

10 September 2025

PHARMAC PO Box 10254 The Terrace Wellington 6143

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

Dear Sir/Madam.

Re: Consultation on the draft 2025/26: Invitation to tender for health care professionals

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.

Our submission presents feedback from a community pharmacy perspective on the draft 2025/26 Invitation to Tender (ITT) and builds on our 16 June 2025 submission on the consultation on possible brand changes through the 2024/2025 Annual Invitation to Tender, which outlined concerns around sole supply fragility, adherence risks, stock wastage, operational disruption and increased workload.

We support the overall intent of the annual tender process to secure medicine supply, deliver savings to the health system, and improve access for patients. However, we recommend that implementation carefully balances these objectives with the need to safeguard patient safety, uphold equity for vulnerable and priority populations, and maintain the financial and operational sustainability of community pharmacies. This includes ensuring that brand changes, funding restrictions, and supply transitions are planned and communicated in ways that minimise disruption to patients, reduce unnecessary workload for community pharmacies, and protect the continuity and quality of care across the health sector.

1. Brand change appropriateness

We support the use of tendering where the overall health system benefits are clear. However, as highlighted in Pharmac's draft 2025/2026 ITT consultation, not all medicines are equally suited to brand change. We recommend that Pharmac delay or avoid brand switches of pharmaceuticals in situations where risks to patient safety or operational disruption are high and mitigation options are limited to protect patients and maintain confidence in the health system. This is particularly critical for the following examples:

- Narrow therapeutic index (NTI) or dose-critical medicines, such as lithium IR, methotrexate, strong opioid oral liquids, where even small differences in formulation or absorption may result in toxicity or reduced efficacy.
- Device- and usability-sensitive products, such as inhalers, patches, injectables, or paediatric liquids, where technique, excipient variation, or taste can significantly impact adherence.

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• Psychotropic medicines in stable patients, where even minor formulation or packaging changes may destabilise treatment due to nocebo effects or pharmacokinetic variation.

Given the ITT grants Principal Supply Status through to 30 June 2029 with 95% market capture, the consequences of a poorly managed switch are magnified. To mitigate these risks, we recommend:

- Extended transitions periods, providing sufficient time for prescribers, pharmacists and patients to adapt and coordinate safely.
- Higher Alternative Brand Allowance (ABA), particularly for high-risk categories, to increase flexibility during transitions and reduce reliance for Exceptional Circumstances applications.
- Targeted pharmacy-level resourcing, including funding for staff training, patient communication, and the additional time requirement to manage complex brand changes safely.

2. Features to consider when evaluating medicines

The draft Pharmac 2025/26 ITT consultation specifically invites feedback on what features should be taken into account when evaluating tendered medicines, and we recommend the following considerations be prioritised to protect patient safety, reduce dispensing errors, and minimise unnecessary workload in community pharmacy:

- Pack sizes and presentation: Maintain 30- and 90-day bottle packs where already noted in the draft ITT, as limiting supply to blister-only formats significantly increases pharmacy repackaging workload, contributes to higher waste and disrupts established supply chains. Pack sizes and presentations are also particularly relevant in aged care and disability support settings, where consistency of supply format is essential.
- Formulation and excipients: For oral liquids, parenteral products, and modified-release medicines, Pharmac should require detailed comparison tables should clearly set out differences in excipients, such as sweeteners, preservatives, or viscosity agents, as these variations can impact tolerability, palatability, adherence, and safety, particularly in paediatric, elderly, and other vulnerable populations.
- Look-alike/sound-alike (LASA) risk: Tender evaluation should consider the potential for name or packaging confusion, and suppliers should be required to provide packaging that visibly and unambiguously differentiates brands to reduce LASA-related dispensing and administration errors.
- IT readiness: Before any brand change takes effect, all relevant symptoms, including the NZULM, prescriber patient management systems (PMS), and pharmacy patient management and dispensing systems (PhMS), must be updated to reflect new listings. Additionally, a national change calendar should be published and maintained to give prescribers and pharmacies clear advanced notice of upcoming changes, supporting planning and reducing the risk of prescribing or dispensing errors at the transition point.
- Equity and accessibility considerations: When evaluating presentations, Pharmac should also consider accessibility needs, for example, the availability of scored tablets for flexible dosing, easy-to-open packaging for older adults, and culturally appropriate patient information materials to support medicine use across diverse communities.

3. Three-month supply

While extended dispensing intervals can deliver system efficiencies and convenience for some patients, monthly dispensing remains a critical safeguard for adherence, monitoring, and patient safety. To balance these factors, we recommend the following:

- Pharmacist discretion: Pharmacists should retain the ability to dispense medicines monthly where clinically justified, supporting patient-centered care and ensuring professional judgement is not overridden by rigid supply rules. Clear national guidance would also support practice while still enabling flexibility.
- Exclusion/caution list: Pharmac should publish and regularly update a clear list of medicines not suited to three-month supply and should include narrow therapeutic index medicines, therapies requiring titration or close monitoring, paediatric oral liquids, and other high-risk categories where treatment stability or adherence could be compromised.
- Active monitoring of outcomes: Pharmac should establish monitoring processes to actively
 track signals of increased wastage or harm following any change, such as analysis on rising
 returns from patients, unused stock, or anomalies in claims data. Importantly, there should
 be a clear mechanism for reversing or adjusting policy if negative impacts emerge.
- Equity considerations: Longer dispensing intervals may disproportionately affect some population groups, for example where adherence is already challenging or where reduced health professional touchpoints could result in missed opportunities for intervention. An explicit equity lens should therefore guide evaluation of three-month supply impacts to ensure the policy does not widen disparities, with co-designed information for Māori, Pacific peoples, and other priority groups.
- Implementation supports: Any move of a medicine towards three-month supply should be accompanied by a comprehensive communications and change-management plan, ensuring prescribers, pharmacists, and patients have clarity on which medicines are affected, why the change is occurring, and what safeguards are in place.

4. Alternative Brand Allowance (ABA)

In community pharmacy practice, the current Alternative Brand Allowance (ABA) limit of 5% is often insufficient to manage transitions safely and efficiently, particularly for higher-risk medicines and vulnerable patient groups. We recommend the following measures to safeguard patients during brand changes, support community pharmacies and enhance the overall effectiveness of the annual tender process:

- Increase ABA limits: Raise the ABA limit to a minimum of 10% for narrow therapeutic index (NTI) medicines, paediatric liquids, and device-dependent products, allowing pharmacies greater flexibility to maintain continuity of supply for patients who cannot safely switch brands, reducing the risk of treatment disruption, adverse effects, or non-adherence.
- Streamlined ABA access for high-risk patients: Introduce a simplified and timely process that allows pharmacists to apply ABA for safety-critical patients, avoiding the delays inherent in Exceptional Circumstances application approvals. This should also include clear guidance on which categories of patients and medicines qualify, ensuring clinical decisions are made efficiently and consistently across pharmacies.
- Monitoring and evaluation: Actively track ABA usage and outcomes post-transition, including metrics such as adherence, adverse effects, and stock wastage, where feedback from these data should be used to inform future tender cycles, ABA policy adjustments and targeted support of high-risk medicines.
- Integration with IT systems: Ensure that ABA allowances and approvals are fully integrated into prescriber patient management systems (PMS) and pharmacy patient management and dispensing systems (PhMS), where alerts or prompts in these systems could support prescribers and pharmacists in identifying patients eligible for ABA use, reducing administrative burden and minimising the risk of errors during transitions.

- Communication and training support: Provide targeted guidance, training, and resources for pharmacists on ABA policy, including case examples and workflows to ensure consistent application and support pharmacists in managing complex brand changes safely.
- Equity considerations: Pharmac should ensure an ABA policy explicitly considers vulnerable populations, such as children, elderly, and patients with complex chronic conditions, to prevent widening disparities during brand transitions.

5. Funding restrictions

We support Pharmac's approach in the draft 2025/26 ITT consultation to review funding restrictions and remove or relax them where clinically appropriate, such as rosuvastatin or vancomycin oral capsules, where alignment with ASID 2025 guidance supports more flexible use. However, any relaxation of funding restrictions must be paired with robust implementation safeguards to ensure patient safety and access, continuity of care, optimise therapy and system efficiency, and reduce administrative barriers:

- **Supply resilience:** Ensure that sufficient stock and reliable supply chains are in place prior to implementing funding changes and restrictions to avoid shortages, treatment interruptions, or substitution pressures that could compromise patient outcomes.
- Alternative Brand Allowance (ABA) flexibility: Complement relaxed restrictions with increased ABA, particularly for higher-risk medicines or vulnerable patient groups, to support community pharmacies in maintaining continuity of supply safely during transitions and prevent clinical and operational disruption.
- **Pharmacy support and counselling:** Provide targeted guidance, professional training, and patient-facing information to assist pharmacists in counselling patients effectively, particularly when a funding change coincides with a brand change or new formulation to reduce confusion, prevent errors and maintain confidence in treatment.
- Monitoring and evaluation: Actively track the impact of funding restriction changes on prescribing patterns, adherence, stock wastage, and patient outcomes, with feedback mechanisms in place to inform future tender cycles and policy adjustments if unintended negative consequences arise.
- Equity considerations: Ensure that changes in funding do not disproportionately impact Māori, Pacific peoples, or other priority populations, where co-designed patient materials and engagement strategies should be implemented to support equitable access and safe medicine use.

6. Transition timing and communication

We support the draft 2025/26 ITT consultation highlighting the importance of careful planning and communication when implementing brand changes, where effective transition timing and robust communication strategies are critical to maintaining patient safety, adherence, and operational efficiency, along with confidence in the health system. To support safe and equitable implementation, we recommend that Pharmac consider the following:

- Lead times: Implement minimum transition periods of six months for oral solid medicines and nine to twelve months for narrow therapeutic index (NTI) medicines, liquid formulations, or device-dependent products, allowing prescribers, pharmacies, and patients to adapt safely, reduce the risk of errors, and support continuity of care, particularly for higher-risk medicines or vulnerable populations.
- Patient communication: Develop co-designed, multilingual, plain-language resources that clearly explain changes, where resources should include visual tools showing differences between old and new brands, covering packaging, dosing, and administration, to minimise

- confusion and promote adherence. Priority should be given to resources designed for Māori, Pacific peoples, and other priority groups, ensuring equitable access to information.
- **Digital synchronisation**: Ensure that all prescriber patient management systems (PMS), pharmacy patient management and dispensing systems (PhMS), and the NZULM are updated and fully operational before the effective dates of brand changes to reduce the risk of prescribing and dispensing errors and support seamless implementation across the health system.
- Stakeholder engagement: Involve community pharmacies, prescribers, and patient groups early in planning, providing opportunities to test communications, clarify implementation processes, and raise potential challenges before go-live.
- Monitoring and feedback: Track the impact of transitions on adherence, dispensing errors, and patient outcomes, using feedback to inform ongoing adjustments and support future tender cycles.
- Integration with other supports: Align transition planning with Alternative Brand Allowance (ABA), funding changes, and pharmacy-level resourcing to ensure that patients and pharmacies are adequately supported during the switch, to reduce operational strain and improve patient safety outcomes.

7. Financial sustainability and stock handling

We are aligned with Pharmac's draft 2025/26 ITT consultation recognising the need to support community pharmacies in managing operational impacts associated with brand changes. To maintain financial sustainability and safe stock handling, while ensuring that operational and financial challenges associated with brand changes do not compromise patient safety, adherence, or equitable access to medicines, we recommend the following measures:

- Brand switch fee: A consistent brand switch fee should apply to all clinically significant changes and should be reviewed and adjusted to reflect the actual time, complexity, and professional effort involved in counselling patients, handling stock, updating records, and coordinating with prescribers, to ensure pharmacies are appropriately compensated for the additional workload required to safely implement brand changes.
- Stock credits and returns: Supplier and wholesaler credit and returns policies should ensure community pharmacies are not financially penalised for residual stock remaining after delisting or brand transitions, and should be clear, timely and designed to minimise administrative burden, supporting safe and efficient stock handling.
- **High-cost or low-margin items:** For medicines that are high-cost or low-margin, including narrow therapeutic index (NTI) medicines or device-dependent products, we suggest introducing a consultation or handling payment, which would offset the additional workload associated with complex brand changes, helping pharmacies remain financially sustainable while delivering safe and high-quality patient care.
- Integration with transition planning: Financial support should be coordinated with transition timelines, Alternative Brand Allowance (ABA) policies, and funding changes, ensuring that pharmacies have the resources and capacity to manage changes without compromising patient safety, adherence or operational efficiency.
- Monitoring and evaluation: Actively track the effectiveness of financial support in reducing
 operational strain, preventing stock wastage, and maintaining pharmacy engagement,
 where feedback should inform future tender processes and policy refinements, ensuring
 that financial support remains fit-for-purpose and responsive to real-world pharmacy
 practice.
- **Equity and accessibility considerations:** Financial support should be designed with an equity lens, ensuring that pharmacies serving high-need populations, including Māori, Pacific

peoples, and other priority groups, are adequately resourced to deliver uninterrupted access to medicines during transitions.

8. Equity and vulnerable populations

Equity should remain a central consideration in the implementation of Pharmac's 2025/26 ITT, where brand changes, funding adjustments, and supply transitions can disproportionately affect vulnerable patient groups, including older adults, paediatric patients, neurodiverse patients, and those with mental health conditions. To safeguard these populations, we recommend that Pharmac prioritise the following measures to minimise disruption, protect patient safety, and ensure that all populations maintain uninterrupted access to medicines:

- Flexibility in supply: Ensure Alternative Brand Allowance (ABA) policies and pharmacist discretion are applied generously for patients at higher risk of disruption, enabling continuity of therapy without compromising safety, particularly important for narrow therapeutic index (NTI) medicines, device-dependent products, and liquid formulations.
- Extended transition periods: Implement longer lead times for high-risk medicines and vulnerable populations to allow prescribers, pharmacists and patients sufficient time to adapt, reducing the likelihood of errors, non-adherence, or treatment interruptions.
- Accessible and culturally appropriate patient resources: Develop co-designed, plain-language, multilingual resources tailored to the needs of vulnerable populations, which should include clear visual comparisons between old and new brands, dosing instructions, and administration guidance, with priority given to materials designed for Māori, Pacific peoples, and other priority groups, ensuring equitable access to information and health literacy support.
- Integrated support across care pathways: Coordinate ITT implementation with pharmacy counselling, prescriber communication, and monitoring systems to proactively identify and support vulnerable patients who may experience challenges during brand transitions.
- Monitoring and evaluation: Track key outcomes such as adherence, adverse events, patient safety, and equity indicators to identify populations at risk and inform necessary adjustments to transition processes, communication strategies or support mechanisms, strengthening future tender cycles and ensure continuous improvement.
- Stakeholder engagement: Engage patient groups, sector organisations, and community pharmacies early in the planning and implementation process to ensure that the perspectives and needs of vulnerable populations are reflected in transition planning, resources and communication strategies.

9. Non-hormonal intrauterine devices (IUDs)

We support the Additional Special Terms proposed for non-hormonal intrauterine devices (IUDs) in the draft 2025/26 ITT consultation. To ensure safe, effective, and equitable access, we recommend that Pharmac considers the following measures:

- Supplier-funded training and resources: Require suppliers to provide funding for clinician training, procedural resources, and patient education materials to ensure that healthcare providers are confident and competent in device insertion, counselling, and follow-up, reducing the risk of complications, supporting high-quality care, and improving patient outcomes.
- Mandatory Medical Device Regulation (MDR) certification: Require MDR certification for all non-hormonal IUDs to ensure that devices meet robust international standards for safety, quality, and traceability, providing assurance of consistent product quality, strengthens clinical confidence, and enhances patient safety.

- Patient information and counselling: Ensure suppliers provide accessible, culturally
 appropriate, and multilingual patient resources, including clear guidance on insertion, use,
 follow-up, and potential side effects, where materials should be co-designed with patients
 and priority groups, including Māori and Pacific peoples, to support informed decisionmaking, health literacy, and equitable access to care.
- Integration with implementation supports: Align these requirements with transition planning, pharmacy and clinical workflows, and IT systems to ensure seamless adoption, minimal disruption to service delivery and maintain continuity of care for patients.
- Monitoring and evaluation: Consider tracking uptake, insertion success rates, adverse events, and patient satisfaction, using data to inform ongoing improvements in device provision, education, and support for both clinicians and patients.

10. Item-level observations (community pharmacy and patient impact)

We welcome the opportunity to provide feedback on particular medicines listed in the draft 2025/26 ITT consultation, particularly regarding medicines where packaging, formulation and access considerations have significant implications for community pharmacy operations, patient safety, and treatment adherence. We recommend that Pharmac carefully consider the following medicine-specific issues:

- Omeprazole capsules (all strengths): Maintain 30- and 90-day bottle packs and avoid fragmented pack sizes, reducing unnecessary repackaging, minimising medicine waste, and supporting efficient dispensing in high-volume community settings.
- Statins and antihypertensives: Preserve bottle packs and ensure tablets are scored to support dispensing efficiency, enable flexible dose adjustments, and support adherence, particularly in older patients and polypharmacy contexts.
- **Lithium IR**: Treat as a narrow therapeutic index (NTI) medicine and apply extended transition periods, increase ABA allocations, and provide enhanced counselling and monitoring to safeguard patient safety during brand switches.
- Morphine and oxycodone oral liquids: These controlled drugs will require child-resistant packaging, full disclosure of excipient information, and verification of device compatibility to protect patient safety, particularly for children and vulnerable populations, and support correct dosing and adherence. Preference should be for pack sizes less than 250ml to fit into controlled drug safes and shelf lives to be greater than 30 days after opening.
- Vancomycin oral capsules: If widened access is approved, ensure early alignment between hospital and community pharmacy supply, combined with adequate ABA to maintain continuity of therapy and prevent supply disruption during the transition.
- **Permethrin, benzyl benzoate, and malathion:** Pair these products with health-literacy-friendly patient guides, ensure clear instructions for use, and maintain sufficient stock levels to manage seasonal demand spikes, reducing the risk of treatment delays and uncontrolled spread of infection.
- **Combination antihypertensives:** Preference for scored tablets and bottle formats to support accurate dispensing, patient adherence, and dose titration when required.
- Antibiotic granules for oral liquid: Recommend inclusion of an appropriate measuring device to ensure accurate dosing of young patients and shelf lives greater than 10 days after reconstitution to reduce wastage.
- Adapalene 0.1% gel: Removal of the restriction of a maximum of 30g per prescription as this quantity is insufficient for some patients treating multiple areas of their body.
- **Diazepam tablets (2mg and 5mg):** Request scored tablets to enable accurate dose reductions and flexible prescribing.

- Econazole nitrate 1% foaming solution sachets: Removal of the part charge, which currently acts as a barrier to access, leading to untreated fungal infections that may become harder to manage.
- Gliclazide 80mg tablets: Preference for scored tablets to support lower or dividing dosing.
- **Ketoconazole 2% shampoo:** Removal of the restriction of one bottle per prescription as this is inadequate for many patients requiring ongoing treatment.
- Quetiapine tablets (all strengths): Preference for scored tablets, particularly the 25mg strength, to allow for safe titration and lower doses where clinically required.

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