Increased pressure on community pharmacies to source, hold, and manage emergency medicines for unpredictable PSO supply, particularly intravenous TXA and ketamine, where usage may be infrequent, unpredictable, or highly variable. Without sufficient volume or turnover, community pharmacies may face challenges related to expiry, wastage, and cashflow.
- Risk of stock shortages or disrupted supply chains if PSO volumes rise without coordinated
 procurement and supply planning, particularly for medicines that are already subject to supply
 constraints or require specific storage and handling arrangements.
- Risk of limited visibility of centralised national utilisation data if PSO activity continues to rely
 on fragmented and paper-based systems, hindering pharmacovigilance, stock forecasting, and
 system-level supply planning, making it difficult to assess whether the proposals' objectives are
 being achieved.
- Need for clarity around clinical and legal accountability, particularly where medicines supplied under PSO are used in non-traditional or non-facility settings, where clear guidance is required to avoid ambiguity and risk around responsibility for storage, administration, documentation, and incident management.

3. Are there any practical or operational issues Pharmac should consider?

3.1 Traceability, monitoring, and audit

Medicines supplied under PSO must maintain an appropriate level of traceability to support patient safety, pharmacovigilance, and recall management:

• At a minimum, PSO supply should enable patient-level or episode-level traceability, including batch-number recording where feasible, to meet safety and quality obligations.

- Pharmac should consider adopting the Health Quality and Safety Commission's (HQSC) 2020
 principles on medicines traceability, which highlight the clinical and safety risks created when
 medicines data is fragmented across unlinked providers and settings, particularly for palliative
 and emergency medicines, which are often administered in high-risk, time-critical contexts.
- Pharmac should explore the development and adoption of a digital or nationally standardised PSO recording mechanism, which would improve auditability, support quality improvement, enable accurate utilisation monitoring, and reduce reliance on paper-based processes that are inconsistent and difficult to reconcile at a national level.

3.2 Community pharmacy workload and cost recovery

The proposals must ensure that pharmacies are not left absorbing additional workload or costs without appropriate recognition and reimbursement. This includes, but is not limited to:

- Procurement effort and liaison with wholesalers.
- Stockholding costs and inventory management, including managing low-turnover emergency medicines.
- Cold chain storage and monitoring where relevant.
- Administrative time associated with PSO supply, including monitoring, reconciliation, and wastage requirements.

Pharmac must work with HNZ to ensure that funding arrangements for community pharmacies fully recover costs and that contractual expectations are clearly defined, as without this, there is a risk that community pharmacy participation, particularly in rural areas, may be undermined, compromising timely access to critical medicines in high-need settings.

3.3 Equity of access to stock and supply chain resilience

Expanding funded PSO access to PRIME providers and LMCs will place additional pressure on supply chains and underscores the need for coordinated planning. Pharmac should consider mechanisms to support:

- Dedicated supply chain assurance for emergency and palliative medicines, ensuring that sufficient stock is available to meet clinical need.
- Clear prioritisation rules during periods of constrained supply, so pharmacies can make decisions that balance competing clinical demands fairly and transparently.
- Practical guidance for community pharmacies to manage potential conflicts between the needs of consumers, prescribers, PRIME providers, and LMCs.

3.4 Training, competency, and clinical guidance

Several of the medicines included in this consultation, such as ketamine and intravenous TXA, are high-risk medicines that require appropriate training and competency assurance, with key competencies related to preparation and reconstitution, accurate dosing, administration, monitoring, and recognition and management of adverse events.

Pharmac should ensure that implementation of these proposals is accompanied by clear, up-to-date, and nationally consistent clinical guidance, developed or endorsed in collaboration with relevant professional bodies to ensure safe and effective use across diverse community settings and practitioner groups.

3.5 Interface with community pharmacy clinical governance and regulatory obligations

Community pharmacies require clear guidance on how these proposals interface with existing regulatory frameworks to support clinical governance, manage risk, and ensure compliance, including:

- Legal obligations under the Medicines Act 1981 and Medicines Regulations 1984.
- Controlled drug requirements and security obligations for ketamine.
- Responsibilities for storage, security, expiry management, and wastage once medicines are supplied to the PSO holder.

4. Do you have feedback on the specific proposals?

4.1 Funding PRIME treatments via PSO

To support effective and sustainable implementation, we recommend that Pharmac:

- Partner with HNZ Data & Digital team to develop a standardised national PSO framework, including digital PSO forms, minimum data capture standards, and consistent record keeping expectations.
- Ensure alignment with the New Zealand ePrescription Service (NZePS) and Medicines Data Repository (MDR), to avoid further fragmentation of medicine-use data across community, ambulance, and hospital settings.
- Provide clear guidance on funding parameters, including any caps, expected volumes, and what constitutes "reasonable quantities" for emergency stockholding, to support consistent application across regions and community pharmacies.
- Establish a dedicated emergency medicines supply category to improve long-term visibility, utilisation monitoring, and supply planning for medicines intended for trauma and emergency use in community settings.

4.2 Funded access to intravenous TXA for LMCs via PSO

To support safe and effective implementation, we seek clarification on several practical matters to help ensure consistency, safety, and sustainability as funded access is rolled out:

- Whether Pharmac expects community pharmacies to proactively stock intravenous TXA for home birth PSO supply, and how this expectation will be supported through funding and supply planning.
- Whether LMCs will be required to undertake refresher training or credentialing as part of implementation, and how this will be coordinated nationally.
- Whether a central digital register can be established to track PSO usage, support auditability, and ensure safety monitoring for both mothers and infants.

4.3 Ketamine for palliative care via PSO

Ketamine is a controlled drug, and its supply and use via PSO requires robust governance arrangements. The following are essential to safe implementation:

- PSO supply of ketamine must comply fully with stringent controlled drug governance, including the use of triplicate controlled drug PSO forms where applicable.
- Pharmacists supplying ketamine under PSO must be clearly protected from inappropriate liability, provided they act in accordance with approved protocols and legal requirements.
- Clear, nationally consistent clinical protocols and emergency management guidelines must be in place for community-based administration, including dosing guidance, monitoring requirements, and emergency management of adverse effects.

We recommend that Pharmac confirms alignment of expectations with Medsafe to ensure that regulatory, professional, and operational requirements are clear and consistent across the system.

5. Is there anything else we should consider?

5.1 Need for a national digital PSO solution

The expansion of funded access to emergency and palliative medicines via PSO further highlights that paper-based PSO processes are no longer fit for purpose. Reliance on manual documentation limits traceability, increases the risk of transcription and reconciliation errors, and contributes to fragmented national medicines utilisation data.

Given the high-risk nature of several medicines included in this consultation, and the increasing use of PSO in community-based care, we strongly encourage Pharmac to support the development of a digitised, auditable, and interoperable national PSO solution. This work should be undertaken collaboratively with key system partners, including:

- HNZ Data & Digital team
- Conporto Health
- Prescriber management system (PMS) and community pharmacy management system (PhMS) vendors
- Pharmacy Guild of New Zealand and other relevant community pharmacy professional organisations

A national digital PSO framework would significantly improve patient safety, enable real-time visibility of medicine supply and use, support pharmacovigilance, reduce administrative burden for clinicians and pharmacists, and support consistent national standards, while aligning with broader health system digitalisation initiatives.

5.2 Avoiding unintended expansion of PSO supply

Pharmac should clearly articulate that these proposals are not intended to broaden the use of PSOs within general practice, nor to extend prescribers' access to funded or unfunded emergency stock beyond the defined contexts of PRIME services, LMCs, and community palliative care contexts.

Clear boundaries are important to prevent unintended scope creep, maintain clarity around funding intent and eligibility, protect community pharmacy supply chains from unplanned pressures, and ensure that this consultation remains focused on improving access in clearly identified high-need settings.

If you have any questions about our feedback, please contact our Senior Advisory Pharmacists, Martin Lowis (martin@pgnz.org.nz, 04 802 8218) or Cathy Martin (cathy@pgnz.org.nz, 04 802 8214).

Yours sincerely,

Nicole Rickman

General Manager - Membership and Professional Services