PHARMACY GUILD OF NEW ZEALAND

8 July 2025

Medicines Classification Committee Secretary
Medsafe
Wellington

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

Dear Committee Members,

Re: Agenda for the 74th meeting of the Medicines Classification Committee (MCC)

Thank you for the opportunity to provide feedback on the upcoming MCC agenda items.

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.

Our feedback covers the following agenda items:

- 5. Submissions for reclassification:
  - 5.1 Tenofovir disoproxil and emtricitabine (Burnett Foundation)
  - 5.2 Respiratory Syncytial Virus (RSV) vaccine, adjuvanted (GSK New Zealand)
  - 5.3 Bilastine (Menarini New Zealand Pty Limited)
  - 5.6 Paracetamol – proposal to allow provision by vaccinators (Te Whatu Ora, Health NZ)
  - 5.7 Peptide Groups (Medsafe)
- 7. Harmonisation of the New Zealand and Australian Schedules:
  - 7.2 Decisions by the Secretary to Department of Health and Aged Care Australia (or the Secretary's Delegate):
    - 7.2a Desloratadine
    - 7.2b Atropa belladonna
- 8. Matters arising:
  - 8.2 Brimonidine
  - 8.4 Cetirizine

5. Submissions for reclassification

5.1 Tenofovir disoproxil and emtricitabine (Burnett Foundation)

The Guild continues to strongly supports the proposal by the Burnett Foundation for the reclassification of disoproxil and emtricitabine to a prescription medicine, except when supplied for HIV prophylaxis to people who are over 18, are HIV negative, and meet the clinical and eligibility criteria of an approved training programme, when provided by a pharmacist who meets the requirements of the Pharmacy Council. This proposal represents a significant step forward in improving access to HIV pre-exposure prophylaxis (PrEP) in New Zealand, which is a proven option that can reduce the risk of HIV transmission by up to 99%. Enabling pharmacist-led supply removes key barriers to access and promotes more equitable access to this vital preventative treatment, contributing to a reduction of both individual and community-level HIV risk.

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Access to culturally competent sexual health prevention, treatment, and care is essential for people living with HIV and priority populations in New Zealand. Recent data from the University of Otago's HIV Epidemiology Group highlights growing concern and in 2024, the country recorded its highest number of AIDS diagnoses in over a decade, with 28 new cases. Alarmingly, 20 of these were diagnosed with AIDS within three months of their initial HIV diagnosis, highlighting a pattern of late detection. Despite the proven effectiveness of HIV prevention tools like PrEP, uptake remains below target, particularly among Māori and Pacific communities, and ongoing barriers such as limited geographic access, inconvenient appointment times, a shortage of prescribers offering PrEP, and cultural challenges continue to hinder progress. The National HIV Action Plan for Aotearoa 2023–2030 prioritises combination prevention, integrating biomedical, behavioural, and structural approaches to reduce new infections. To bridge these gaps, innovative models of service delivery are urgently needed and strategies such as expanding telehealth, enhancing community outreach, enabling rapid point-of-care testing in primary care, and developing new access pathways for PrEP, including pharmacist-led supply, can play a crucial role in improving equitable access.

Community pharmacies offer a largely untapped opportunity to improve access to PrEP for HIV prevention. As trusted and highly accessible healthcare providers, often in convenient locations with extended hours and no need for appointments, pharmacies are well positioned to reduce stigma and address barriers that prevent people from accessing care. Research has shown that patients already turn to community pharmacists for PrEP advice and value the discretion, accessibility, and familiarity they provide. Although PrEP has been publicly funded since 2018, many eligible individuals, particularly those at highest risk, such as recent migrants, people without stable housing, or those experiencing stigma, remain underserved. Reclassifying PrEP to allow pharmacist supply would open up a critical new access point for these groups, with this model prompting appropriate testing for HIV, STIs, and other conditions, enabling early intervention, improved health outcomes, and stronger links to broader health services. It would also uphold the principles of informed choice and alignment with the Health and Disability Code by ensuring accessible, safe, and evidence-based care. With robust safeguards, referral processes, and clinical oversight, pharmacist-led PrEP provision has the potential to increase uptake, reduce inequities, and contribute meaningfully to New Zealand's goal of eliminating HIV.

Pharmacists are well-positioned to deliver PrEP services, leveraging their expertise in pharmacotherapy, patient counselling, and managing drug interactions, and play a key role in supporting medicine adherence, addressing related health concerns, and reducing pressure on general practice, while also contributing to the normalisation of sexual health care. The proposed pharmacist-led model is underpinned by robust safety mechanisms, including standardised protocols, clinical checklists, structured referral pathways, and mandatory training to ensure safe, appropriate supply. Pharmacists will be trained to identify key contraindications and refer complex cases according to clear clinical criteria, and for those new to PrEP or without recent test results, pharmacists will facilitate access to necessary testing, including self-request options where appropriate. Pharmacists are well equipped to support the safe and responsible provision of PrEP, with established systems for documentation, referral, and clinical oversight. While they do not directly order or receive laboratory results, pharmacists routinely review results provided by patients or through robust platforms and have proven capability in managing medicines that require laboratory monitoring, such as clozapine, allopurinol, and Paxlovid, and are skilled in interpreting laboratory data, assessing clinical risks, and collaborating effectively within the wider primary care network. Pharmacists are also supported by strong digital infrastructure, including secure access to national health information systems such as Conporto via the reCare platform, and maintain accurate, confidential records through established pharmacy IT systems. Their trusted

role within the community, combined with strong relationships with other healthcare providers further supports an integrated, patient-centred approach in the delivery of PrEP.

We strongly encourage the MCC to give full consideration to the proposal to reclassify tenofovir disoproxil and emtricitabine as 'prescription medicine except when,' allowing accredited pharmacists to supply PrEP to HIV-negative individuals who meet clearly defined criteria. We acknowledge and support the leadership shown by the Burnett Foundation in advancing this model, which has the potential to significantly improve access to HIV prevention, particularly for unenrolled, marginalised, or vulnerable populations, and directly address existing inequities in PrEP uptake. With New Zealand committed to reducing new HIV infections and eliminating transmission by 2030, expanding access through trained accredited community pharmacists would complement existing services, help bridge existing gaps in healthcare delivery, support broader public health objectives, and move the country closer to achieving its HIV elimination target.

5.2 Respiratory Syncytial Virus (RSV) vaccine, adjuvanted (GSK New Zealand)

The Guild strongly supports the proposal by GlaxoSmithKline (GSK) to reclassify the adjuvanted Respiratory Syncytial Virus (RSV) vaccine to enable pharmacist vaccinators and other authorised vaccinators to administer the vaccine to adults aged 50–59 years who are at increased risk of RSV disease.

RSV can cause significant respiratory complications, particularly in older adults with underlying health conditions and international regulatory developments and clinical evidence reflect growing recognition of the vaccine's value for at-risk adults aged 50-59. In June 2024, the United States FDA approved the adjuvanted RSV vaccine for use in adults aged 50–59 with heightened risk, followed by European Commission approval in August 2024 and is already approved for use in older adults across multiple jurisdictions, including the United Kingdom, Canada, and Japan, demonstrating global confidence in its safety and effectiveness. Importantly, the adjuvanted RSV vaccine can be co-administered with inactivated seasonal influenza vaccines, including high-dose and adjuvanted formulations, with this co-administration compatibility supporting efficient integration of RSV vaccination into existing winter immunisation programmes, enhancing accessibility for patients, and easing pressure on other parts of the healthcare system.

Pharmacist vaccinators are already highly experienced in delivering adult immunisations and have rapidly incorporated RSV vaccination into their routine services alongside influenza, Covid-19 boosters, and other vaccines. They are trained to conduct thorough pre- and post-vaccination assessments, provide tailored education, and support informed decision-making for patients and caregivers. Since the RSV vaccine's launch, pharmacist vaccinators have received ongoing education from both GSK and IMAC to ensure safe and effective administration. With access to the national Aotearoa Immunisation Register (AIR) and robust digital infrastructure, pharmacists are well placed to expand RSV vaccine delivery in the same accessible settings where patients already receive other immunisations, particularly during peak flu season. Community pharmacy immunisation programmes have consistently demonstrated their effectiveness in improving both uptake and equity, with pharmacies administering nearly 500,000 influenza vaccines in 2024 alone.

Māori and Pacific peoples are disproportionately affected by severe RSV illness and hospitalisation and are more likely to have chronic conditions such as COPD, asthma, and heart disease, further elevating their risk. These communities also face systemic barriers to accessing primary healthcare. Enabling pharmacist vaccinators and authorised vaccinators to administer the adjuvanted RSV vaccine to at-risk adults aged 50–59 would support more timely and convenient access to vaccination, particularly in rural or underserved areas where general practices may be limited or

overburdened, and this approach will also reduce the need for GP visits solely for vaccination, easing pressure on the wider health system and empowering patients to receive vaccines where and when it suits them best. When paired with culturally responsive outreach and tailored health messaging, pharmacist-led immunisation offers a practical and effective way to reduce long-standing inequities and improve outcomes for high-priority populations.

We strongly urge the MCC to consider the proposed reclassification of the adjuvanted RSV vaccine to enable pharmacist vaccinators and other authorised vaccinators to administer the vaccine to adults aged 50-59 years who are at increased risk of RSV disease. Expanding access in this way would provide timely protection to a vulnerable population, align New Zealand's approach with international regulatory best practice, and leverage the accessibility and capability of community pharmacy to strengthen public health outcomes.

5.3 Bilastine (Menarini New Zealand Pty Limited)

The Guild supports the proposed reclassification of bilastine to a pharmacy-only medicine for oral use and for ophthalmic use in adults except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board.

Allergic conjunctivitis is an inflammatory condition triggered by an IgE-mediated hypersensitivity reaction following direct contact between an allergen and the conjunctiva. It involves both an early phase, driven by mast cell degranulation and histamine release, and a later phase characterised by the involvement of additional pro-inflammatory mediators. Symptoms usually affect both eyes and may include itching, redness, tearing, eyelid and conjunctival swelling, and a stinging or burning sensation. In more severe cases, patients may also experience blurred vision and sensitivity to light and can significantly affect quality of life. Although the prevalence of allergic conditions is increasing, ocular allergies remain underdiagnosed and undertreated. While allergen avoidance remains a key goal in management, this is not always feasible, therefore, early pharmacological intervention is often necessary to control symptoms and prevent progression to chronic disease.

Optimal management of allergic conjunctivitis focuses on relieving symptoms and suppressing the underlying inflammatory response. Topical ocular treatments are generally preferred, as they offer rapid symptom relief, targeted delivery, and higher local bioavailability than systemic medicines. Eye drops are also convenient, non-invasive, and well-tolerated by patients. Due to histamine's key role in allergic reactions, H1-antihistamines are commonly used, with these agents either blocking histamine receptors (neutral antagonists) or acting as inverse agonists, which both prevent receptor activation and stabilise the receptor's inactive form to reduce baseline activity. Additional treatment options include mast cell stabilisers, dual-action agents, allergen-specific immunotherapy, and corticosteroids, depending on symptom severity and frequency.

Bilastine is a potent, second-generation non-sedating antihistamine with high affinity for H1 receptors and inverse agonist activity and provides fast, long-lasting relief of symptoms associated with allergic rhinitis, urticaria, and allergic conjunctivitis. With a well-established safety and tolerability profile, bilastine has been available internationally for over a decade and is marketed in approximately 100 countries, including New Zealand, where the oral tablet has been classified as a pharmacy-only medicine since 2018. More recently, a new ophthalmic formulation of bilastine has been developed specifically for allergic conjunctivitis. The ocular formulation was first registered in Ireland on 22 July 2022, and as of March 2024, bilastine eye drops are registered in 23 countries, 22 in the European Economic Area, and in Switzerland. Clinical trials have shown this formulation delivers high concentrations to the conjunctiva, the primary site of action, while systemic absorption remains minimal. Phase II and III studies confirm its efficacy, safety, and tolerability,

demonstrating a rapid onset of action, sustained symptom control, and low systemic exposure. A recent dose-finding study of the 0.6% preservative-free eye drop demonstrated that it significantly reduced ocular itching within minutes, with effects lasting up to 16 hours, supporting convenient once-daily dosing and enhancing patient adherence.

The introduction of bilastine eye drops as a pharmacy-only medicine is a logical and appropriate extension of existing non-prescription treatment options for allergic conjunctivitis. In New Zealand, pharmacists have long been authorised to supply oral and ocular treatments for allergic conjunctivitis without a prescription, such as lodoxamide, ketotifen, and azelastine, with strong evidence supporting the effective management of these conditions in the pharmacy setting. Reclassifying bilastine eye drops would simply expand the range of antihistamine options available to adults. As pharmacy-only medicines may be sold by retail staff under a pharmacist's supervision, it will be important to mitigate risks such as inappropriate use in cases of infection or rebound redness. To support this, we recommend that the supplier provide training for both pharmacists and pharmacy/retail assistants, which should cover identification of ocular comorbidities and polypharmacy (e.g. concurrent use of multiple eye drops), best practice in managing allergic conjunctivitis, and product-specific information including bilastine's mechanism of action, correct dosage, administration, safety profile, contraindications, and referral points to optometrists or eye specialists. We also recommend that packaging include clear warnings, usage and storage instructions, contraindications, and an easy-to-understand consumer leaflet to ensure safe and appropriate use.

5.6 Paracetamol – proposal to allow provision by vaccinators (Te Whatu Ora, Health NZ)
The Guild strongly supports Te Whatu Ora Health New Zealand's proposal to amend the classification of paracetamol to include a provision allowing authorised vaccinators to administer liquid paracetamol to children under two years of age at the time of receiving the meningococcal B vaccine, Bexsero, for the prevention and treatment of fever. This proposal represents a logical and necessary step toward more equitable and consistent vaccine delivery, helping to advance public health goals for the meningococcal B vaccination rollout.

We view this proposal as a vital enabler for pharmacist, intern pharmacist and authorised vaccinators to support the safe and effective delivery of select childhood vaccines by supporting efforts to improve vaccination uptake among tamariki and acknowledging the need for a practical mechanism that allows vaccinators to provide paracetamol oral liquid in clearly defined circumstances, in line with current clinical guidelines and best practice. It is important to note that vaccinators are already permitted to obtain funded paracetamol oral liquid via a Bulk Supply Order (BSO) for this purpose and the direct provision by a pharmacist of up to 200ml of liquid paracetamol in conjunction with immunisation of a child under 2 years of age with meningococcal B multicomponent vaccine was funded last year. Extending the provision of the administration of liquid paracetamol removes a practical hurdle, aligns with Ministry of Health guidance, and better supports the principles of accessibility, efficiency, and coordinated care within the healthcare system.

We fully support this proposal for several key reasons relating to the role of pharmacist and intern pharmacist vaccinators in community pharmacy:

- Pharmacists' qualifications and expertise: Pharmacists undergo rigorous professional training and maintain comprehensive knowledge of pharmacology, dosing, and patient safety, equipping them to accurately calculate and provide appropriate dosages of paracetamol oral liquid tailored to each individual patient's age, weight, and health status. This specialised

competence makes pharmacists uniquely qualified to assume this responsibility within the community healthcare setting, reinforcing safe access to essential medicines.

- Trusted healthcare professionals: Pharmacists are among the most accessible and frequently consulted healthcare professionals throughout the motu, often serving as the first point of contact for health advice in the community and their longstanding role in ensuring the responsible use, distribution, and monitoring of medicines has earned them a high level of public trust. Pharmacists consistently provide accurate, practical, and evidence-based information, supporting informed decision-making and promoting safe medicine use. Enabling pharmacist and intern pharmacist vaccinators to provide and administer paracetamol oral liquid reinforces and builds upon this trusted relationship and acknowledges their integral role in safeguarding public health and ensuring tamariki and their whānau receive timely, appropriate care in a familiar and supportive environment.

- Expert guidance on medicines: Pharmacists routinely provide expert, patient-specific advice on the safe, effective, and appropriate use of medicines, including paracetamol, to patients, parents, and caregivers and are uniquely positioned to assess potential interactions, dosing errors, or contraindications based on the patient's age, weight, health status, and concurrent medicines. This clinical insight is particularly important in paediatric care, where precision and vigilance are critical. Pharmacists already play a key role in educating whānau on correct administration techniques, dosing schedules, and recognising signs of adverse effects and allowing pharmacist and intern pharmacist vaccinators to provide and administer funded paracetamol oral liquid as part of the Bexsero vaccination process ensures a seamless experience for caregivers, reduces the risk of dosing errors, and supports better health outcomes through timely access to evidence-based advice at the point of care.

- Reducing vaccine hesitancy: Enabling pharmacist and intern pharmacist vaccinators to provide and administer funded paracetamol oral liquid to children receiving the Bexsero vaccine is a proactive step toward improving the overall vaccination experience. Pain and fever are common post-vaccination side effects that can cause distress for tamariki and anxiety for their caregivers and by managing these symptoms effectively at the time of vaccination, vaccinators may help reduce the likelihood of negative experiences being associated with immunisation. This, in turn, can lower the chance of vaccine hesitancy for follow-up doses of Bexsero and future vaccines more broadly, where caregivers are more likely to return for subsequent doses if they feel confident that their child's comfort and wellbeing are being prioritised and supported.

- Advanced record-keeping systems: Pharmacists operate within highly structured digital environments, supported by sophisticated dispensing and clinical management software, where these systems enable precise documentation of medicine provision, including dose, timing, and recipient details, all of which are crucial for ensuring safe, accountable healthcare delivery. When pharmacist and intern pharmacist vaccinators supply and administer funded paracetamol oral liquid in conjunction with Bexsero vaccinations, the transaction can be seamlessly recorded in real-time, linked to the patient's national health record, supporting accurate auditing, improving pharmacovigilance, and enhancing data quality for service monitoring and future policy decisions.

- Improved access and convenience for whānau: Community pharmacies are one of the most accessible healthcare touchpoints across Aotearoa, with extended hours, walk-in availability, and widespread geographic coverage, including in rural and high-needs areas. Empowering

pharmacist and intern pharmacists to supply and administer funded paracetamol oral liquid when administering childhood vaccinations removes a significant barrier to uptake by streamlining the experience for caregivers, where whānau can receive both vaccination and necessary supportive care in a single visit, at a location and time that suits their daily lives, reducing logistical burden, travel time, and stress, particularly for those juggling work, transport constraints, or multiple dependents. By creating a smoother, more convenient vaccination journey, pharmacist and intern pharmacist vaccinators in community pharmacies are well positioned to deliver this integrated care with cultural responsiveness and consistency, supporting the hauora of tamariki and whānau.

5.7 Peptide Groups (Medsafe)

The Guild fully supports the proposal from Medsafe to classify a range of unscheduled peptides as prescription medicines and acknowledges the growing complexity and prevalence of novel peptides entering the New Zealand market, often promoted with unverified therapeutic claims and lacking robust safety or efficacy data. We agree that the current legislative gap poses significant risks to public health and safety, particularly as these products are frequently imported by individuals intending to self-administer them without clinical oversight, and pharmacists are often approached by consumers with questions about such substances, highlighting the urgent need for a more controlled framework.

We commend the proactive efforts of Medsafe's Investigation and Enforcement Team, which has clearly demonstrated the need for regulatory action, with the data indicating that over 50 parcels containing peptides or selective androgen receptor modulators (SARMs) were intercepted at the border in less than two months is deeply concerning. While SARMs are appropriately scheduled as prescription medicines, many peptides remain unclassified, creating a regulatory loophole that is being actively exploited. Of particular concern is the marketing of these products online as "research-only" compounds, when in reality they are being purchased and used by individuals for purposes such as performance enhancement, cognitive improvement, or sexual function, without medical supervision or assurance of product quality.

We support the proposed introduction of the ten group entries to classify currently unscheduled peptides as prescription medicines and consider this a prudent and necessary regulatory response to the escalating risks associated with the unregulated use of these substances. Group scheduling provides a more efficient and future-focused mechanism for Medsafe to respond to emerging peptides, reducing the reliance on individual classifications while maintaining appropriate regulatory control. We also endorse the proposed prescription classification of the six named peptides – larazotide, PTD-DBM, AICAR, B7-33, PNC-27, and SS-31 – which exhibit similar patterns of use and concern. This regulatory action is essential to protect public safety, minimise the risk of harm from products with unverified claims or questionable provenance, and ensures that any therapeutic use of peptides is grounded in clinical evidence and delivered within a framework of professional oversight. By reclassifying these substances as prescription medicines, healthcare professionals will be better equipped to provide clinical guidance, assess potential risks or interactions, and ensure appropriate patient monitoring. We commend Medsafe for its proactive leadership in addressing this issue and fully support the proposed amendments to the Medicines Schedule as a necessary and timely response to this emerging public health risk.

Harmonisation of the New Zealand and Australian Schedules

7.2a Desloratadine

The Guild does not support the harmonisation with the recent decision in Australia to reschedule desloratadine to permit general sales supplies when in divided preparations for the treatment of seasonal allergic rhinitis in a primary pack containing 10 dosage units or less when labelled for adults and children 6 years and over and labelled with a recommended daily dose not exceeding 5mg of desloratadine, as it poses significant risks to medicine safety, appropriate use, and equitable healthcare access.

Desloratadine is a second-generation antihistamine that works by inhibiting the body's production of histamine, helping to relieve and prevent symptoms associated with both seasonal and perennial allergies. As the active metabolite of loratadine, desloratadine is more potent, with a typical adult dose of 5mg. It also has a longer duration of action, providing up to 24 hours of symptom relief, whereas loratadine generally offers relief for 12 to 24 hours. While desloratadine is generally well tolerated, it remains a pharmacologically active medicine that can interact with other medicines or exacerbate certain health conditions, such as liver or kidney impairment. Without access to professional advice, there is a greater risk of misuse, overuse, or inappropriate use, particularly in children or individuals managing complex allergic conditions on their own.

Desloratadine is already readily accessible as a pharmacy-only medicine where it can be purchased over the counter under the supervision of a pharmacist. Removing the pharmacist's role would offer little advantage in terms of affordability or access. Allergic symptoms such as rhinitis or urticaria can be signs of more serious or chronic conditions, and pharmacists play a crucial role in assessing symptom severity and duration, identifying co-existing conditions, such as asthma or eczema, recommending the most suitable antihistamine, and checking for contraindications or drug interactions. They also provide advice on safe use in special populations (children, older adults, pregnant or breastfeeding individuals), environmental triggers, and non-pharmacological management strategies and their involvement ensures accurate assessment and referral when needed. Reclassifying desloratadine to general sale, even in small pack sizes, risks giving consumers the impression that it is completely risk-free and pack size is not an effective safeguard against inappropriate use, prolonged self-treatment, or delayed diagnosis of underlying conditions like chronic sinusitis, asthma, nasal polyps, or skin disorders. There is no compelling public health need or access barrier to justify the removal of professional oversight, and doing so would diminish opportunities for clinical guidance and increase the potential for harm through unsupervised use.

Community pharmacy-based supply ensures safe and equitable access to self-care medicines, particularly for individuals managing multiple medicines or living with chronic conditions. Pharmacists are uniquely positioned to assess polypharmacy risks, identify potential sedating effects from inappropriate product substitution, and consider co-existing health issues. Removing this layer of professional oversight disproportionately impacts underserved populations, such as Māori, Pacific peoples, and rural communities, who often face greater barriers to healthcare access and are more likely to benefit from pharmacist support when making informed medicine choices. Allowing general sale access, even for small packs, creates a two-tiered system, one offering informed, supported self-care through community pharmacies, and the other promoting unsupervised, potentially inappropriate use via general retail. This shift risks widening health disparities and may lead to poorer outcomes for those already facing health literacy and access challenges. Maintaining pharmacy-only classification for all antihistamines, including desloratadine, ensures equity by upholding a consistent minimum standard of care across all population groups.

While Australia has reclassified small packs of desloratadine to general sale, we are not aware of robust post-market surveillance or health outcome data justifying this change. New Zealand's classification decisions should reflect our unique healthcare landscape, regulatory environment, and equity challenges and harmonisation should not occur at the expense of public safety or effective medicine stewardship. Maintaining all pack sizes of desloratadine as a pharmacy-only medicine ensures continued safe and convenient access while retaining an essential layer of pharmacist oversight, ensuring allergic conditions are appropriately managed, misuse is minimised, and consumers are supported to make informed, safe self-care choices. We recommend the MCC retain desloratadine's current classification in the interests of medicine safety, responsible self-care, and equitable access to quality advice.

7.2b Atropa belladonna

The Guild supports the proposed harmonisation with Australia to reschedule *Atropa belladonna* by introducing an age restriction and limiting oral use to adults and children aged 6 years and over for pharmacy-only supply to safeguard younger children from accidental exposure or inappropriate use.

Atropa belladonna, commonly known as deadly nightshade, is a highly toxic plant belonging to the Solanaceae family. The toxic effects of *Atropa belladonna* are attributable to its alkaloid content, which possesses potent anticholinergic properties and have been traditionally used in preparations to treat the common cold and gastrointestinal issues but is no longer a commonly used product having been superseded by safer, more effective treatments. Various parts of the plant, including the roots, leaves, and berries, contain different alkaloids, including atropine, hyoscyamine, and scopolamine, and these potent tropane alkaloids are responsible for the plant's toxicity and can cause a range of severe adverse effects in both humans and animals upon ingestion or contact. Currently there are no approved *Atropa belladonna*-containing products on the New Zealand market, and its usage is expected to be minimal, however, *Atropa belladonna* is sometimes present in herbal or homeopathic products, including compounded preparations for infant colic relief. In these formulations marketed as "natural" or "homeopathic", the presence of *Atropa belladonna* may not be clearly disclosed or recognised by consumers and this lack of transparency can lead to uninformed parental use, accidental ingestion by children, and misuse driven by the common misconception that natural products are inherently safe. Therefore, introducing age-based restrictions remains an important safety measure.

The TGA has reported multiple adverse events in Australia associated with the use of *Atropa belladonna*, many of which were linked to accidental overdose, and the FDA in the United States have also issued warnings against the use of *Atropa belladonna*-containing products in infants, especially in teething tablets and homeopathic remedies, due to serious adverse events including death. The severity of symptoms depends on the amount ingested, with even small doses capable of causing anticholinergic toxicity, such as dry mouth, difficulty swallowing, flushing, blurred vision, agitation, urinary retention, and hallucinations. In more serious cases, ingestion can lead to rapid heart rate, seizures, and respiratory failure. Skin contact may also result in irritation or rashes. Due to its high toxicity, *Atropa belladonna* has a long history of use as a poison, and its medical use today is tightly regulated. While the risk associated with homeopathic products is expected to be low due to their minimal concentration of active ingredients, any use, particularly in vulnerable populations such as children, warrants caution.

Given the potential for serious harm in children, the absence of robust evidence supporting paediatric benefit and growing international concern, introducing an age restriction on the oral use

of *Atropa belladonna* in New Zealand is a prudent, proactive, and evidence-based measure to enhance medicine safety and reduce the risk of accidental exposure or misuse.

8. Matters arising

8.2 Brimonidine

The Guild remains supportive of the proposed classification change for low dose brimonidine tartrate 0.025% (low dose brimonidine) eye drops to harmonise with the TGA decision in Australia and feel it is a prudent step in ensuring efficient and safe expansion of access to this medicine in New Zealand and allowing low dose brimonidine to be used for the relief of red eyes, itching, or irritation, which is easily identified and commonly self-managed, offering a well-tolerated alternative with minimal risk of misuse or abuse. Unlike existing ophthalmic decongestants in New Zealand, brimonidine does not carry the same risk of rebound redness or reduced effectiveness with ongoing use.

Aligning with the TGA's decision, reclassifying brimonidine in New Zealand as "*prescription only, except when supplied by a pharmacist for the relief of eye redness due to minor irritation in ophthalmic preparations for adults containing no more than 0.025% brimonidine*" acknowledges the specialised knowledge and expertise that pharmacists possess in determining the suitability of this medicine for patients under the supervision of a qualified healthcare provider, enabling improved access while supporting patient care and ensuring that brimonidine is used safely and effectively for its intended purposes.

Low dose brimonidine eye drops are an ocular decongestant, and a highly selective α2-adrenergic receptor agonist used to alleviate eye redness caused by minor irritations, eye dryness and eye fatigue due to external allergens. In New Zealand, the currently available pharmacy-only ocular decongestants, naphazoline and tetrahydrozoline (tetryzoline) eye drops, are both mixed α1- and α2-adrenergic receptor agonists, with α1-adrenergic activity potentially leading to reduced effectiveness over time and rebound redness upon discontinuation. In contrast, clinical trials of brimonidine 0.025% eye drops, with its selective α2-adrenergic activity, have demonstrated significant reduction in ocular redness without evidence of tachyphylaxis, minimal rebound redness, and a favourable safety profile, further supporting its suitability for broader access.

Low dose brimonidine eye drops are currently available over the counter in the United States and Canada, and in Australia, a new Schedule 2 classification for ophthalmic preparations containing no more than 0.025% brimonidine for adults aged 18 years and over came into effect on 1 June 2023. This availability in North America, along with the recent reclassification in Australia, underscores the suitability and safety of low dose brimonidine eye drops for over-the-counter use in pharmacies. Although there are currently no approved products in New Zealand that fall under the pharmacy-only classification (i.e., containing no more than 0.025%), aligning with Australia's scheduling could improve access for New Zealand patients and support supply and commercial viability by enabling shared packaging between the two countries.

The introduction of low dose brimonidine eye drops as a pharmacy-only medicine is a logical and appropriate expansion of existing non-prescription options for relieving eye redness. In New Zealand, pharmacists have long been authorised to supply ocular decongestants, supported by strong evidence demonstrating their effective management of these conditions within the pharmacy setting and the proposed reclassification of low dose brimonidine eye drops to align with the TGA decision in Australia would simply broaden the range of ocular decongestants available to adults. Since pharmacy-only medicines may be sold by retail staff under a pharmacist's supervision,

it will be important to manage risks such as inappropriate use, overuse, and rare allergic reactions. To address these concerns, we recommend that suppliers provide comprehensive training for both pharmacists and pharmacy/retail assistants, which should cover best practices for managing eye redness, the importance of short-term use, considerations when used alongside other ocular medicines or in patients with a history of eye disease, and detailed product information including brimonidine's mechanism of action, correct dosage and administration, safety profile, contraindications, and appropriate referral points to optometrists or eye specialists. Additionally, packaging should include child-resistant caps and clear warnings emphasising short-term use only, storage instructions, contraindications, and guidance to seek medical attention if redness persists, worsens, or is accompanied by pain. An easy-to-understand consumer leaflet should also be provided to ensure safe and appropriate use.

8.4 Cetirizine

The Guild maintains its opposition to harmonising New Zealand's pack size regulations for cetirizine with the recent TGA decision in Australia, despite the recommendation made at the 71st MCC meeting on 14 November 2023 to reclassify cetirizine in alignment with Australia.

We continue to emphasise that the decision made by the MCC in 2020 to allow a five-day supply pack as general sale was based on a robust assessment process, with patient safety as the overriding priority, with a five-day supply pack being sufficient to support the general treatment goals of allergic rhinitis while encouraging appropriate use and timely engagement with healthcare professionals. In this context, New Zealand should remain guided by its commitment to safeguarding public health and not adopt harmonisation measures that may compromise safety without clear evidence of benefit.

The use of cetirizine during pregnancy and breastfeeding is not routinely recommended, and it is important that consumers have the opportunity to discuss the potential risks and benefits with a healthcare professional of taking cetirizine in managing allergic rhinitis. Access through a community pharmacy ensures that appropriate information, advice, and verbal reinforcement can be provided to support safe decision-making. Although allergic rhinitis is often self-diagnosed, its symptoms can closely resemble those of other conditions, such as the common cold, sinusitis, conjunctivitis, or more serious eye disorders and increasing the availability of larger pack sizes in general sale outlets may inadvertently delay individuals from seeking timely professional advice, which could lead to misdiagnosis or suboptimal treatment. In contrast, limiting supply to smaller pack sizes encourages more frequent interaction with pharmacists, promoting early intervention and best-practice care – an approach more aligned with public health objectives.

The management of allergic rhinitis is multifaceted, and optimal treatment decisions should be made in consultation with a health professional to ensure that consumers are informed not only about pharmacological options like cetirizine but also about additional or alternative treatments and non-pharmacological strategies. These may include allergen avoidance, saline nasal sprays, or steam inhalation, with each playing a valuable role in alleviating symptoms and improving quality of life. Cetirizine has a higher likelihood of causing sedation and cognitive impairment compared to other non-sedating but equally effective antihistamines. Sedation is a commonly reported adverse effect in most cetirizine datasheets, and while second-generation antihistamines are generally considered less sedating, a low risk still remains, and this risk should be clearly communicated to consumers, which can only be adequately achieved through consultation with a healthcare professional. The sedative effects of cetirizine are dose-dependent and can be exacerbated by alcohol or other medicines that impair memory or psychomotor performance, further increasing the potential for adverse outcomes.

Should the MCC maintain its decision to allow the general sale of cetirizine for oral use in treating seasonal allergic rhinitis specifically in primary packs containing no more than 10 days' supply and labelled with a maximum daily dose of 10mg, we strongly recommend that the minimum age for use be set at 12 years and older, rather than the 6 years and over in Australia. This aligns with the age restriction for loratadine and helps mitigate the risk of dosing errors, inappropriate prolonged use in children, and delayed diagnosis of more serious underlying conditions such as asthma, sinusitis, or viral infections.

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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