PHARMACY GUILD OF NEW ZEALAND

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Sent via email to: meg.larken@health.govt.nz

Dear Meg,

Re: Proposal to amend the Medicines Act 1981 to enable pharmacist prescribers to prescribe unapproved versions of listed medicines

Thank you for the opportunity to provide feedback on the above consultation.

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

We support amending the Medicines Act 1981 (the Act) to enable pharmacist prescribers to prescribe unapproved versions or brands of medicines. Pharmacist prescribers possess specialised clinical, pharmacological, and pharmaceutical knowledge and skills that are essential for providing individualised medicine management services. Allowing pharmacist prescribers to prescribe unapproved medicines would empower them to perform their essential roles effectively, reduce the burden on medical practitioners – who are currently the only ones authorised to prescribe unapproved medicines under the legislation – and ensure continuity of care, streamlining healthcare delivery and enhancing overall patient care.

We would also support this change to the Act being extended to all authorised prescribers, defined as anyone with prescribing rights under the Health Practitioners Competence Assurance Act 2003, including nurse practitioners, optometrists, dentists, and registered midwives.

Background – summary of current requirements

The Act mandates that Ministerial consent, delegated to Medsafe, must be obtained before any medicine can be sold, supplied, distributed, or advertised in New Zealand as an approved medicine. Section 29 of the Act permits the sale or supply of unapproved medicines solely to registered medical practitioners, defined as health practitioners registered with the Medical Council of New Zealand. Under this provision, registered medical practitioners can prescribe unapproved medicines that are either manufactured in New Zealand by licensed manufacturers or imported by licensed wholesalers and pharmacies, if the Director-General of Health (delegated to Medsafe) is notified of the supply. In contrast, an authorised prescriber that is not a medical practitioner cannot prescribe unapproved medicines supplied from within New Zealand.

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

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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.

Pharmacists may only supply unapproved medicines to patients under the authorisation of a medical practitioner as outlined in section 29 of the Act. Section 29 of the Act also mandates that the patient must be known at the time of supply, which means that supplying on a Practitioner's Supply Order (PSO) is generally not permitted, except in exceptional cases, such as snake anti-venom or the rabies vaccine, where having an emergency supply on hand may be crucial for patient safety.

As part of their responsibility in ensuring ready access to funded medicines for the New Zealand public within a fixed budget, Pharmac initiate a tender process with suppliers for a particular medicine. Typically, this results in one supplier being awarded sole supply status in the funded market, making this winning supplier responsible for ensuring that their brand of the medicine is readily available. Suppliers that do not win the tender often struggle to maintain sufficient sales and may shift their focus to other countries. If a supply issue arises, both Pharmac and the sole supplier will attempt to source alternative approved brands of the medicine. However, if that fails, Pharmac may temporarily fund an unapproved brand until the sole supply brand becomes available again or the unapproved brand receives provisional approval from Medsafe.

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 stock shortages of approved medicines listed on the Pharmaceutical Schedule, and the current practice by Pharmac to address these 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, which led to global shortages of key medicine ingredients, and this trend continues to expand and is now impacting the availability of common medicines across the motu.

While we recognise that Pharmac's use of unapproved medicines is preferable to having no access to medicines at all, this practice can create legal vulnerabilities. This is especially true for medical practitioners, who are currently the only prescribers authorised to prescribe unapproved medicines, as well as for pharmacists. Both may face potential legal issues, charges of professional misconduct, or other disciplinary actions, 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.

Proposal – current unaddressed issues

While we acknowledge that this proposal's scope focuses exclusively on enabling pharmacist prescribers to prescribe unapproved medicines, we would like to highlight that broadening the range of prescribers authorised to do so (which we support) simply shifts a bigger issue to more prescribers and doesn't address the overarching problem. There remains a critical gap in understanding the legal and operational requirements for both prescribers and pharmacists when it comes to prescribing and dispensing unapproved medicines, both at the initiation of a prescription and when transitioning from an approved brand to an unapproved brand of a

medicine during the life of an existing valid prescription, due to the changes in funding by Pharmac.

We attempt to summarise these concerns below so that they can also be considered when Cabinet is making their decision.

- General challenges in New Zealand's medicine supply chain, stemming from global production, freight, and availability issues, can result in frequent updates of the Pharmaceutical Schedule, with funded approved medicines being substituted for funded unapproved medicines throughout the month. Some changes may be implemented immediately in response to urgent needs, while others will be scheduled to coincide with the start of a new month. Unlike community pharmacy management systems (PhMS), which must be regularly updated to ensure accurate funding and payment of dispensing services, there is no requirement for prescriber management systems (PMS) to have the same level of updates. As a result, prescribers may not realise that a funded approved medicine has been replaced by a funded unapproved medicine when prescribing it, leading them to fail to fulfil their legal and ethical obligations when prescribing an unapproved medicine.

- The absence of a datasheet for an unapproved medicine creates barriers for prescribers in determining whether it is clinically appropriate to substitute an unapproved medicine for an out-of-stock approved medicine. Conversations with medical practitioners and pharmacists reveal differing assumptions about Pharmac's due diligence, leading some to believe they do not need to verify the clinical appropriateness of such substitutions. As both prescribers and pharmacists are obligated by professional and ethical standards to prioritise patient safety and adhere to legal requirements, this may lead to ethical dilemmas where both healthcare professionals must balance meeting patient needs against the risk of potential harm, all while protecting their professional reputations and avoiding disciplinary actions from their regulatory bodies.

- During the lifespan of a funded prescription – three months for most medicines, six months for oral contraceptives, and 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. In some cases, an approved brand of a medicine may be available for the initial supply to a patient, but subsequent supplies might involve an unapproved brand of the medicine being listed as the funded alternative on the Pharmaceutical Schedule. In these cases, the prescriber was not aware at the time of the prescribing that their patient would receive an unapproved brand of a medicine, thereby potentially failing to meet their legal and ethical obligations when it comes to the prescribing of an unapproved medicine.

- According to section 29 of the Act, pharmacists must obtain authorisation from a medical practitioner before an unapproved medicine can be supplied to a patient. However, when we have approached community pharmacies, we have observed varying practices when there are changes to the approval of a funded medicine, whether at the first dispensing of the prescription or midway through the lifespan of a prescription (e.g. a repeat supply of a medicine). These varied practices stem from several factors, including a lack of understanding of the legal and ethical requirements for both the prescriber and pharmacist due to the absence of clear guidelines. Some individuals assume that legal and ethical obligations are not necessary, believing that Pharmac’s regular substitutions of unapproved medicines in place of approved medicines on the Pharmaceutical Schedule indicate prior arrangements with Medsafe. Additionally, there is pressure and negativity from patients, who are not aware of the

rules governing the procurement, prescribing and dispensing of unapproved medicines, and pharmacists facing abusive comments from prescribers when seeking authorisation or a new prescription further complicates the situation. Examples of the varied practices in community pharmacy when there are changes to the approval of a funded medicine include:

- The pharmacist supplies an unapproved brand of the prescribed medicine to the patient, providing counselling and explaining that there is a new funded brand of the prescribed medicine, with no further explanation about the fact that the alternative brand of medicine is unapproved, nor is the prescriber notified that an unapproved medicine has been dispensed and supplied to their patient under their prescription, and no informed patient consent has been obtained.

- The pharmacist notifies the patient that the approved brand of their prescribed medicine is out of stock and that Pharmac has permitted the substitution of an unapproved brand of the same medicine. The pharmacist provides an explanation to the patient as to what an unapproved medicine is and asks the patient if they are comfortable receiving it as an alternative (although it is not a requirement of the pharmacist to undertake this process). If the patient is comfortable to receive the alternative unapproved funded medicine, the pharmacist proceeds to supply it. In this scenario, the pharmacist may or may not notify the prescriber about the dispensing and supply of the unapproved funded brand of medicine for their patient, so that the prescriber can fulfil their legal and ethical obligations and contact the patient to obtain informed consent.

- The pharmacist informs the patient that the approved brand of their prescribed medicine is out of stock and that Pharmac has funded an unapproved brand of the same medicine as a substitute. However, the pharmacist explains to the patient that they are not authorised to supply the unapproved brand without first notifying the prescriber, who must discuss the substitution with the patient and obtain their informed consent. The pharmacist must then inform the prescriber of the situation and wait for them to have a conversation with the patient. The prescriber must then communicate their authorisation for the pharmacist to dispense the unapproved funded brand of medicine once the patient consents. In this scenario, the pharmacist may or may not send a hard copy of the prescription back to the prescriber to endorse with their authorisation that the unapproved funded brand of medicine can be supplied as informed consent has been obtained from the patient. All these steps will take time for both the pharmacist and the prescriber and may result in the patient being without their medicine if these steps cannot be completed in a timely manner.

- The pharmacist informs the patient that the approved brand of prescribed medicine is out of stock and that Pharmac has funded an unapproved funded brand of the same medicine as a substitute. However, since the original prescription was written by a prescriber who is not authorised to prescribe unapproved medicines, the patient will need to obtain a new prescription from a prescriber who has the legal authority to do so before they can receive their next supply of prescribed medicine. This may result in a number of scenarios, including the patient being without their medicine and/or incurring additional costs. This particular scenario would be removed if the proposal was expanded to include all authorised prescribers, not just pharmacist prescribers.

- Currently, there is insufficient IT infrastructure to facilitate timely communication between prescribers and pharmacists. The NZePS is still under development, and the removal of funding from the Health New Zealand's Hira programme has 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. Without these essential IT systems in place, communication between prescribers and pharmacists relies on phone calls or emails, which can be delayed due to workforce pressures.

- With any proposal to change the supply of a medicine for treating a diagnosed condition, we must consider the impact the change has on patients. As highlighted earlier, there are several areas where the patient will be adversely affected by the rules under section 29 of the Act. For instance, pharmacies are unable to procure unapproved medicines in anticipation of a prescription, which can lead to delays in obtaining the necessary treatment for a patient. Furthermore, pharmacists cannot process a repeat supply of a medicine without a request from the patient. If the repeat supply involves an unapproved brand of the medicine, the pharmacist must wait for the patient's request before ordering it, potentially causing further delays in treatment. While this may be circumvented by the pharmacy 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 the number of funded unapproved medicines increases, community pharmacies are facing frustrated and distressed patients who do not understand the legislation and ethical obligations involved in procuring, prescribing, and supplying unapproved medicines. These requirements can delay patients from receiving their prescribed treatments, negatively impacting their health and leading to customer complaints.

- It is important to recognise that suppliers of alternative funded brands of unapproved medicines have little incentive to seek provisional or full approval from Medsafe. Since Pharmac's tendering process typically grants sole supply status to one specific brand of medicine for a set duration, the alternative unapproved brand is likely to be used only for a short period of time. Given the costs associated with obtaining provisional or full approval from Medsafe, some suppliers may not see it as financially worthwhile to pursue the process and pay the fees, especially if their sales will be limited until the sole supply brand becomes available again.

Thank you for considering our additional feedback. We look forward to engaging with you further on this proposal.

Yours sincerely

Andrew Gaudin
Chief Executive