PHARMACY GUILD OF NEW ZEALAND

16 June 2025

PHARMAC
PO Box 10254
The Terrace
Wellington 6143

Sent via email to: *consult@pharmac.govt.nz*

Dear Sir/Madam,

Re: Consultation on possible brand changes through the 2024/2025 Annual Invitation to Tender

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 appreciate the opportunity to provide feedback. Rather than provide specific feedback on each individual medicine included in the 2024/2025 Invitation to Tender, our response is structured around the key questions outlined in the online feedback form, and where relevant, we have included examples from the proposed medicine list to illustrate our concerns.

What would be the key issues for Pharmac to consider if there was a change in funded brand for the proposed medicines?

- **Supply chain vulnerability from sole supply arrangements** – While sole supply contracts may offer short-term cost savings, they create a fragile and inflexible supply chain vulnerable to disruption, where reliance on a single supplier means that any manufacturing, regulatory, or logistical issue can quickly cause nationwide shortages. These shortages have serious impacts on patient care, including treatment delays, therapeutic compromise, and increased risk of harm, which is particularly concerning for high-demand medicines like oral antibiotics (e.g., cefalexin) and critical-use items (e.g., mitomycin C, water for injection). These disruptions also burden healthcare providers, who are forced to spend time prescribing or dispensing new medicines, adjusting treatment plans, and providing additional patient counselling.

- **Risks to patient adherence due to patient-specific factors –** Brand changes can impact adherence in certain patient groups. Medicines that are visually or sensorially distinctive, such as liquids (e.g., cefalexin oral suspension, ferrous sulphate liquid, paracetamol oral liquid), or those with a noticeable colour, size, taste, texture, or smell (e.g., bisacodyl, docusate sodium with sennosides, ferrous sulphate, colchicine, celecoxib) may be rejected by patients. Mental health patients stable on existing regimens (e.g., sertraline, fluoxetine, citalopram) may experience anxiety, nonadherence, or a perceived loss of efficacy due to nocebo effects. Older adults, especially those with dementia or cognitive decline, may become confused or distressed by even minor changes in medicine appearance, packaging, or instructions,

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disrupting well-established routines, particularly for patients who manage complex or multiple medicines independently.

- **Stock wastage and financial impact –** Pharmacies may incur a financial loss if they are left to write off residual stock of delisted brands, which is concerning for high-volume (e.g., docusate sodium with sennosides, amoxicillin, cefalexin, paracetamol oral liquid) or slow-moving medicines, particularly if they are of high cost (e.g., fulvestrant, pirfenidone, mitomycin C), where residual stock may not be used before expiry or delisting takes effect. This is especially challenging for smaller or rural pharmacies with less flexibility in managing stock turnover. There must be measures in place for pharmacies to mitigate this risk but with sufficient lead-in time to adjust their stock and dispensing practices, clear communication regarding timelines for the brand change and return/credit options with wholesalers and supplies to enable pharmacies to return unused stock of the outgoing brand without financial penalty.

- **Operational disruption and increased workload –** Changing brands can cause substantial operational disruption within community pharmacies, where such switches require multiple workflow adjustments, including updating dispensing software and inventory systems, managing stock rotation to avoid wastage, and purchasing of new canisters for dispensing robots. With existing workforce pressures, pharmacy teams must spend extra time counselling patients, explaining differences in appearance, addressing concerns about effectiveness or safety, and managing any adverse reactions or confusion, which can be time-consuming for vulnerable populations such as children, the elderly, or those with low health literacy.

Are there any groups of people for whom it would be clinically inappropriate or more difficult to undergo a brand change for the proposed medicines?
Yes, there are specific groups of people that Pharmac should pay close attention to, particularly where clinical disadvantage or difficulty with transitioning may arise. The key groups include:

- **Paediatric patients** – Infants and children prescribed oral liquid medicines are highly vulnerable to changes in excipients, such as preservatives, sweeteners, and flavouring agents, where substances like propylene glycol, benzoates, parabens, and certain other excipients can pose risks of toxicity or hypersensitivity reactions in this population. Even minor variations in taste, viscosity, texture, colour, or appearance can significantly affect a child's acceptance of the medicine, potentially leading to refusal and reduced adherence. Changes in concentration or formulation can also increase the likelihood of dosing errors by caregivers, compromising treatment safety, efficacy and therapeutic outcomes. This is particularly important for the medicines frequently used in children, such as paracetamol, cefalexin, ferrous sulphate, and phenoxymethylpenicillin.

- **Older adults or individuals with cognitive impairment –** Elderly patients and those with dementia or cognitive decline may become confused or distressed when familiar medicines are substituted with unfamiliar brands. Changes in the colour, shape, size, packaging, brand names, or instructions of a medicine can disrupt well-established routines, especially those who self-manage complex or polypharmacy regimens, and can heighten the risk of dosing errors. While the majority of the proposed medicines could be used in older adults, the medicines of concern include citalopram, fluoxetine, and sertraline, where nonadherence may result in mood destabilisation or relapse of mental health conditions, and enalapril, furosemide, celecoxib, and colchicine, which are commonly used in older or frail individuals,

where even minor errors or reduced adherence can lead to clinical deterioration, falls, or toxicity.

- **Patients with critical conditions –** Brand changes in this group carry significantly higher clinical risk due to potential variability in absorption, formulation, excipients, and bioavailability between products. Even minor differences can lead to subtherapeutic or toxic effects, particularly for those with a narrow therapeutic index, where maintaining consistent drug levels is essential to avoid treatment failure, adverse drug reactions, or clinical destabilisation. The following medicines from the proposed list warrant particular caution:
    - Methadone – even small variations in dose or formulation may result in under- or overdosing, posing serious risks due to methadone's potency and long half-life.
    - Enalapril and losartan with hydrochlorothiazide – in patients with heart failure or unstable cardiovascular conditions, even slight inconsistencies in formulation may impact blood pressure control or fluid balance.
    - Pirfenidone – used in the management of idiopathic pulmonary fibrosis, a progressive and life-threatening condition, where stable and reliable dosing is critical to slowing disease progression.
    - Fulvestrant and mitomycin C – both medicines are used in oncology, where precise dosing is essential due to their narrow therapeutic margins, and any variability may compromise treatment efficacy or increase the risk of toxicity.

- **Patients with excipient sensitivities and formulation differences** – Although the active ingredient remains consistent across brands, differences in excipients, such as sweeteners, colourants, preservatives, dyes, gluten, lactose, and stabilisers, can significantly impact tolerability, particularly in individuals with known allergies, sensitivities, or intolerances. This is especially important in paediatric, elderly, or medically complex patients, where even minor formulation changes can trigger allergic reactions or gastrointestinal symptoms, potentially leading to adverse effects, non-adherence, or reluctance to continue treatment. While this consideration applies broadly across the proposed medicine list, additional caution is advised for the following medicines:
    - Oral liquids and suspensions – often contain sweeteners, dyes, alcohols, and preservatives that may cause intolerance.
    - Chloramphenicol eye drops – some patients are sensitive to changes in preservatives.
    - Methadone tablets – excipient differences may affect absorption or tolerability due to the medicine's narrow therapeutic index.
    - Ferrous sulphate tablets – associated with gastrointestinal side effects and formulation differences can influence absorption and tolerability.
    - Colchicine – has a narrow therapeutic window and gastrointestinal side effects from excipients may increase toxicity risk.
    - Heparin sodium injection – variations in preservatives or stabilisers can trigger hypersensitivity reactions.
    - Mitomycin C and fulvestrant – excipient tolerability is critical in oncology patients with heightened sensitivity.
    - Ethinyloestradiol with levonorgestrel – may contain dyes, lactose, or sugars, and excipient or formulation differences can affect tolerability and, rarely, contraceptive efficacy, due to altered absorption.

- **Mental health patients stable on a current regimen –** Patients with psychiatric conditions who are stable on a particular antidepressant regimen may experience a decline in therapeutic

response following a brand switch, which may be due to actual differences in bioavailability between formulations or the psychological impact of brand changes (placebo or nocebo effects), where even minor variations in excipients or drug release profiles can affect drug absorption, tolerability, or perceived effectiveness. For patients managing chronic mental health conditions, these disruptions can lead to destabilisation, increased anxiety, reduced adherence, or relapse. Consistency in the brand and formulation is particularly important for this group and any changes in brand should be made cautiously and with clinical oversight, e.g., citalopram, fluoxetine, sertraline, and methadone.

- **Neurodiverse patients –** Children and adults who are neurodiverse, such as those with ASD, ADHD, or sensory processing disorders, may have heightened sensitivities to changes in taste, texture, smell, colour, brand or appearance of medicines. Even minor variations in formulation, such as switching brands of oral liquids, e.g. paracetamol, ferrous sulphate or cefalexin, can cause significant distress or refusal to take the medicine, resulting in poor adherence, missed doses, or complete treatment failure. For some neurodiverse individuals, rigid routines and predictability are crucial for maintaining wellbeing, and unexpected changes to medicine appearance or administration can trigger anxiety and behavioural issues.

What support or resources would people using these medicines need if a brand change were to occur?

If a brand change were to occur for the proposed medicines, patients would require a range of resources and support to ensure a smooth transition. This includes all the suggested options listed in the online form, with the following key considerations:

- Patients should receive clear, simple, easy-to-understand explanations about the brand change, including why the change is happening, confirmation that the new brand has the same active ingredient, and reassurance that the medicine's safety and effectiveness remain unchanged.

- The messaging should encourage patients to promptly report any side effects, concerns or changes in how they feel after switching to the new brand and educate patients on what changes are normal, e.g., appearance, versus what might need medical attention.

- Resources including visual aids showing the new packaging, tablets, or formulations, such as visual comparisons, should be provided in advance to help patients recognise the new product and reduce confusion or anxiety, especially for those managing multiple medicines.

- Resources should be accessible in a range of languages and formats, such as large print, braille, audio, or hard copy, to meet the needs of diverse populations, including those with limited digital access or different literacy levels. Equity obligations under Pae Ora (Healthy Futures) Act 2022 should be recognised and brand transition resources should be co-designed with Māori and Pacific health experts and made accessible to priority populations.

- All materials should include clear contact information for support services, such as contacting your local healthcare provider or the Pharmac helpline, to ensure patients can easily seek further advice or clarification.

What support or resources would healthcare professionals prescribing or dispensing these medicines need if a brand change were to occur?

If a brand change were to occur for any of the medicines listed, healthcare professionals prescribing or dispensing them would need a variety of support and resources to ensure patient safety, clinical continuity, and minimal disruption. This includes all the suggested options listed in the online form, with the following key considerations:

- A minimum of six months' advance notice of any funded brand change should be provided to healthcare professionals to allow adequate preparation. This lead time is critical for effective planning around stock transition, including ordering and inventory management, to avoid supply disruptions, prevent medicine shortages, and minimise wastage due to overstocking of superseded brands.

- Comprehensive clinical and educational support should be readily available to healthcare professionals when brand changes occur and should include detailed medicine fact sheets or comparison documents that clearly outline any differences in formulation, packaging, route of administration, bioavailability, tapering, dose equivalence, excipients, appropriate monitoring requirements and other relevant factors to assist with safe and effective switching.

- Targeted education and specialist support should be made available when there is a brand change for a medicine with a narrow therapeutic index, that requires close monitoring or is commonly prescribed for vulnerable populations. This includes groups such as older adults, individuals with cognitive impairment, or those receiving treatment for mental health conditions, where changes in the medicine's appearance, packaging, or brand name may increase the risk of confusion, reduced adherence, or increase medicine errors.

- For injectable medicines it is essential that there is targeted training and updated guidance whenever there are changes in formulation, concentration, packaging, preparation, or administration techniques associated with a brand switch. This may include differences in vial size, dilution requirements, compatibility, stability, route of administration, or labelling to support safe handling and prevent administration errors.

- Clear and timely communication of proposed brand changes must be delivered through multiple channels, especially when the medicine involved is not Medsafe-approved. Transparent communication is essential to support prescribers in meeting their obligations under the Code of Health and Disability Services Consumers' Rights by ensuring patients are fully informed and able to provide valid, informed consent. Prompt dissemination of information is also critical to support safe prescribing and dispensing practices and to prevent unnecessary delays, errors, or administrative burden.

- All relevant patient management systems and dispensing software platforms should accurately reflect the new brand details, including subsidy status, Medsafe registration information, pack size, and dosage form. Additionally, proactive system alerts and prompts should be implemented in patient management systems and dispensing software platforms during the transition period to minimise the risk of selection or dispensing errors to help healthcare professionals quickly identify changes, verify medicine equivalence, and ensure the correct product is selected and dispensed.

Are there any additional features of the proposed medicines that should be considered?
Yes, there are other features of the proposed medicines that should be carefully considered prior to implementing a brand change. These include factors such as:

- **Medicine size, shape, and scoring** – Changes in the size, shape, or scoring of an oral medicine can significantly impact patient comfort and ease of swallowing, particularly for children, older adults with dysphagia, and individuals with anxiety or aversions to oral medicines. Scored tablets support easier splitting for dose adjustments or swallowing, and switching to a non-scored version may hinder accurate dosing and reduce adherence. Changes in formulation from tablet to capsule (or vice versa) may also confuse patients, disrupt established routines, and increase the risk of medicine errors, especially among those on multiple medicines or with cognitive decline.

- **Device and packaging size and design** – Variations in the size or design of medicine devices and packaging can impact usability and safety, particularly for patients with arthritis, dexterity issues, cognitive impairment, physical disabilities, or age-related limitations. Devices with different dosing mechanisms, such as syringes, droppers, or inhalers, may confuse patients and caregivers, increasing the risk of dosing errors or reducing adherence. Changes that affect ease of opening, handling, or maintaining sterility are especially important for vulnerable groups such as children and the elderly. Larger or bulkier packaging may also present logistical challenges in pharmacies, particularly for controlled drugs, where safe storage space is limited and new brands may exceed the capacity of existing safes.

- **Look-alike packaging and visual similarity** – When the packaging or appearance of a new brand closely resembles that of another medicine a patient is taking, it can lead to confusion, particularly for those managing multiple medicines, increasing the risk of the wrong medicine or dose being taken or inadvertently mixing up medicines. Visual similarity can also pose a significant risk within pharmacy dispensaries, where different strengths of the same medicine, or entirely different medicines, may be packaged in near-identical containers. This heightens the potential for selection and dispensing errors, especially in busy environments or where pharmacy workflows rely heavily on visual cues, and clear differentiation in packaging, labelling, and physical appearance is critical to ensuring both dispensing and patient safety.

- **Bulk pack size considerations for dispensing** – The pack size of medicines supplied for use in dispensing must be appropriate and practical for pharmacy workflows. Bulk pack formats that require manual "count and pour" processes or de-blistering for compliance pack repackaging significantly increase the time required for dispensing, which not only reduces efficiency but diverts dispensary staff from providing more patient-centred services and adds to the workload of an already stretched community pharmacy workforce. When selecting medicines through procurement or tender processes, greater consideration should be given to the format in which medicines are supplied. The lowest tender price for a bulk-packed medicine does not reflect the true cost to the health system, as additional costs, such as labour, consumables, and time involved in repacking, are absorbed by pharmacies.

Further feedback

- **Support for consistent application of the brand switch fee** – We strongly support the continued use of the brand switch fee and advocate for its consistent application across all clinically significant brand changes, including those in this proposal. Past brand changes have

placed additional burden on pharmacy teams, who spend considerable time addressing patient concerns about unfamiliar brands and this should be acknowledged within the brand switch fee framework. These efforts, along with updating dispensing software and explaining brand switches to prescribers, often exceeds the value of the current brand switch fee, particularly when multiple medicines change concurrently.

- **Dispensing frequency and clinical oversight –** We recommend that Pharmac carefully consider the clinical implications when determining whether a medicine should be eligible for three-monthly dispensing versus monthly dispensing. While three-monthly dispensing may offer increased convenience for some patients, a growing body of evidence demonstrates that monthly dispensing supports improved medicine adherence and better health outcomes, with each monthly dispensing enabling more frequent contact and a valuable clinical touchpoint between patients and the pharmacy team. During these encounters, pharmacists conduct essential activities such as medicine reviews, adherence monitoring, patient counselling, and safety checks. These regular interactions allow pharmacists to identify and respond to emerging concerns, including side effects, changes in clinical condition, or signs of non-adherence, before they escalate into more serious health issues.

- **Addressing medicine wastage -** Medicine wastage remains a major challenge for community pharmacies, impacting both the sustainability of healthcare funding and the quality of patient care. We encourage ongoing collaboration between stakeholders to develop and implement practical strategies to counteract this, such as the optimisation of pack sizes, where selecting pack sizes that align with common prescribing durations and clinical needs may help minimise excess medicine being dispensed and subsequently discarded. Similarly, reducing the use of unnecessarily complex or single-patient blister packaging, especially when not required for safety or adherence, can also reduce both product wastage and the generation of non-recyclable pharmaceutical waste. Medicine wastage is further exacerbated when medicines are eligible for three-month dispensing, where large quantities of unused medicines are returned, some of considerable value, due to changes in therapy, adverse effects, nonadherence, or hospital admissions, resulting in not only financial loss to the health system but also contributing to environmental waste and raising safety concerns regarding stockpiling and inappropriate medicine use.

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
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