PHARMACY GUILD OF NEW ZEALAND

19 May 2025

Committee Secretariat
Health Committee
Parliament Buildings
Wellington

Sent via portal submission: *Parliament Submission Portal*

Re: Medicines Amendment Bill 2025

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.

We support the government's intention to modernise the Medicines Act 1981 (the Act) and view this as a critical step toward improving equitable access to medicines, enhancing the efficiency of the healthcare system, and delivering accessible, patient-centred care across the motu.

We broadly support several of the proposed amendments in the Medicines Amendment Bill (the Bill), which we believe have the potential to enhance timely access to medicines and strengthen the healthcare system. We have expanded on these below.

Key areas of support

1. Streamlined verification pathway for medicines approved for distribution in New Zealand
The introduction of a verification-based approval model represents a progressive shift that aligns New Zealand's regulatory framework with contemporary international best practice. By reducing unnecessary duplication of effort, this model enhances regulatory efficiency while maintaining robust safety and quality standards. We support the use of two recognised overseas regulatory authorities as the basis for approval, as this approach can significantly accelerate access to new and innovative medicines for New Zealand patients and leveraging the rigorous assessment processes of trusted international regulators will allow Medsafe to focus resources where they are most needed, ultimately supporting faster, more efficient decision-making without compromising patient safety.

While the introduction of a verification-based approval model offers clear benefits, there are some potential risks and implications for community pharmacy that should be carefully considered:

- **Limited familiarity with new medicines** – Faster approvals via overseas regulators may outpace the availability of local tailored guidance or training for pharmacists, which may create challenges in staying informed on new indications, contraindications or safety profiles, and providing appropriate patient counselling.
- **Inconsistent product information** – Overseas-approved product information may differ from New Zealand standards in terms of format, content, terminology, or dosing conventions, increasing the risk of confusion or misinterpretation in the dispensing process or an increased risk of dispensing errors if not adapted to the New Zealand context.
- **Patient expectations and demand** – Faster approvals of new medicines may raise consumer awareness and demand before funding or supply systems are in place.
- **Supply chain and stock management** – A wider range of approved medicines may create complexity in sourcing, increase the risk of confusion between similar-sounding or looking products, and challenges in maintaining continuity of supply if overseas-approved products are subject to export restrictions or variable manufacturing standards.

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- **Pharmacovigilance and post-market monitoring** – Medicines approved via this pathway may not have robust post-market surveillance frameworks established in New Zealand, potentially delaying identification of adverse reactions and placing more responsibility on pharmacists to detect and report safety concerns without adequate support or guidance.

We also believe clarity is needed on how pharmacists will access, verify, and counsel patients on medicines approved through this pathway and we recommend that implementation protocols include direct input from the community pharmacy sector, as this change will add complexity to pharmacy workflows, and involving pharmacists in the design of these processes is essential to ensure safe and practical application.

2. **Nurse practitioners enabled to prescribed unapproved medicines under section 29 of the Medicines Act 1981**

Enabling nurse practitioners to supply unapproved medicines under section 29 of the Act is a positive step towards more responsive and flexible patient care and enhances timely access to necessary therapies, particularly in a range of environments, including underserved or rural communities or in aged residential care, where nurse practitioners often serve as primary healthcare providers. This change recognises the advanced clinical expertise of nurse practitioners and will enable them to act promptly in situations where approved treatment options may be unsuitable or unavailable, ultimately supporting a more integrated, patient-centred care and reduced delays in treatment.

The Code of Health and Disability Services Consumers' Rights imposes obligations on the provider of services (in this case the prescriber) to ensure that all treatments adhere to ethical and professional standards. When prescribing an unapproved medicine, obtaining patient consent is essential, and consumers have the right to be fully informed. The prescriber is required to provide clear and comprehensive information, including discussing the evidence and their reason for the use of the unapproved medicine and any potential associated safety concerns and risks. Additionally, under Rule 3 of the Health Information Privacy Code, consumers must be informed that their information will be shared with the manufacturer, supplier, or importer when an unapproved medicine is used, with a subset of that information being provided to Medsafe and recorded in a database, as required by the Act.

Enabling nurse practitioners to prescribe unapproved medicines brings benefits but also introduces potential risks for both community pharmacy and patients that must be considered, including:

- **Variable prescriber experience and knowledge** – While nurse practitioners are highly trained, extending prescribing rights to unapproved medicines introduces variability in familiarity with the specific legal, ethical, and documentation requirements involved. Clear, consistent guidance and training on the obligations of prescribing unapproved medicines will be essential to support safe and effective practice.
- **Increased counselling and communication burden** – Unapproved medicines often lack local data on safety, efficacy, and usage, leaving pharmacists to provide advice or monitor for adverse effects with limited clinical guidance. Patients may be unaware they are receiving an unapproved medicine or may not fully understand the associated risks. If this hasn't been clearly communicated by the nurse practitioner, pharmacists may need to spend additional time explaining the rationale and managing expectations.

We also support amending the Act to allow all authorised prescribers, defined as those with prescribing rights under the Health Practitioners Competence Assurance Act 2003, to prescribe unapproved versions or brands of medicines, not just those funded by Pharmac as alternatives during medicine shortages, as proposed in the Bill. Expanding this authority would better reflect the clinical capabilities of a wide range of healthcare professionals, reduce over-reliance on medical practitioners (currently the only group permitted to do so under the legislation), and enable all prescribers to act within their scope to meet patient needs, fostering a more

collaborative and efficient healthcare system, support continuity of care, and improve timely access to appropriate treatments.

3. **All authorised prescribers to prescribe unapproved medicines that are funded by Pharmac as alternatives to approved medicines that are in short supply**

Enabling all authorised prescribers to prescribe unapproved medicines funded by Pharmac as alternatives to approved medicines in short supply represents a practical and necessary step to improve the health system's responsiveness and patient access during medicine shortages, reducing unnecessary delays in treatment, alleviating pressure on medical practitioners, and ensuring patients continue to receive timely and appropriate care.

Section 29 of the Act was originally intended to be used for situations where an approved medicine was unavailable, allowing for the importation and supply of unapproved medicines on a case-by-case basis. It was never intended as a solution for managing stock shortages of approved, funded medicines listed on the Pharmaceutical Schedule, however Pharmac's current use of this pathway to address such shortages circumvents the original purpose of the legislation. There is now a substantial number of funded unapproved medicines on the Pharmaceutical Schedule, particularly since the Covid pandemic, and this trend continues to expand and is now impacting the availability of common medicines across the motu.

We acknowledge that Pharmac's use of unapproved medicines is often necessary to maintain patient access during shortages, however this approach creates potential legal and professional vulnerabilities. This is especially true for medical practitioners, who are currently the only prescribers authorised to prescribe unapproved medicines but will also be extended to other authorised prescribers under the Bill, as well as for pharmacists dispensing prescriptions written for unapproved medicines. Both authorised prescribers and pharmacists involved in supplying unapproved medicines may face potential legal exposure, charges of professional misconduct or other disciplinary action, particularly if patients are not fully informed that they are receiving an unapproved medicine, if the prescriber has not had a discussion with the patient on the use of an unapproved medicine and obtained the patient's consent, or if proper documentation is lacking.

While we acknowledge that this section of the Bill is limited to enabling all authorised prescribers to prescribe unapproved medicines funded by Pharmac as alternatives during medicine shortages, we would like to highlight that broadening the range of prescribers authorised to do so simply shifts a bigger issue to more prescribers and does not address the overarching problem – there is still a lack of clarity around the legal and operational requirements for both prescribers and pharmacists when initiating or continuing treatment with an unapproved medicine, including situations where a patient transitions from an approved to an unapproved brand when a prescription is written in advance or during the course of an existing prescription due to funding changes by Pharmac. These concerns include:

- **Frequent supply chain changes and system misalignment** – Ongoing global supply challenges often lead to frequent updates to the Pharmaceutical Schedule, with funded approved medicines replaced with funded unapproved alternatives, sometimes mid-month or immediately in urgent cases. While community pharmacy systems are regularly updated to reflect these changes for accurate dispensing and reimbursement, there is no equivalent requirement for prescriber management systems (PMS). This misalignment can lead prescribers to unknowingly prescribe a medicine that has been replaced by an unapproved version, potentially risking failure to meet their legal and ethical obligations.
- **Lack of datasheets for unapproved medicines** – The absence of datasheets for an unapproved medicine creates barriers for prescribers to assess the clinical suitability of substituting an unapproved medicine for an out-of-stock approved medicine. Discussions with clinicians and pharmacists reveal differing assumptions about Pharmac's due diligence, leading some to believe they do not need to independently verify the clinical appropriateness of such substitutions. This creates ethical and legal dilemmas, as both prescribers and pharmacists must balance meeting patient needs against the risk of potential harm.

- **Changing funding status during a prescription's lifespan** – Over the course of a funded prescription (typically three months for most medicines, six months for oral contraceptives, or one month for certain controlled drugs), changes can occur in what brand of medicine is funded and if that funded brand is approved or unapproved by Medsafe. This means a prescriber may issue a prescription expecting an approved medicine to be supplied, unaware that a substitution to an unapproved brand may occur later, and, as a result, the prescriber may unintentionally fail to meet their legal and ethical obligations related to prescribing unapproved medicines.
- **Uncertainty around authorisation requirements** – Under section 29 of the Act, pharmacists must obtain authorisation from the prescriber before supplying an unapproved medicine. However, feedback from community pharmacies reveals varying practices, particularly when the approval status of a funded medicine changes, either at the first dispensing or during repeat supplies, with these inconsistencies including a lack of understanding of the legal and ethical requirements for both the prescriber and pharmacist due to the absence of clear guidelines from Medsafe. Some individuals assume that Pharmac's regular substitutions of unapproved medicines in place of approved medicines in the Pharmaceutical Schedule indicate prior arrangements with Medsafe, while others face pressure from patients unaware of the rules, or encounter resistance and negative reactions from prescribers when requesting authorisation or a new prescription.
- **Insufficient IT infrastructure** – Currently, there is insufficient IT infrastructure to facilitate timely communication between prescribers and pharmacists. The NZePS is still under development and the funding cuts to Health New Zealand's Hira programme have stalled the development of a comprehensive patient medicine history platform as the one source of truth that can be accessed by any healthcare professional across the country. In the absence of these tools, communication between prescribers and pharmacists relies on phone calls or emails, which can be delayed due to workforce pressures.
- **Patient impact and delays in treatment** – Under section 29 of the Act, pharmacies are unable to procure unapproved medicines in anticipation of a prescription, leading to delays in obtaining the necessary treatment when prescriptions are presented. Repeat supplies involving unapproved medicines also require patient-initiated requests before ordering, potentially causing further delays in access. While community pharmacies may try to pre-empt this by asking or reminding the patient to notify them a few days in advance if they need their next supply of a medicine, this does not always occur and there can be a cost incurred by the pharmacy in providing this service. As more unapproved medicines are funded, community pharmacies are facing increased pressure from frustrated and distressed patients who are unaware of the legal and ethical obligations in procuring, prescribing and supply unapproved medicines, resulting in treatment delays and leading to complaints.

4. Changes to the membership requirements for the Medicines Classifications Committee (MCC)

The proposed changes to the structure of the MCC are a positive step for primary healthcare, including community pharmacy, as they will modernise the Committee's membership requirements and remove outdated provisions from the Act, making the framework more flexible and responsive to change and support a more contemporary, inclusive approach to medicine access decisions.

Moving from a fixed membership model of six members with specific nomination sources to a flexible minimum of seven members will allow the Minister to have greater scope to appoint a more diverse and multidisciplinary committee and require the Minister to be satisfied that each appointee is "suitably qualified", placing stronger emphasis on merit and relevant expertise rather than solely relying on nominations from professional bodies. This approach will also reduce potential bias or perceived conflicts of interest, particularly when decisions impact the interests of specific professional groups, better supporting a collaborative, whole-system perspective on medicine classification.

However, we have concerns that without clear transparency and well-defined criteria for what constitutes being "suitably qualified," the appointment process risks becoming politicised or

subjective, potentially overlooking essential frontline expertise. There is also a real possibility that pharmacy representation could be diminished or lost altogether if appointments are not carefully balanced to ensure all relevant sectors are fairly included. To address these risks, we advocate that there must be the establishment of transparent, objective selection criteria and a robust, accountable appointment process to actively safeguard the inclusion of pharmacy professionals alongside other key stakeholders, such as general practice, ensuring the committee retains diverse perspectives that reflect the realities of prescribing, dispensing, and patient care. Additionally, ongoing review mechanisms should be implemented to monitor the committee's composition and performance, maintaining a balance of expertise that supports effective, equitable decision-making in medicine classification.

The proposed change in the Bill also distinguishes Ministry of Health-appointed members, who would serve "during the pleasure of the Minister," from other members with fixed three-year terms and possible reappointment, offering flexibility to align with government priorities while preserving stability for non-Ministry members. However, the Minister's discretion could lead to uncertainty or politicisation, risking the committee's independence and consistent public health representation, with shorter, unpredictable terms for Ministry appointees affecting cohesion, long-term planning, and the balance of expertise. To keep this change positive, we encourage the Ministry to set clear appointment and tenure guidelines to prevent politicisation and turnover, ensuring consistent pharmacy representation and balanced expert input vital for primary healthcare and community pharmacy.

Missed opportunities
While the Bill is a positive step, it misses key opportunities to strengthen medicine access and supply infrastructure, including:

- **Pharmacist prescribing**: The Bill extends prescribing rights to others but fails to include different pharmacist prescribing pathways, missing alignment with global best practice.
- **Pharmacovigilance oversight**: The repeal of sections 29(2) and (3) removes prescriber reporting obligations without replacing them with a pharmacist-led framework.
- **Digital integration**: No legislative support is provided for medicine traceability, digital prescribing minimum standards, or system synchronisation.

Thank you for your consideration of our response. 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,

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