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,

Nicole Rickman
General Manager – Membership and Professional Services

PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

03 July 2025

Medicines Classification Committee Secretary
Medsafe
PO Box 5013
Wellington 6145
via email: committees@moh.govt.nz

Dear Medicines Classification Committee,

MEDICINES CLASSIFICATION COMMITTEE (MCC)
COMMENTS TO THE 74th MEETING AGENDA 23 July 2025

Thank you for the opportunity to submit comments on the agenda for the 74th meeting of the Medicines Classification Committee.

The Pharmaceutical Society of New Zealand Inc. (the Society) is the professional association representing over 2,500 pharmacists, from all sectors of pharmacy practice. We provide to pharmacists professional support and representation, training for continuing professional development, and assistance to enable them to deliver to all New Zealanders the best pharmaceutical practice and professional services in relation to medicines. The Society focuses on the important role pharmacists have in medicines management and in the safe and quality use of medicines.

Regarding the agenda items for the above meeting of the Medicines Classification Committee, the Pharmaceutical Society would like to note the following comments for consideration:

5.1 Tenofovir disoproxil and emtricitabine – proposed down scheduling to include provision by pharmacists under certain conditions
In keeping with our previous comments, the Society is still supportive of the Burnett Foundations application to increase access to HIV prophylaxis medication in New Zealand as a key step in the goal of eliminating local HIV transmission by 2030, set out in the National HIV Action Plan for Aotearoa 2023-2030.[1]

Considering the resubmission provided to the MCC on 28 May 2025, the Society are supportive of the revised Pharmacist Initiation Pathway, which promotes a more collaborative care model, and provides support to those that are unenrolled or unwilling to discuss PrEP with their GP. For unengaged clients, any proactive health behaviour such as seeking PrEP connects them to health services and pharmacists are well placed to provide a strong and supportive referral network.

5.2 Respiratory Syncytial Virus (RSV)
The Society supports the proposal to expand the classification of the RSV vaccine to include persons aged 50-59 who are at increased risk of RSV disease, thus aligning with the approved indications on the medicines data sheet[2].

[1] National HIV Action Plan for Aotearoa New Zealand 2023-2030 | Ministry of Health NZ. URL [cited 1/7/25].
[2] Arexvy Datasheet URL [accessed 26/6/25)

5.4 Lithium (Prof Julia Rucklidge)
The Society does not support the reclassification of Lithium. Whilst there are many dietary supplements available overseas containing lithium orotate there is no clear indication for its use at the doses proposed in the submission.

5.5 Vitamin D (Prof Julia Rucklidge)
The Society does not support the proposal to change the classification of Vitamin D. The current guidelines for vitamin D supplementation in patients at risk of deficiency (frail or institutionalised individuals, veiled individuals, people with dark skin living at southern latitudes) recommend dosages of colecalciferol is 10mcg (400IU) per day [3]. This dose is easily achieved via a general sale product under the current classification. Higher doses are only recommended for confirmed deficiency and require investigation and input by a registered practitioner.

In addition, Vitamin D supplements taken at the recommended dose are generally well tolerated and considered safe. However, adverse effects and toxicity (hypervitaminosis D) are possible with long-term use of excessive daily doses (e.g. > 4,000 IU/day), e.g. hypercalcaemia, decreased bone mineral density, increased fracture and falls risk. Reports of toxicity are increasing, due in part to increasing prescribing and use of OTC supplements, e.g. multivitamins[4]. By raising the limit of vitamin D to 3000IU as proposed, this will also likely increase the risk of adverse effects.

The Society is supportive of harmonisation with Australian classifications, which would be altered by any change to the current classification.

5.6 Paracetamol administration by authorised vaccinators
The Society supports amending the classification of paracetamol to enable authorised vaccinators to administer liquid paracetamol to children under the age of 2 years concurrently with the Bexsero vaccine. The number of pharmacist vaccinators progressing to whole of life vaccinators is increasing, and this amendment would negate the need for pharmacists to work under a standing order to administer recommended treatment.

8.3 Sedating antihistamines
The Society supports the recent inclusion of age restrictions in the classification statements for sedating antihistamines when indicated for insomnia or sedation. The recommended reclassification statements deliver on the Medicines Adverse Reactions Committee (MARC) suggestions and ensure there is alignment with the current approved indications.

Thank you for consideration of this submission. I would be happy to discuss any aspect of this further, if required.

Yours sincerely,

Sarah Norwood
Professional Practice Pharmacist, Practice and Policy team
Pharmaceutical Society of New Zealand Inc.

[3] bpac^{nz} Vitamin D Supplementation: An Update URL [accessed 26/6/25]
[4] bpac^{nz} Vitamin D Supplementation: An Update URL [accessed 01/7/25]

Submission: Clinical Oversight in Self-Requested Testing for PrEP Eligibility

This submission outlines the safeguards, infrastructure, and oversight that currently exist within Awanui's self-requested testing model, and how these may support future healthcare delivery models that require patients to present verified lab results in community-based settings, such as pharmacies.

Awanui has implemented a robust self-requested testing model through our web platform, enabling patients to access key diagnostic tests—including STI panels, HIV, liver function (LFT), Hepatitis B/C, renal (eGFR), and HCG—without requiring a prior GP consultation. Recognising the importance of clinical safety, Awanui has partnered with registered general practitioners offering online GP services to provide wraparound clinical oversight for our testing services. In addition, Awanui pathologists are involved in oversight of test selection, interpretation frameworks, and clinical governance of our testing panels, further strengthening the clinical robustness of the model.

Test results that exceed defined safety thresholds (e.g. elevated creatinine or positive HIV/syphilis results) are automatically flagged for GP review and follow-up, supporting patients who may not have a regular GP. This ensures risks are identified and managed appropriately, even in a self-requested context.

Patients receive their results via a secure digital report, which they can download or share as needed. Currently, test results from our self-requested pathway are not integrated into regional clinical repositories such as TestSafe. However, we are actively investigating mechanisms to improve interoperability. In the interim, patients can present results directly, and we maintain a dedicated MedTech inbox with our GP partners to enable secure data exchange where needed. With sufficient lead time, Awanui is committed to developing solutions that enhance the clinical safety and accessibility of self-requested testing, including:

- Lab test kits that cover the full set of diagnostics commonly used to assess PrEP eligibility;
- GP partnership pathways that provide timely clinical oversight of test results;
- Future project specific integration of lab data into systems accessible by clinicians or pharmacists.

For reviewing drug histories and conducting symptom screens for acute HIV, we believe this would need to form part of any broader programme delivered outside of a specific Awanui self request PrEP bundle. This step is critical to ensuring appropriate prescribing and safeguarding against missed diagnoses of acute infection.

It is also important to note that Awanui's current service coverage does not include some regions (such as Palmerston North, the West Coast of the South Island, and Bay of Plenty/Lakes), though the remainder of the country is well supported.

In summary, self-requested diagnostic testing is an established and evolving model within New Zealand. Awanui's current approach incorporates clinical safeguards, with further enhancements planned to ensure safe, reliable access to laboratory testing in alignment with emerging healthcare delivery needs.

Kind regards,

Ngā mihi

Awanui

[redacted]

Immunisation Advisory Centre

Secretary
Medsafe Classification Committee
Ministry of Health
via email: committees@health.govt.nz

RE: Agenda of 74th Meeting of the Medicines Classification Committee (MCC)

Kia ora koutou,

The Immunisation Advisory Centre ("IMAC") welcomes the opportunity to comment on the agenda items of the 74th meeting of the MCC. IMAC is a nationwide organisation that provides independent, evidence-based advice, education and training on the safe, effective and equitable delivery of Immunisation Services in New Zealand.

We strongly support Agenda item 5.6 to amend the regulations to permit administration of liquid paracetamol alongside Bexsero in line with clinical recommendations. Prophylactic use of an antipyretic alongside Bexsero is important to reduce the risk of fever occurring in infants, particularly to reduce the potential for unnecessary hospital-based investigations and treatments for infants with a fever. The current requirement for vaccinators to act under prescription or standing order to administer paracetamol in these circumstances is a barrier for non-GP providers and creates inequities for whānau using these providers.

We suggest a few minor changes to the proposed drafting of the reclassification to ensure the regulations are clear and flexible to future changes in clinical guidance and programme requirements.
Specifically, we recommend:

- removing reference to the current aged-based recommendations for prophylactic paracetamol and specific brand names and instead referencing the Immunisation Handbook for details on clinical guidance. Ensuring this flexibility in the regulations is important recognising the highly dynamic nature of the immunisation space with new vaccines and vaccination schedules.
- adding in the words "authorised" and "pharmacist vaccinators" to make it clear that in addition to completing relevant training such vaccinators must be authorised, having completed relevant clinical assessments, updates and all processes required to obtain and maintain authorisation and pharmacist vaccinator status.

Our marked-up changes to the suggested wording are as follows:

Pharmacy-only; except when administered by authorised vaccinators, registered pharmacist vaccinators, or registered intern pharmacists who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who comply with the immunisation standards of the Immunisation Handbook, ~~to a child under the age of two~~ with the administration of ~~Bexsero~~ Meningococcal B vaccine to prevent and treat fever where and as indicated by the Immunisation Handbook.

Thank you for the opportunity to comment.

Ngā mihi

Dr Nikki Turner
Principal Medical Advisor
The Immunisation Advisory Centre
Professor, Department of General Practice and Primary Care
The University of Auckland

Jane Morphet
Programme Manager
The Immunisation Advisory Centre

7th July 2025

The Medicines Classification Committee Secretariat
Medsafe
PO Box 5013
Wellington 6140

Dear Secretariat,

RE: Comments on the Medicines Classification Committee 74th meeting agenda item 5.6 Liquid Paracetamol – proposal to allow provision by vaccinators (Te Whatu Ora)

Reckitt welcomes the opportunity to provide comment on the subject MCC agenda item, to be discussed at the 74th meeting of the Medicines Classification Committee (MCC) on 23 July 2025, which seeks to amend the classification of paracetamol to include a statement that permits authorised vaccinators to administer liquid paracetamol to children under the age of 2 years concurrently with the Bexsero vaccine to prevent and treat fever:

> *Pharmacy-only; except when administered by vaccinators, registered pharmacists, or registered intern pharmacists who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who comply with the immunisation standards of the Immunisation Handbook, to a child under the age of two with the administration of Bexsero vaccine to prevent and treat fever.*

Reckitt is aligned in principle to the proposed amendment to the classification of pharmacy-only paracetamol in New Zealand and suggests that this same amendment should also be made to the pharmacy-only scheduling of ibuprofen to align with the current **Immunisation Handbook**[1] (2025, version 3) which also recommends ibuprofen be given prophylactically with Bexsero (**Section 2.3.2 Recommendations for fever and pain management).**

To ensure consistency and avoid confusion, any decision made by the committee should align with the recommendations in the immunisation handbook (2025 version 3). As such Reckitt proposes that any consideration given to the pharmacy-only scheduling changes to paracetamol to permit authorised vaccinators to administer liquid paracetamol to children under the age of 2 years concurrently with the Bexsero vaccine should include the same consideration for the pharmacy-only scheduling of ibuprofen.

Reckitt takes this opportunity to highlight that the arguments presented in the submission to amend the scheduling of pharmacy-only paracetamol, similarly apply, to pharmacy-only ibuprofen. Reclassifying liquid ibuprofen to allow direct administration by vaccinators would also:

- remove the need for a Standing Order or prescription
- improve adherence to best practice
- enable timely and equitable access for whānau
- enhance operational efficiency in immunisation clinics

Applying the proposed scheduling changes to paracetamol suspensions to ibuprofen as well will ensure clinical best practice through adherence to published guidelines in New Zealand and will empower the vaccinator, registered pharmacist, or registered intern pharmacist with the ability to choose the most appropriate analgesic option to provide temporary relief of pain and fever associate with the administration of the Bexsero vaccine.

[1] https://www.tewhatuora.govt.nz/for-health-professionals/clinical-guidance/immunisation-handbook

Yours faithfully,

[redacted]

[redacted]

8 July 2025

Medicines Classification Committee Secretary
Medsafe
PO Box 5013
Wellington 6145
via email: committees@health.govt.nz

Re: Agenda item 5.6 Liquid Paracetamol – proposal to allow provision by vaccinators (Te Whatu Ora)

Tēnā koe Medicines Classification Committee

We are writing to support Health New Zealand's submission "Re: Proposed medicine classification amendment for your consideration" dated 9th June 2025.

We support the reclassification of Paracetamol suspension to include provision by vaccinators under certain conditions. We agree with Health NZ that the expansion of vaccination outside of General Practice has highlighted the challenges for non-prescribers to access Standing Orders for Paracetamol suspension.

Reclassification of Paracetamol suspension to allow authorised vaccinators to administer it with the Bexsero vaccine will improve equitable access of the medicine to whānau and reduce the administrative burden for health practitioners.

Three doses of Paracetamol suspension are recommended when a child aged under two years old receives a Bexsero vaccine. This is because fever can occur in some children as part of their normal response to Bexsero. Administration of Paracetamol suspension as recommended reduces the risk of high fever and injection site pain after the vaccination and does not reduce the effectiveness of the vaccine.

Whānau Āwhina Plunket has an authorised vaccinator workforce

Whānau Āwhina Plunket currently has ten sites where our authorised nurse vaccinators administer vaccines to whānau. Our focus is on increasing access to vaccination for whānau who may not be enrolled in a General Practice or who have other factors that make accessing immunisation services challenging.

Currently, we have a Standing Order that enables our vaccinators to administer and provide Paracetamol suspension to whānau when administering the Bexsero vaccine. However, Standing Orders present a significant administrative burden for our workforce, and not all community immunisation services have a Standing Order, or access to a prescriber for individual prescriptions for whānau.

Reclassification of Paracetamol suspension will improve equitable access

There is inequity of access to many health services, including vaccination. We recognise that many whānau who access community or outreach vaccination services may be doing so as they do not have access to a GP.

Not having access to a GP makes it difficult to obtain a prescription, and the cost of purchasing Paracetamol suspension over the counter at a pharmacy can be prohibitive for many whānau. Having Paracetamol suspension supplied at the vaccination event would remove these barriers. It is important that whānau who access vaccination through a community provider have the same quality of service as those who access vaccination through a GP, and administration of Paracetamol suspension with the Bexsero vaccine is part of this.

Reclassification of Paracetamol suspension will reduce unnecessary administrative burden on health practitioners

The administrative burden of a Standing Order or accessing individual prescriptions, especially for vaccinators who do not have access to a prescriber, is an inefficient way to operate. Authorised vaccinators, including nurses, pharmacists and paramedics, routinely advise on appropriate paracetamol dosage and use; they should not be required to use standing order or access prescriptions to do this as part of our National Immunisation Programme.

We agree with Health New Zealand that the reclassification of Paracetamol suspension will improve equitable and efficient vaccine delivery for authorised vaccinators working outside of the General Practice setting and support their proposed medicine classification amendment.

Medicines Classification Committee

Medsafe

17 June 2025

[redacted]

Kia ora

This is a personal submission on Agenda item

5.6. Paracetamol – proposal to allow provision by vaccinators (Te Whatu Ora, Health NZ)

This submission (PDF, 109KB, 2 pages) proposes to amend the classification of paracetamol to include a statement that permits authorised vaccinators to administer liquid paracetamol to children under the age of 2 years concurrently with the Bexsero vaccine to prevent and treat fever:

Pharmacy-only; except when administered by vaccinators, registered pharmacists, or registered intern pharmacists who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who comply with the immunisation standards of the Immunisation Handbook, to a child under the age of two with the administration of Bexsero vaccine to prevent and treat fever.

As an authorised vaccinator, I am very pleased to see this proposal before the committee and would support its approval. Acknowledging that it would not apply to registered intern pharmacists vaccinators as the Bexsero vaccine is not reclassified for their use in children under 16 years.

Pharmac has already provided an enabler to allow Authorised vaccinators to access paracetamol through the BSO process, and if this application was successful, it would remove the barrier of administration of paracetamol to children aged under 2 years receiving the Bexsero vaccine. The barrier of providing a prescription or working under a standing order has meant that some services who do not have a prescriber have been unable to offer the paracetamol which is resulting in unequable service delivery. Other providers have worked with external prescribers who have been willing to provide standing order cover outside their regular workplace and this increases the compliance cost of immunisation service provision as additional audit/review is required.

The regulated health professionals involved in this reclassification, have the appropriate skill and knowledge around paracetamol use and its risk, and access to resources to support them in the administration of it.

Ngā mihi, na

[redacted]

BAUSCH + LOMB

7 July 2025

Medicines Classification Committee
Medsafe
PO Box 5013
Wellington

Via email – committees@health.govt.nz

RE: Agenda for the Medicines Classification Committee (MCC) 74th meeting - Item 8.2 Brimonidine

Dear Sir/Madam,

Thank you for the opportunity to submit comments on the agenda for the 74th meeting of the MCC. Our submission addresses agenda item 8.2 regarding brimonidine.

We support the rescheduling of brimonidine from *prescription medicine* to:

- Prescription: except when specified elsewhere in this schedule.
- Pharmacy-only: in ophthalmic preparations containing not more than 0.025% brimonidine.

We acknowledge the two valid objections that were received regarding the proposed rescheduling and would like to provide information to address these concerns.

1. Some topical decongestants have a history of inappropriate use and/or overuse

First-generation ocular decongestants (such as tetrahydrozoline, naphazoline and phenylephrine) have a documented history of inappropriate and excessive use.[1] A study on 70 patients identified cases of conjunctival inflammation caused by excessive use of eye drops containing tetrahydrozoline, naphazoline or phenylephrine. These decongestants were used daily for a median of 3 years. The frequency of daily eye drop application ranged from 1 to 12 times (mean 3.7 times per day).[2]

The sustained use of first-generation ocular decongestants has been associated with tachyphylaxis (acute loss of effectiveness) and rebound redness.[1,3] Tachyphylaxis has been documented after repeated daily use of tetrahydrozoline over as few as 5 to 10 days.[3] Rebound redness was observed upon discontinuation of naphazoline or tetrahydrozoline after days, weeks, or months of continuous use.[3] Tachyphylaxis and rebound redness can lead to a vicious cycle of abusing decongestant eye drops. As the effectiveness wears off, patients may use the eye drops more frequently or in higher doses to get the same relief. Furthermore, patients may use the decongestant eye drops to treat or avoid the rebound redness, leading to chronic use and dependence.

Meanwhile, in clinical trials of brimonidine tartrate 0.025% eye drops (low-dose brimonidine), there was no evidence of tachyphylaxis after 4 weeks of treatment.[4] Rebound redness after treatment discontinuation was rare.[4] Even at the high doses investigated for lowering intraocular pressure (0.2%) or for treatment of facial erythema of rosacea (0.5%), studies of brimonidine did not show evidence of tachyphylaxis with long-term use.[5,6] The difference in adrenergic receptor binding accounts for the reduced risk of tachyphylaxis and rebound redness observed with brimonidine. Brimonidine is a highly selective α2-adrenergic receptor agonist, whereas tetrahydrozoline and phenylephrine are selective α1-

receptor agonists and naphazoline is a mixed α1/α2 receptor agonist.[3] Through its selectivity for α2-receptors, brimonidine has greater constrictive effect on conjunctival venules than arteries, as α2-adrenergic receptors are predominantly expressed in veins.[3]

Currently in New Zealand, only naphazoline and tetrahydrozoline products are available and indicated for use in eye redness and/or minor eye irritation.[7] These products are readily available to consumers as they are sold as pharmacy-only medicines. This highlights the unmet clinical need for an alternative decongestant eye drop that has a reduced risk of tachyphylaxis and rebound redness. Furthermore, it emphasises the importance of rescheduling low-dose brimonidine so that it is just as accessible to consumers as the naphazoline and tetrahydrozoline products. If access to low-dose brimonidine is more restrictive, patients may opt for decongestant eye drops which are more convenient for them to purchase but have a higher risk of tachyphylaxis and rebound redness. Therefore, it is in the interest of public health to reschedule low-dose brimonidine to pharmacy-only medicine, as it may be better suited for ocular decongestion over the currently available pharmacy-only preparations.

Eye redness caused by minor irritations is a condition that can be self-diagnosed. Labelling the product appropriately can help minimise the risk of it being overused or used for conditions that require medical attention. As a pharmacy-only medicine, the advice and guidance of a pharmacist can be promptly accessed. If required, the pharmacist can refer patients to a doctor or eyecare professional for more serious conditions.

2. The risk of allergic reaction and whether this risk would be reduced for products with strengths lower than 0.025% should be further investigated

Ocular allergic reactions have been reported in studies with higher strengths of brimonidine (0.2% and 0.15%).[5,8-9] The incidence appears to be dose-related, as there was a lower rate of ocular allergic reaction associated with the 0.15% strength compared to the 0.2% strength.[8-9] In an integrated analysis of four clinical trials on brimonidine 0.025%, no ocular allergic reactions were observed.[4] The 0.025% strength of brimonidine represents a 6- to 8-fold reduction in concentration relative to the 0.15% and 0.2% strengths. Hence, brimonidine 0.025% may be associated with a negligible risk of ocular allergic reactions.[10]

In addition to safety, the efficacy also needs to be considered when selecting the optimal strength of a medicine. Decreasing the concentration of brimonidine below 0.025% can compromise the effectiveness of the medicine in treating ocular redness. Torkildsen et al. (2017) chose the 0.025% strength of brimonidine for their efficacy and safety study following dose-response data which found that the 0.025% strength had a stronger effect in alleviating ocular redness than the 0.01% strength.[10] Other clinical trials on low-dose brimonidine have also focused on the 0.025% strength.[4]

Overall, there appears to be a relatively low risk of ocular allergic reactions with brimonidine 0.025% and a potential for reduced efficacy with strengths lower than 0.025%. Therefore, at present, further investigation into whether the risk of allergic reaction would be reduced for strengths below 0.025% does not appear to be warranted.

Discussion and Conclusion

The benefits of increasing access to ophthalmic preparations containing not more than 0.025% brimonidine through a pharmacy-only scheduling outweigh the potential risks. Pharmacy-only scheduling provides an optimal balance between convenient access to the medicine and the availability of pharmacist advice. Appropriate labelling will also help mitigate any potential risks and can be managed through the product registration process.

From a supply perspective, harmonised scheduling with Australia can help facilitate access for New Zealand patients as it promotes commercial viability (for example, through the potential for pack sharing and meeting minimum order quantities from manufacturers). The availability of brimonidine 0.025% as an over-the-counter medicine in the USA and Canada and the Schedule 2 classification in Australia (equivalent to New Zealand pharmacy-only) reinforces the suitability of low-dose brimonidine as a pharmacy-only medicine in New Zealand.

As low-dose brimonidine may be a better alternative for ocular decongestion over the currently available pharmacy-only products, it would be beneficial for it to be readily available on the pharmacy shelf when consumers are self-selecting a redness reliever eye drop. Overall, the favorable risk-benefit profile supports the rescheduling of low-dose brimonidine to a pharmacy-only medicine.

Yours sincerely,

Regulatory and Medical Affairs ANZ
Bausch & Lomb (NZ) Ltd

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RANZCO The Royal Australian and New Zealand College of Ophthalmologists
THE LEADERS IN COLLABORATIVE EYE CARE

NEW ZEALAND BRANCH

8 July 2025

Medicines Classification Committee (MCC) Secretary

Via email: committees@health.govt.nz

COMMENTS ON THE AGENDA FOR THE 74TH MEETING OF THE MEDICINES CLASSIFICATION COMMITTEE TO BE HELD ON 23 JULY 2025

Thank you for providing the Royal Australian and New Zealand College of Ophthalmologists (RANZCO) with the opportunity to submit a comment on item 8.2.2. – Brimonidine – on the agenda for the 74th meeting of the Medicines Classification Committee to be held on 23 July 2025, following a call for comment at the 71st meeting of the Medicines Classification Committee held on 14 November 2023.

This submission is based on feedback from New Zealand ophthalmologists and input from Australian and New Zealand members of the RANZCO Therapeutics Committee.

We do not feel there is significant clinical benefit from products designed to "treat" red eyes, such as Brimonidine 0.025%. Any treatment of a red eye should be directed at the underlying cause of the redness, whether this be allergy, infection or inflammation. There is the potential for these types of products to, at least temporarily, mask more serious eye disease, leading to presentation to optometrists and ophthalmologists with more advanced disease. A good example of a disease where this could occur is acute anterior uveitis. Given there are already several ocular decongestants available in New Zealand, such as naphazoline and tetrahydrozoline, and our previous comment on their lack of clinical benefit, we do not believe there is need for another product available at the pharmacy.

The main safety concern about re-classifying Brimonidine 0.025% as a Schedule 2 medicine is the risk of CNS depression/somnolence in children. Brimonidine 0.2% used for lowering intra-ocular pressure in glaucoma is contraindicated in children under 2 and not recommended for use in children below 12 years of age. As far as we are aware, this is no safety or efficacy data for Brimonidine 0.025% in children or adolescents.

Even though the Brimonidine 0.025% is a lower strength preparation, we believe similar precautions should be in place restricting its use in children. If the classification were to align Canada and Australia, where use is restricted to those 18 and older, these safety concerns would be addressed.

In summary, although we do not see a significant clinical need for Brimonidine 0.025% in New Zealand, we assess the risk of this product is low if restrictions are in place to avoid its use in children.

Johnson & Johnson Pacific

08th July2025

Medicines Classification Committee
Medsafe
PO Box 5013
Wellington 6145

Dear Sir/Madam,

Re: Agenda for the 74th meeting
Item 8.4 Cetirizine – Harmonisation of the classification of cetirizine with Australia

JNTL Consumer Health (New Zealand) Limited (JNTL) appreciates the opportunity to provide comment on agenda item 8.4 Cetirizine, which is the Delegate's proposal to harmonise the classification of Cetirizine with Australia, with a particular focus on the age limits for general sale supply.

Support for Harmonization
JNTL supports the recommendation based on the well-established history of safe use of cetirizine. The decision would enhance health outcomes for children by facilitating access of allergy treatment outside of normal pharmacy trading hour, allowing for timely treatment of the prevalent symptoms of Seasonal Allergic Rhinitis (SAR) via retailers that have extended trading hours such as supermarkets, while also easing the burden on parents.

Furthermore, while we note the Delegate is focusing on the age limits for general sale, we would like to emphasise the importance of fully harmonising with the scheduling conditions in Australia which allow for a 10-day pack supply which is the typical duration of SAR/Hayfever episode, and has been available in Australia since 2017.

This will bring Cetirizine in line with other comparable second-generation antihistamines in New Zealand such as Loratadine, which allow for a 10 day supply for children 6 years and over in general sale. It will also bring New Zealand into closer alignment with other like global markets that allow 10 mg Cetirizine in pack sizes of 10 or greater for children 6 years and over as general sale. Examples include:

- United States (no pack restrictions)
- United Kingdom (pack size 30)
- Canada (no pack restriction)
- Sweden (pack size 30)
- Netherlands (pack size 10)
- Norway (pack size 30)

Safety and Efficacy of Cetirizine

Cetirizine has a well-established safety profile, and its efficacy in treating SAR is supported by extensive clinical trials and post-marketing experience. The safety data for cetirizine in children is excellent with a low incidence of adverse effects, including somnolence. In clinical trials, the incidence of somnolence in children aged 6-12 years was 1.8% for cetirizine versus 1.4% for placebo[1].

There is sound evidence demonstrating that second generation antihistamines including cetirizine, loratadine and fexofenadine are very similar in terms of safety.[2,3,4] While there are some differences in Central Nervous System potential between the second generation antihistamines, in October 2005 the National Drugs and Poisons Schedule Committee of Australia acknowledged the available evidence that indicates 10 mg cetirizine showed minimal sedative effects which is comparable to 10 mg loratadine.

Cetirizine has over 20 years of history in the Australin market as an OTC medicine. In 2012 cetirizine was approved as a general sale medicine when limited to a 5 days supply and more recently in 2017 the pack size was expanded to allow a 10 day supply for use in SAR for adults and children 12 years and over. The decisions of the Australian Advisory Committee on Medicines Scheduling (ACMS) and TGA scheduling Delegate have consistently acknowledged the well characterised toxicity and safety of cetirizine and there is no evidence to suggest abuse potential.[5]

Given the MCC's established precedent that the benefits of a 10 day supply of 10 mg loratadine outweigh the risks, it is reasonable to extend the same consideration to 10 mg cetirizine given their well established similar safety, efficacy and tolerability profiles, as well as the extensive experience with 10-day supply in Australia and other global markets with its positive benefit-risk profile.

Public Health Benefits

The symptoms of SAR are easily recognised and able to be treated by the consumer without the requirement for medical intervention. The pack size limit of 10 days' supply for children 6 years and over is appropriate for a medicine available by general sale. SAR can last longer than 5 days and given antihistamines remain a first-line treatment for mild to moderate allergic rhinitis[6,7] the proposal is logical and will benefit New Zealand families. Additionally, the proposal is consistent with other medicines in the same class as cetirizine, such as Loratadine.

It has already been recognised by the TGA that allowing the general sale of cetirizine for the 6-11 year age group would enhance health outcomes by facilitating access outside of normal pharmacy trading hours. This allows timely treatment of symptoms via retailers with extended trading hours such as supermarkets, while also easing burden on parents who may wish to purchase regular use medicines with other household needs.[6]

Throughout the years the TGA has made several key scheduling decisions for cetirizine. As highlighted above, Cetirizine had been available for general sale 8 years when limited to a 5 days

supply and more than 4 years when limited to a 10 day supply, and from October 2022, available in a 10 day supply for children 6 years and over for use in SAR. Their tiered scheduling approach reflect the TGA's assessment of cetirizine's safety profile, usage pattern, public health outcomes and the need for professional oversight in certain cases. This is an example of how regulatory flexibility can enhance public health outcomes without compromising safety which the New Zealand population can benefit from.

It is well accepted that patients already have an awareness of their allergic conditions (particularly with SAR) and/or knowledge of how to manage these allergies with little help or counselling from a pharmacist or doctor, particularly as symptoms arrive at the time allergens are in the environment which can be unpredictable. The alignment to Australia's scheduling will allow for a greater number of treatment options for consumers. The following points should be considered:

1. **Alignment with Symptom Duration**: SAR symptoms can last longer than 5 days. A 10-day supply aligns better with the duration of these symptoms, ensuring that consumers have sufficient medication to manage their condition effectively.

2. **Enhanced Self-Care**: Providing a 10-day supply for children 6 years and older enhances self-care options for allergy sufferers. Many individuals with SAR do not seek medical advice despite severe symptoms, and a larger pack size would allow them to manage their condition more independently.

3. **Reduced Environmental Impact**: Increasing the pack size and widening the age group range reduces the frequency of purchases, which can have positive environmental impacts by minimizing packaging waste and the carbon footprint associated with multiple trips to the pharmacy.

4. **Convenience and Quality of Life**: A 10-day supply for children six years and over improves convenience and quality of life for allergy sufferers, particularly those in remote areas or with limited access to pharmacies. It ensures they have enough medication on hand during peak allergy seasons without the need for frequent repurchasing.

5. **Consistency with Other Medications**: The proposed supply limit and age restriction on general sale is consistent with those already in place for other medicines in the same class as cetirizine, such as Loratadine.

The public health benefits of allowing 10 mg cetirizine to be made available in general sale in a pack size of 10 day supply for children 6 years and over are significant.

Conclusion

In conclusion, JNTL support the proposal to align with scheduling of cetirizine in Australia and emphasise the need for full harmonization including a 10-day supply. This will ensure that cetirizine is available in an accessible format for consumers. The proposed changes will also ensure that

consumers, including children, have appropriate access to cetirizine, better serving the needs of New Zealand families, particularly those in remote areas or with limited access to pharmacies. Overall, harmonising Cetirizine's classification with Australia in its entirety is a step towards better public health outcomes.

Yours faithfully,

[redacted]