PHARMACY GUILD OF NEW ZEALAND

5 October 2026

Medicines Classification Committee Secretary
Medsafe
Wellington

Sent via email to: committees@health.govt.nz

Dear Committee Members,

Re: Agenda for the 76th meeting of the Medicines Classification Committee (MCC)

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.

Thank you for the opportunity to provide feedback on the upcoming MCC agenda items. Our comments focus on the implications for community pharmacies and the patients they serve, including access to treatment, safe supply and practical implementation.

Our feedback covers the following agenda items:

- 6. Submissions for reclassification:
  - 6.1 Pseudoephedrine (Reckitt Benckiser New Zealand)
  - 6.2 Terbinafine (NP Brands (NZ) Ltd)
- 7. New medicines for classification
  - 7.4 GHK-Cu (for injection)
- 8. Harmonisation of the New Zealand and Australian schedules:
  - 8.2 Decisions by the Secretary to Department of Health and Aged Care Australia (or the Secretary's Delegate):
    - 8.2a Celecoxib
    - 8.2b Fluticasone
    - 8.2c Intravenous potassium salts
    - 8.2d Intranasal adrenaline

6. Submissions for reclassification

6.1 Pseudoephedrine (Reckitt Benckiser New Zealand)

We do not support the proposed reclassification of small-pack pseudoephedrine from a restricted (pharmacist-only) medicine to a pharmacy-only medicine on the evidence currently presented. However, we do acknowledge the importance of ensuring that controls remain proportionate while supporting timely access to effective treatment.

While the illicit methamphetamine market has changed considerably since pharmacy-sourced pseudoephedrine was a significant precursor source, the proposed 240 mg pack limit does not address repeated purchases or purchases across multiple pharmacies. In our view, limiting pack size and retaining pharmacist oversight address different risks, and the former does not necessarily substitute for the latter.

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Pseudoephedrine returned to non-prescription pharmacy supply in New Zealand in 2024 under a restricted medicine framework requiring pharmacist involvement. The reported absence of significant diversion or increased pharmacy crime since reintroduction is reassuring. However, this experience has occurred with mandatory pharmacist assessment in place and does not establish whether that safeguard is no longer needed. We consider it too soon to conclude that pharmacist involvement is no longer warranted.

Reducing diversion of pseudoephedrine from the legitimate pharmacy supply chain and reducing the wider availability or harmful use of methamphetamine are separate outcomes. The applicant's discussion of Australia's Project STOP illustrates this distinction: pharmacy diversion may be reduced without materially affecting the wider illicit methamphetamine market.

For therapeutic use, the relevant issue is whether the proposed safeguards adequately replace individual pharmacist assessment. Although small pack sizes limit the quantity supplied, they do not remove contraindications or interactions or prevent duplicate therapy and inappropriate use. Labelling also relies on consumers recognising when their medical conditions or other medicines are relevant. Pharmacy-only classification would retain access to pharmacist advice but would remove the requirement for pharmacist assessment at each supply. We do not consider pack size and labelling alone to provide an equivalent safeguard.

The applicant presents reduced pharmacist workload and improved pharmacy workflow as benefits of reclassification. We support reducing unnecessary administrative burden and allowing pharmacists to devote more time to clinical care. However, these benefits should be weighed against the safety and public-interest value of pharmacist involvement. Where an assessment identifies inappropriate treatment or supports safer use, the time involved is clinical activity rather than simply regulatory burden. We consider pharmacist involvement in pseudoephedrine supply continues to provide such value.

We recommend that the MCC retain the existing restricted medicine classification of pseudoephedrine at this time. Future reconsideration should draw on New Zealand sales volumes, attempted inappropriate or repeated purchases, theft or diversion incidents, pharmacists' practical experience, relevant Police information, and clinically inappropriate supply identified through pharmacist assessment. Evidence from comparable overseas pharmacy-only arrangements would also be relevant. This would help the MCC assess the contribution of existing safeguards and whether they remain necessary.

If the MCC nevertheless recommends a pharmacy-only entry, we recommend consideration of quantity limits, storage and display requirements, recording of repeat purchasing, and proportionate monitoring of clinically inappropriate use, misuse and diversion following reclassification.

6.2 Terbinafine (NP Brands (NZ) Ltd)

We support the proposed amendment to enable pharmacy-only supply of terbinafine preparations for application to the nails, provided this is supported by clear guidance on diagnosis, patient selection, treatment and referral. This reclassification would expand treatment options for adults with mild to moderate fungal nail infections and align access with existing pharmacy-only nail treatments, such as amorolfine and ciclopirox.

The proposed 10% terbinafine hydrochloride solution (equivalent to 98 mg/mL terbinafine), intended for application to the nails to treat mild to moderate fungal nail infections in adults, has

very low systemic absorption, supporting its suitability for pharmacy supply, and may provide an additional option for patients for whom topical treatment is appropriate, including those unable to use oral antifungals.

While we support improved access, we do not agree that nail discolouration and thickening can reliably establish a fungal diagnosis or that the scope for misdiagnosis is necessarily limited, as other nail disorders can have similar appearances. New Zealand clinical guidance recommends laboratory confirmation before antifungal treatment, and pharmacy supply should therefore be supported by clear advice on diagnostic confirmation and referral where the diagnosis is uncertain. Guidance should explain when an existing confirmed diagnosis is sufficient and when patients should be referred for testing before treatment, so pharmacists can apply the recommendations consistently.

Patients with diabetes, impaired circulation, immune disorders, painful or severely damaged nails, extensive infection or involvement of the nail growth area should seek medical assessment before commencing treatment. We recommend that the supplier provide free product-specific education and practical resources for pharmacists and pharmacy staff which cover recognition of suitable presentations, referral criteria, correct application, adverse effects, monitoring of response and when treatment should be reviewed.

It is also important that consumers understand the commitment involved. Daily treatment may be needed for approximately six months for fingernails and nine to twelve months for toenails, with costs accumulating over the course, and clearing the fungal infection does not necessarily mean the nail will return to a normal appearance. Product information and advertising should set realistic expectations and claims that this product is more effective than existing treatments should be supported by evidence for this formulation. Consumers should receive clear advice on when to seek further assessment if the condition worsens, adverse effects occur or treatment is not helping. This would help avoid continued repeat purchasing where treatment is inappropriate or ineffective.

We also recommend that Medsafe ensure the classification wording consistently addresses nail application across the prescription and pharmacy-only entries. As the application concerns a particular nail formulation and adult indication, these should be clearly reflected in the approved product information, with appropriate age restrictions and warnings. With these safeguards, pharmacy-only access would provide an appropriate additional treatment option while supporting informed choice, responsible antifungal use and timely referral.

7. New medicines for classification

7.4 GHK-Cu (for injection)

We support Medsafe's proposal to classify GHK-Cu for injection as a prescription medicine.

We note Medsafe's advice that injectable forms have been intercepted at the border and are being imported by individuals who sell or intend to administer them for therapeutic purposes, despite uncertainty regarding product quality, efficacy and interactions with other medicines. This is materially different from the cosmetic use of topical copper tripeptide products.

Products intended for injection introduce additional risks relating to sterility, product quality, dose, administration and adverse effects. Where injectable products are being promoted or supplied for therapeutic purposes without an established evidence base or regulatory oversight, prescription medicine classification is a proportionate public-safety measure.

8. Harmonisation of the New Zealand and Australian schedules

8.2a Celecoxib

We support the reclassification of celecoxib in tablets or capsules of 200 mg or less, in a primary pack not containing more than 10 dosage units, from a prescription medicine to a pharmacist-only (restricted) medicine for the short-term treatment of acute pain due to primary dysmenorrhoea or musculoskeletal or soft tissue injuries in adults aged 18 years and over.

Celecoxib is a selective cyclooxygenase-2 (COX-2) inhibitor with an established role in pain management. The proposed restrictions appropriately recognise celecoxib's established role in acute pain management while retaining pharmacist assessment of relevant gastrointestinal, cardiovascular and renal risks, concomitant medicines, and the appropriateness of short-term treatment.

We consider that community pharmacists are well placed to provide safe and clinically appropriate access to celecoxib within the proposed indications. Pharmacists already routinely assess and manage patients requiring NSAIDs and are experienced in identifying contraindications, managing drug interactions, and ensuring medicines are used appropriately and for the correct duration. These established competencies provide a strong foundation for safe pharmacist-led supply within an appropriate regulatory framework. Importantly, pharmacist consultation provides an additional clinical safeguard to ensure celecoxib is used appropriately and not to mask ongoing symptoms or delay the diagnosis of a more serious condition. Where a patient's clinical presentation, risk profile, or treatment expectations are not consistent with short-term use, pharmacists will recommend alternative options or facilitate timely referral to a general practitioner.

Enabling pharmacist supply of celecoxib would improve timely access for patients requiring short-term management of acute pain and inflammation, particularly where access to prescribers is limited or delayed. This is consistent with broader health system objectives to utilise community pharmacy as an accessible first point of care. Australia provides a relevant precedent for supply with mandatory pharmacist involvement, defined indications and small packs. The proposed pack size of 10 dosage units is appropriate to reinforce short-term use and minimise the risk of adverse events associated with prolonged or inappropriate use. However, clear advice on treatment duration and repeat requests is also needed to avoid prolonged use through successive purchases.

To support consistent implementation, we recommend clear, nationally consistent product information and practical guidance for pharmacists covering:

- Approved indications, dosing and treatment duration, including a maximum of five days without medical advice, consistent with the Australian non-prescription product.
- Relevant contraindications, precautions and interactions, including cardiovascular, gastrointestinal and renal risks, pregnancy, allergy history and concurrent NSAID use.
- Patient advice on correct use, potential adverse effects and when to seek medical assessment.
- Referral where symptoms persist, worsen or are atypical, and management of repeat requests to avoid prolonged use.
- Clear communication to pharmacists, prescribers and consumers about the scope of non-prescription supply.

8.2b Fluticasone

We support the pharmacy-only classification of fluticasone aqueous nasal sprays delivering 50 micrograms or less per actuation. This would permit a maximum recommended daily dose of 400

micrograms, explicitly include treatment of rhino-conjunctivitis, and allow treatment for up to six months in adults and children aged 12 years and over, subject to the approved product instructions.

Allergic rhinitis and associated ocular symptoms are common presentations in community pharmacy. Reclassification would support timely access to treatment and advice through pharmacy, helping patients manage their symptoms without a separate prescriber appointment where self-care is appropriate. It would also provide clearer conditions of supply for pharmacists and pharmacy staff. Explicitly including rhino-conjunctivitis would better reflect clinical practice, as nasal and ocular allergic symptoms frequently occur together. This is consistent with Medsafe's existing interpretation that products for rhino-conjunctivitis fall within the pharmacy-only classification.

We support increasing the permitted maximum daily dose from 200 to 400 micrograms where consistent with the approved product's dosing instructions. Australian pharmacy-only access and UK non-prescription product information provide relevant precedents. However, the higher limit should not be presented as the usual dose for all consumers, and consumers should use the lowest effective dose and reduce the dose once symptoms are controlled.

We also support specifying treatment for up to six months, recognising that allergic rhinitis may require treatment over a prolonged season or with ongoing allergen exposure. Consumers should receive clear advice to seek review sooner if treatment is ineffective and to reduce the dose once symptoms are controlled.

Community pharmacists are well placed to advise on appropriate treatment, correct spray technique, regular use and when further assessment is needed. We recommend that reclassification be supported by clear product information and practical guidance for pharmacists and pharmacy staff covering:

- Age restrictions, dosing and reduction to the lowest effective dose.
- Correct administration, expected time to benefit, and review where symptoms remain inadequately controlled.
- Relevant precautions, other corticosteroid use and medicine interactions, including ritonavir and cobicistat.
- Referral for persistent nosebleeds, nasal ulceration, unilateral symptoms, eye pain or visual changes.
- Review of prolonged treatment, particularly in adolescents and patients who continue to require higher doses.

The approved product instructions should remain the basis for supply and counselling, including any shorter treatment or review intervals. Clear communication to pharmacies and consumers should explain that the classification change does not automatically alter the approved directions for every existing product.

8.2c Intravenous potassium salts

We support in principle the proposed prescription medicine classification for concentrated intravenous potassium preparations.

Concentrated intravenous potassium is a high-risk medicine, and incorrect preparation or rapid administration can result in serious harm, including cardiac arrest and death. The proposed approach appropriately distinguishes concentrated preparations from lower-concentration preparations and pre-mixed infusion bags, recognising that regulatory controls should improve safety without unnecessarily restricting legitimate clinical access.

We also support Medsafe's proposal to specifically exclude parenteral nutrition replacement preparations from the New Zealand entry, as the equivalent exclusion occurs through a different mechanism in Australia.

From a community pharmacy perspective, our principal concern is avoiding unintended consequences. Although concentrated intravenous potassium is predominantly used in secondary care, the classification change should be checked against approved New Zealand products and any existing legitimate community-based supply arrangements. We recommend that Medsafe confirm that the wording captures the intended preparations and exemptions, and that any changes to requirements for pharmacies supplying community-based services under appropriate clinical authorisation are clearly communicated before implementation.

8.2d Intranasal Adrenaline

We support the proposed classification of intranasal adrenaline in preparations containing 2% or less of adrenaline, as a pharmacist-only (restricted) medicine, should an appropriate product be approved for use in New Zealand.

Adrenaline is a well-established, life-saving medicine and remains the first-line treatment for anaphylaxis. Its pharmacological effects include rapid reduction in airway oedema, reversal of bronchospasm, and support of cardiovascular function through vasoconstriction and increased cardiac output. Prompt administration of adrenaline is critical, as delayed or absent use is associated with increased risk of biphasic reactions, prolonged hospitalisation, and mortality. However, despite clear clinical guidance, underuse of adrenaline in anaphylaxis is widely reported, with key barriers identified including lack of immediate access to an adrenaline auto-injector at the time of the reaction, reluctance to carry a device, needle phobia, and uncertainty around correct administration technique.

Intranasal adrenaline offers a non-invasive, rapid-delivery alternative to intramuscular injection, with the potential to help overcome some of these barriers in emergency situations. This may be particularly beneficial for children, individuals with needle phobia, or those who may be hesitant or unable to administer an injection in an acute setting. In addition, intranasal delivery removes risks associated with injection-related errors, such as accidental digital injection and associated local complications.

Australia's pharmacist-only classification provides a relevant precedent, with intranasal products also being approved in the United States and European Union. These approvals support establishing a classification pathway in New Zealand, with supply and advice based on the characteristics of the product ultimately approved.

Community pharmacists already support access to adrenaline auto-injectors and provide advice on recognising anaphylaxis, administration technique and emergency management. Pharmacist supply of intranasal adrenaline would build on this role, improving access to another emergency treatment option, while pharmacist assessment and counselling would support appropriate patient selection and patient and caregiver education.

Community pharmacies also provide a wide range of vaccination services. Pharmacist vaccinators are trained to recognise and manage anaphylaxis, including administering adrenaline and arranging emergency assistance. This experience provides a strong foundation for introducing a new formulation, supported by product-specific education. Clear guidance will be needed on any

role for intranasal adrenaline within vaccination services, including its place alongside existing requirements for intramuscular adrenaline and emergency equipment.

A pharmacist-only classification provides an appropriate balance between improved access and professional oversight. Pharmacists' existing experience in anaphylaxis management and patient counselling would support supply of this additional treatment option.

To support introduction of any approved product, we recommend clear product information and practical guidance covering:

- Approved indications, age and weight limits, nasal conditions that may affect absorption, dosing and repeat dosing, and when an injectable adrenaline product is preferred.
- The number of devices patients should carry, storage, expiry dates and replacement after use.
- Patient and caregiver advice on recognising anaphylaxis and correct administration, including the instruction to administer adrenaline promptly and call 111 immediately, even if symptoms improve.
- Consistent advice across intranasal products and adrenaline auto-injectors, including their place in patients' anaphylaxis action plans.
- Clear labelling and instructions that are easy to follow during an emergency.

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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