

16 January 2025

Medicines Classification Committee Secretary  
Medsafe  
Wellington

Sent via email to: [committees@health.govt.nz](mailto:committees@health.govt.nz)

Dear Committee Members,

**Re: Agenda for the 73<sup>rd</sup> 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 representing community pharmacy owners. 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:

- 6. Submissions for reclassification:
  - 6.1 Lidocaine (lignocaine) – proposed up-scheduling of oromucosal lidocaine containing products (Medsafe)
  - 6.2 Tenofovir disoproxil and emtricitabine (Burnett Foundation)
  - 6.3 Travel vaccines (Green Cross Health Limited)
  - 6.4 Recombinant Varicella Zoster Virus Vaccine (GSK New Zealand)
  - 6.5 Allopurinol (Arthritis New Zealand Mateponapona Aotearoa, Green Cross Health, Dr Natalie Gauld, Associate Professor Peter Gow)
- 7. New medicines for classification:
  - 7.3 Cytisine
- 8. Harmonisation of the New Zealand and Australian Schedules:
  - 8.2.a Naratriptan

**6. Submissions for reclassification**

**6.1 Lidocaine (lignocaine) – proposed up-scheduling of oromucosal lidocaine containing products (Medsafe)**

The Guild supports the proposal by Medsafe to reclassify external use medicines containing lidocaine, intended for oromucosal use in children under 12 years of age (except for throat lozenges and throat sprays that contain lidocaine 2% or less), to a restricted medicine classification (Option 1), in line with the MARC recommendations.

We acknowledge the importance of ensuring patient safety when using lidocaine-containing oromucosal products and support the introduction of mandatory warning statements specifically relating to lidocaine-containing medicines, such as relating to excessive and/or prolonged use, or maximum doses. This mandatory requirement will help ensure the safe use of these medicines, especially by others in the household who may not have been involved in the initial discussion with the pharmacist.

Pharmacists play a critical role in identifying and treating minor health conditions and are uniquely positioned to provide expert guidance on the appropriate use of lidocaine-containing oromucosal

products, educating patients and caregivers about safe dosage, application methods, duration of use and managing side effects, as well as when to seek further medical attention is necessary. Effective pharmacist oversight can also alleviate the pressure of unnecessary GP visits, especially for self-limiting conditions like mouth ulcers or teething pain. This reclassification supports pharmacists' ability to ensure the safe and effective use of lidocaine-containing products, leading to improved public health and wellbeing.

While we support the up-scheduling of external use medicines containing lidocaine that are intended for oromucosal use in children under 12 years of age, we would like to highlight the following key considerations:

- **Pharmacist education and training:** It is essential that pharmacists are equipped to effectively communicate the risks and proper use of lidocaine-containing oromucosal products to patients and caregivers, with training focusing on safe use, highlighting risks like excessive or prolonged use, and enhancing communication skills to ensure clear explanations for individuals with varying health literacy. Pharmacists should also be educated to identify high-risk patients, such as those with pre-existing conditions or potential drug interactions, so that they can provide tailored advice, and recognise signs of misuse or adverse reactions, enabling early intervention and appropriate referrals when necessary.
- **Clinical tools:** Clear guidelines and access to appropriate clinical tools, including updated training and dosing calculators, will be essential to equip pharmacists for their expanded role in overseeing the use of lidocaine-containing oromucosal products. These tools should include detailed age-based dosing recommendations, specific warnings about maximum doses, and guidance on the duration of use, particularly for children under 12 years of age, to ensure that pharmacists can make informed decisions and communicate effectively with patients and caregivers, reducing the risk of misuse or overdose.
- **Revenue and access concerns:** The proposed changes could inadvertently lead to supply chain restrictions, potentially impacting the availability of lidocaine-containing oromucosal products for patients who require them for legitimate medical needs and reducing revenue in community pharmacies, especially those that rely on these products as part of their regular offerings. While the restricted classification aims to improve safety, it will be crucial to ensure that these products remain readily available to those who need them, particularly for self-limiting conditions like mouth ulcers or teething pain.
- **Enhanced communication from Medsafe:** Clear communication from Medsafe about the specific dose forms affected by the reclassification is vital to ensure pharmacists, healthcare providers, and the public understand the reclassification changes and to facilitate a smooth transition with minimal disruptions. This communication should detail which lidocaine-containing oromucosal products are affected, any exceptions, and an implementation timeline to allow pharmacies time to adjust their inventory and procedures. A public awareness campaign, involving Plunket and other child health organisations, would also be beneficial to inform caregivers and the public about the new restrictions, potential dangers of misuse, and safe usage of these products, particularly for children under 12 years of age.
- **Mandatory warning statements are easily understandable for the public:** To maximise the effectiveness of the mandatory warning statements, they should be written in clear, simple language that is accessible to individuals with varying levels of health literacy and prominently displayed on the product. Caregivers, who may not have a healthcare background, should be

able to quickly understand the potential risks, such as the dangers of excessive use, maximum dosage limits, and the importance of not exceeding recommended duration of treatment.

## **6.2 Tenofovir disoproxil and emtricitabine (Burnett Foundation)**

The Guild 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 aims to expand access to HIV PrEP in New Zealand, a proven option to reduce the risk of HIV transmission by up to 99%, through a pharmacist-led supply model to overcome current barriers to the access of this crucial treatment, increasing equitable access to HIV prevention, and reduction of individual and community risks.

HIV attacks the immune system by targeting CD4 cells (T-cells), which are crucial for fighting infections, making a person more vulnerable to other infections and diseases. Left untreated, HIV can reduce the effectiveness of the immune system to the point where opportunistic infections and cancers cannot be fought off, potentially leading to AIDS, the most severe stage of HIV infection. New Zealand has one of the lowest levels of HIV infection globally, with the population groups most at risk of HIV infection being men who have sex with men, including those who also have sex with women, individuals from countries with high rates of HIV prevalence, and injecting drug users. While there is no cure for HIV, effective treatment with antiretroviral therapy can control the virus, reduce the viral load to undetectable levels, and enable people to live long, healthy lives. Preventive measures like PrEP (pre-exposure prophylaxis) and PEP (post-exposure prophylaxis) can also significantly reduce the risk of HIV transmission.

Access to culturally competent sexual health prevention, treatment, and care is essential for people living with HIV and priority populations in New Zealand. However, significant barriers persist, including geographic constraints, inconvenient appointment times, limited number of prescribers willing to offer PrEP, and cultural challenges. A central focus of the National HIV Action Plan for Aotearoa 2023-2030 is combination prevention, which combines biomedical, behavioural, and structural interventions to reduce new HIV infections. Despite this, the uptake of prevention tools like PrEP is below target, especially among Māori and Pacific communities. To address these gaps, innovative service delivery approaches are needed to improve access to PrEP, such as expanding telehealth, supporting community outreach, enabling rapid point-of-care testing in primary care settings, and developing new models of PrEP access, along with educational programmes to raise awareness and improve service delivery. The reclassification of PrEP to allow pharmacist-led delivery could address barriers to uptake, improve accessibility and convenience, providing a flexible approach that caters to individual needs, and supports continued HIV prevention efforts.

Community pharmacies present an untapped opportunity for expanding access to PrEP for HIV prevention. They are trusted and more accessible than traditional healthcare settings, with convenient locations, extended operating hours, and no appointment requirements, making them ideal for overcoming barriers to care and reducing stigma. They are also highly regulated and have a strong foundation in providing public health services, including dispensing prescriptions, offering sexual and reproductive health advice, and extended clinical services, whilst having access to national health information platforms, such as the Conporto shared medical record, robust IT systems to maintain accurate confidential records, and well-established connections to other healthcare providers. Pharmacists, with their extensive training in pharmacotherapy and patient care, are highly competent to provide PrEP services, offering counselling on adherence, drug interactions, and extending to other concurrent health concerns. Community pharmacies' trusted relationships with local communities and private consultation spaces can also foster a more

approachable environment for PrEP delivery, helping to address gaps and inequalities in current HIV prevention efforts.

We urge the MCC to strongly consider and approve the proposal to reclassify disoproxil and emtricitabine as 'prescription medicine except when,' enabling pharmacists to supply PrEP to HIV-negative individuals who meet specific criteria. We commend the Burnett Foundation for its initiative and believe this pharmacist-led model could significantly enhance access to HIV prevention, lower barriers, and improve equity in PrEP uptake, particularly for underserved communities. With New Zealand's goal to reduce new HIV infections and eliminate transmission by 2030, increasing access to PrEP through accredited pharmacists in community pharmacies could help bridge existing gaps in healthcare delivery, contribute to broader public health objectives, and enable the country to move closer to eliminating HIV transmission.

### **6.3 Travel vaccines (Green Cross Health Limited)**

The Guild strongly supports the proposal by Green Cross Health to reclassify several travel vaccines to enable authorised vaccinators and registered pharmacists who have completed the necessary vaccinator training and hold relevant travel medicine qualifications to administer these vaccines. The reclassification of these travel vaccines will not only improve public access to crucial vaccines for preventable diseases among travellers but also align with the expanding role of pharmacist vaccinators and authorised vaccinators in delivering immunisation services.

International travel is steadily increasing post-Covid, especially to high-risk destinations, putting travellers at greater risk of preventable diseases that can strain both the healthcare system and the economy. Many travellers neglect vaccinations, often due to last-minute travel plans, lack of awareness about vaccine lead times, and health disparities, leading to an increased demand for last-minute advice. Additionally, barriers to accessing travel vaccines, particularly in areas with workforce shortages, leave travellers unprotected, heightening the risk of severe illness or disease transmission. These challenges not only put individuals at risk but also burden the healthcare system, increasing treatment costs, hospitalisations, and pressure on an already stretched workforce. Reducing these barriers through accessible travel health services could lead to significant health and economic benefits and support the broader economy by enabling individuals to travel safely for business, leisure, or humanitarian purposes.

Pharmacist vaccinators are trusted, accessible healthcare providers, playing a vital role in patient education and disease prevention through their immunisation services across the motu. With a well-trained and competent workforce, pharmacist vaccinators are equipped with a strong infrastructure, meeting cold chain and emergency requirements, and are strategically located to meet the growing demand for travel health services, including vaccines, over-the-counter medicines, and in-depth patient counselling. This model, successful in countries like Australia, the United Kingdom, Canada, and the United States, also enhances equity, particularly for rural and underserved populations and regions facing workforce shortages. Pharmacist vaccinators are adept at using resources from the Immunisation Advisory Centre (IMAC) and other evidence-based tools, escalating any clinical queries accordingly and referring patients to other health professionals when needed.

Incorporating pharmacist vaccinators into travel vaccine distribution alongside general practice and travel specialists, will make public health systems more flexible, accessible, and responsive to travellers' needs, preventing the spread of infectious diseases and supporting proactive health management.

Travel vaccines are only one part of a comprehensive pre-travel consultation, which should also address non-vaccine preventable risks like food and water safety, climate and environmental hazards, insect bite and other animal bite avoidance, zoonoses, sexual safety, altitude information and travel insurance. Travel medicine is a specialised field that requires ongoing education in areas such as infectious diseases, epidemiology, and geographical health risks, and travellers with complex health conditions should be referred to a GP or travel medicine specialist for higher-level clinical assessment and advice. We are in agreement, as highlighted in the submission, that pharmacist vaccinators administering travel vaccines and providing a travel health service should complete specialised training in travel medicine through training delivered by IMAC and the University of Otago. There is also a comprehensive online training programme available on Travel Health from the Australasian College of Pharmacy, which is a requirement for pharmacist vaccinators to complete before providing a travel service in Australia.

Expanding the role of pharmacist vaccinators to provide travel vaccinations allows community pharmacies to enhance awareness and reduce vaccine-preventable and travel-related illnesses, offering a valuable service that addresses growing demand and supports safe travel. This expansion enables community pharmacies to offer varying levels of service, from basic administration of travel vaccines to comprehensive travel consultations with risk assessments, tailored to their patient population and available resources, while collaborating with general practices and specialty clinics. It also presents an opportunity to ensure travellers are up to date on routine immunisations, including measles, mumps, rubella, diphtheria, tetanus, pertussis, varicella, influenza, and Covid-19. By broadening their role from simple reactive services responding to travel-related queries to delivering comprehensive pre-travel health risk assessments, pharmacists can play a pivotal role in primary healthcare, contributing to significant public health benefits and the continued evolution of their practice.

#### **6.4 Recombinant Varicella Zoster Virus Vaccine (GSK New Zealand)**

The Guild strongly supports the proposal by GlaxoSmithKline (GSK) for the reclassification of the Recombinant Varicella Zoster Virus vaccine to enable authorised vaccinators and pharmacist vaccinators to administer this vaccine to a person 18 years or over, acknowledging its proven efficacy and the significant role it plays in the prevention of herpes zoster and post herpetic neuralgia in individuals 50 years and over, and for individuals 18 years and over at increased risk of herpes zoster.

However, we would like the proposed classification statement by GSK to be reworded to the following:

*Prescription only except when administered for the prevention of herpes zoster (shingles) to a person 18 years or over by an authorised vaccinator or registered pharmacist who has successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who complies with the immunisation standards of the Ministry of Health (but excluding a vaccinator who has completed the Provisional Vaccinator Foundation Course).*

The Recombinant Varicella Zoster Virus vaccine has a strong safety profile, with proven immunogenicity and effectiveness in reducing the incidence of shingles and its complications, particularly among high-risk populations, contributing to improved health outcomes and a better quality of life for individuals. The reclassification of this vaccine would enable trained registered pharmacists and authorised vaccinators to administer it without the need of a prescription to individuals aged 18 and over, particularly those who are immunocompromised and are more susceptible to infectious diseases such as herpes zoster and allow immunisation at the optimal time with respect to immunosuppression to achieve optimal health outcomes.

This reclassification is essential for several reasons, particularly in the context of improving vaccine access and advancing health equity and proactive health measures across the motu, as shown below:

- **Enhancing access to vaccinations:** Herpes zoster infection and its complications is a significant public health issue, particularly for older adults and immunocompromised individuals. The Recombinant Varicella Zoster Virus vaccine is highly effective in preventing this painful and potentially debilitating condition. However, the current prescription-only classification to those under the age of 50 years restricts access to the vaccine, especially for those who face barriers in visiting a general practitioner for a prescription. Allowing pharmacist vaccinators to administer the vaccine directly without the need for a prescription would significantly reduce cost and delays in vaccination, and this is particularly beneficial in underserved and rural areas or for high-risk patients who require timely immunisation to achieve optimal outcomes, where access to primary healthcare providers may be limited or overburdened.
- **Promoting equity in immunisations:** The reclassification of the Recombinant Varicella Zoster Virus vaccine supports New Zealand's commitment to health equity. Internationally, there is a growing recognition of the vital role pharmacists play in expanding access to immunisations. Countries like the United States, Canada, and the United Kingdom have seen significant success in increasing vaccine coverage and immunisation rates by leveraging pharmacists as accessible healthcare providers. By enabling pharmacist vaccinators in New Zealand to provide the Recombinant Varicella Zoster Virus vaccine to a broader patient population, we can similarly improve vaccine uptake, particularly among underserved populations or those at higher risk of complications from herpes zoster infection.
- **The role of pharmacists in New Zealand:** Pharmacists are among the most accessible primary healthcare professionals in New Zealand, offering extended hours, free consultations, and the convenience of walk-in vaccination services, often serving as the first point of contact for healthcare advice and services. Their successful role in administering vaccines, such as influenza and Covid-19 vaccines, has already demonstrated their capability and the trust the public places in them. Pharmacist vaccinators have been providing the Recombinant Varicella Zoster Virus vaccine to individuals aged 50 years and over for some time and expanding their ability to administer this vaccine without a prescription to a broader patient population is a logical and necessary step to ensure more New Zealanders are protected against shingles and its complications.
- **Training of pharmacist vaccinators:** Pharmacist vaccinators are highly trained to conduct comprehensive assessments and consultations before and after vaccination events, providing education and addressing concerns to support patients and caregivers in making informed decisions. Currently they undergo the same training as other healthcare professionals already administering vaccines in this field and have access to additional training resources, such as from IMAC and the Australasian College of Pharmacy, to further enhance their expertise. With advanced information technology systems and access to the Aotearoa Immunisation Register (AIR), pharmacist vaccinators can track and support individuals in adhering to vaccination schedules and recalls, contributing to overall public health. This is further supported by significant sector investments, including Healthpoint to guide patients to vaccination services and the Book My Vaccine platform for seamless booking.
- **Health sector cost savings:** The potential cost savings for the healthcare sector through pharmacist-administered vaccinations cannot be overstated. In addition to this, the educational services and support provided by pharmacists can enhance public awareness,

address concerns, and encourage greater vaccine uptake. By reducing the need for high-risk patients aged 18 to 49 years to visit general practices solely for their Recombinant Varicella Zoster Virus vaccination, healthcare resources can be reallocated more efficiently, allowing for better use of primary care services. This approach also offers the public increased convenience and accessibility, empowering them to choose when and where they receive their vaccinations, based on their personal preferences and comfort, which can lead to higher vaccination rates and improved health outcomes.

- **International trends and practices:** The global trend towards utilising pharmacists to administer vaccines has proven to be an effective strategy for increasing vaccination rates and reducing the impact of vaccine-preventable diseases. Pharmacist-led vaccination for individuals at high risk of herpes zoster will complement general practice, offering an additional option for administration of this vaccine and reinforcing the importance of vaccination. The WHO and other international health bodies have acknowledged the crucial role pharmacists play in immunisation programmes, and recent efforts to reclassify vaccines in New Zealand align with this global trend, recognising that pharmacists are not only capable, but also essential, in supporting broader public health goals and bridging gaps in vaccine coverage, particularly in underserved or high-risk populations.

The proposed reclassification of the Recombinant Varicella Zoster Virus vaccine for individuals aged 18 and over, as put forward by GSK, represents a significant advancement in improving access to this essential vaccine and fostering health equity in New Zealand. We urge the Medicines Classification Committee to strongly consider and approve GSK's proposal to reclassify the Recombinant Varicella Zoster Virus vaccine, allowing pharmacist vaccinators and authorised vaccinators to extend their reach and play a pivotal role in addressing the public health challenge of herpes zoster infection and its complications.

#### **6.5 Allopurinol (Arthritis New Zealand Mateponapona Aotearoa, Green Cross Health, Dr Natalie Gauld, Associate Professor Peter Gow)**

The Guild strongly supports the reclassification of allopurinol to a prescription medicine except when supplied for prophylaxis of gout to people who meet the clinical and eligibility criteria of an approved training programme, when provided by pharmacists who meet the requirements of the Pharmacy Council. This proposal, created in collaboration with experts and stakeholders, not only addresses critical barriers to effective gout management but also aims to improve gout treatment outcomes and promote health equity, ensuring that all individuals have equal access to high-quality care.

Gout is a common inflammatory arthritis caused by the buildup of monosodium urate crystals in joints, cartilage, bones, tendons, and other tissues. Urate is produced from dietary and endogenous purines, and when blood levels become saturated, crystals form in the joints, causing severe pain, swelling, and redness, often in the big toe but also in other joints like the knee, ankle, and wrist, in some cases affecting the person's ability to work and quality of life. Hyperuricaemia may result from several factors, including age, genetics, kidney dysfunction, cardiovascular disease, certain medications, obesity, and a diet high in purines like red meat, seafood, and fructose-sweetened drinks. While gout can be managed with uric acid-lowering medicines and lifestyle changes, if left untreated, can lead to chronic joint damage, tophi, and increased risks of cardiovascular and kidney complications, reducing life expectancy.

Gout is a prevalent condition in New Zealand, particularly affecting Māori and Pacific populations, with studies showing higher incidence rates compared to the general population, mostly due to genetic factors, such as variants of the SLC2A9 fructose/urate co-transporter genes, contributing to

impaired uric acid excretion, increasing the risk of gout in these communities. Gout is associated with significant healthcare costs and lost productivity, with Māori and Pacific peoples facing more hospital admissions due to the condition. Despite the high prevalence, these groups are less likely to receive regular urate-lowering therapy, which is essential for managing gout and preventing joint damage. Studies show that while Māori and Pacific peoples are more likely to be prescribed urate-lowering treatment, they are less likely to receive it consistently. This inequity in treatment and care needs to be addressed to reduce disparities and improve outcomes for Māori and Pacific patients with this chronic condition.

Pharmacists are highly suited and qualified to supply allopurinol for gout prophylaxis and adjust doses based on uric acid levels due to their extensive expertise in medicine management, including assessing patient regimens, recognising potential drug interactions, ensuring proper dosing, adjusting dosages to keep uric acid levels within target ranges, and closely monitoring patients through access to the Conporto shared medical record, thereby preventing flare-ups and joint damage. With their widespread availability, pharmacists offer convenient access to treatment and timely adjustments, which can lead to improved patient adherence and overall health outcomes. By collaborating with healthcare teams, pharmacists can manage routine aspects of gout care, freeing up resources for more complex cases. Reclassifying allopurinol would empower pharmacists to play a more significant role in gout management, improving access to treatment, reducing complications, and alleviating pressure on GPs and specialists. This shift would also help lower healthcare costs and provide a more efficient, cost-effective approach to managing gout over the long term.

Gout is a significant health issue in New Zealand, particularly affecting Māori and Pacific communities, yet it is often underdiagnosed and undertreated, leading to recurrent flare-ups and higher healthcare costs. Delays in starting urate-lowering treatments, limited consultation time, sub-optimal dosing, insufficient monitoring, lack of health literacy, and difficulty with regular medicine use hinder effective gout management. Reclassifying allopurinol to allow pharmacists to manage and continue prescriptions could reduce these barriers, improve adherence, reduce the need for costly interventions like emergency visits or hospitalisations due to poorly managed flare-ups, and prevent long-term complications. We urge the MCC to strongly consider and approve the proposal to reclassify allopurinol to a 'prescription medicine except when,' enhancing pharmacists to play a more active role in chronic disease management of gout and removing barriers for other community pharmacy gout services to be developed around the country.

## **7. New medicines for classification**

### **7.3 Cytisine**

The Guild supports the scheduling of cytisine, classifying it as a restricted medicine for divided oral and oromucosal preparations with a maximum recommended daily dose of 9mg to aid in tobacco smoking cessation for adults, and as a prescription medicine to capture all other preparations of cytisine. This decision will align with international trends and, given its proven efficacy and safety, makes cytisine an ideal option for the public, enhancing access to a valuable smoking cessation aid under pharmacist supervision whilst supporting national health objectives.

Smoking remains the leading cause of preventable death worldwide, causing approximately eight million deaths annually, with tobacco-related illnesses disproportionately impacting Māori in New Zealand. Smoking is linked to serious health issues such as cancer, cardiovascular disease, COPD, and Type 2 diabetes, exacerbating health disparities and placing a significant financial strain on the public healthcare system. Despite the availability of smoking cessation treatments, high smoking rates and relapse remain problematic, and current treatments, such as varenicline, may not be



suitable for those with mental health conditions. Cytisine offers a major advantage, as studies suggest it could be more cost-effective than other cessation products. The introduction of cytisine to the New Zealand market may provide a cost-effective treatment option, alleviating the burden on existing therapies and offering smokers a valuable new tool in their journey towards quitting, benefiting both public health and the economy.

Māori experience a disproportionate burden of smoking-related harm in New Zealand, with smoking rates significantly higher than the general population, contributing to elevated mortality rates and a higher incidence of tobacco-related illnesses. Māori also face higher relapse rates when trying to quit smoking and encounter barriers to accessing effective cessation treatments, including affordability and appropriateness. Culturally appropriate, accessible, and affordable smoking cessation treatments are urgently needed to address these challenges. Results from studies have shown that Māori smokers are likely to accept cytisine as rongoā Māori, and that they would be likely to attribute greater efficacy to it over and above other cessation products that are currently available. The scheduling and availability of cytisine could play a crucial role in improving quit rates, reducing smoking-related harm, and decreasing health inequalities in the Māori population.

Cytisine, a plant-derived alkaloid primarily extracted from *Cytisus laburnum* and *Sophora* species, has been used for smoking cessation since the 1960s and is currently available in over 20 countries, gaining approval in countries like Canada, the United Kingdom, parts of Eastern and Central Europe and recently Australia. It acts as a partial agonist of nicotinic acetylcholine receptors, functioning similarly to varenicline, but with a lower side effect profile, by reducing nicotine withdrawal symptoms and cravings. Cytisine has been shown to be effective for both short- and long-term smoking cessation, with studies showing comparable results to varenicline and nicotine replacement therapy, while being well tolerated with fewer adverse effects, minimal metabolism, and few drug interactions, making it an attractive smoking cessation option.

Cytisine's suitability as a restricted medicine is supported by its proven safety and low incidence of serious side effects, especially with pharmacist supervision. Due to its structured dosage regimen, pharmacist oversight is essential to ensure proper administration and minimise dosing errors, and pharmacists are well-equipped to provide essential smoking cessation counselling, guidance on managing side effects, and improving adherence, which are crucial for successful cessation. With community pharmacies being accessible and welcoming environments, enabling cytisine to be sold as a restricted medicine will make it easier for consumers to seek support without the need for general practice appointments or long wait times, thus reducing the burden on other healthcare providers. This accessibility would also promote equity, ensuring that smoking cessation treatments are available to everyone, including underserved communities that may otherwise have limited access to healthcare services, making its restricted medicine classification an effective way to meet public health needs and ease the strain on public healthcare services.

Along with supporting the scheduling of cytisine and its harmonisation with Australia, we also recommend:

- Creation of a training and education programme designed specifically for pharmacists to ensure that they are equipped with the knowledge and skills necessary to provide effective counselling and support for smokers seeking cessation with cytisine as a restricted medicine. Providing training will ensure pharmacists can explain its benefits, potential side effects, and proper administration, thus enhancing patient confidence and adherence to the treatment, and enable pharmacists to recognise signs of relapse, intervene early, and offer tailored advice on managing cravings and withdrawal symptoms.
- Leverage existing research, such as Professor Natalie Walker's trials with Māori populations, for providing culturally appropriate care in smoking cessation programmes. Professor Walker's

work highlights the unique challenges and needs of Māori smokers, emphasising the importance of incorporating cultural considerations into treatment approaches. By building on her research, healthcare providers will be able to adapt cytisine-based interventions to better align with Māori values, beliefs, and practices. Understanding the social and historical factors that contribute to higher smoking rates in Māori communities will also tailor support services in a way that resonates with Māori patients, fostering trust and increasing engagement in smoking cessation programmes.

## **8. Harmonisation of the New Zealand and Australian Schedules**

### **8.2.a Naratriptan**

The Guild supports the reclassification of naratriptan from a prescription-only medicine to a restricted medicine, improving accessibility while ensuring safety through pharmacist oversight. While there is currently no naratriptan-based product marketed in New Zealand, the harmonising and reclassification aligns with the scheduling of other triptans like sumatriptan and zolmitriptan, and offers a potential alternative for migraine sufferers, which may be better tolerated than other triptans, when a naratriptan-based product is introduced into the country.

Migraines are a debilitating condition that impose a significant socioeconomic burden, including considerable impacts on the wellbeing of sufferers. Individuals with migraines often experience work absences, decreased productivity, and disruptions to home and social activities, contributing to a substantial economic cost to society. Migraine also has a personal toll, with quality of life significantly lower for sufferers compared to matched controls and negatively affects family life and relationships.

A fundamental requirement for the efficacy of triptans in the acute treatment of migraine is to administer within one hour of the onset of migraine headache. Delaying treatment increases the risk of more severe and prolonged headache pain, inappropriate simple analgesic use, medicine overuse headache (MOH), chronic migraine, and higher economic and productivity costs. The availability of additional triptan options and the ability for pharmacies to provide effective treatment early in an attack will allow migraine sufferers to return to normal activity more rapidly. Furthermore, encouraging consumers to medicate early at the initial onset of symptoms can improve efficacy, reducing the severity of an attack, and enhance overall migraine management.

Naratriptan is a selective serotonin 5-HT<sub>1</sub> receptor agonist used to treat acute migraine attacks. This medicine is most effective when taken at the onset of a headache, rather than during the aura phase or after the headache becomes more severe. Written submissions supporting the down-scheduling of naratriptan in Australia emphasises its effectiveness and tolerability for acute migraine relief, comparable to sumatriptan, and supports the reduction of the inappropriate use of simple analgesics. Since naratriptan is recommended in Australia and in the proposed reclassification in New Zealand only for acute relief in patients with a stable, well-established pattern of symptoms, its down-scheduling offers significant benefits with minimal risk of misuse.

Pharmacists regularly manage consumers with headaches, including migraines, and possess the necessary skills and knowledge to assess migraine symptoms and medical histories. They play a key role in improving access to medicines, particularly since timely administration of a triptan is crucial at the first sign of a migraine and are well-equipped to screen and counsel consumers wishing to purchase naratriptan and manage potential adverse effects, interactions, and contraindications. By offering naratriptan as a restricted medicine, pharmacists can also help reduce healthcare costs by counselling and treating patients who would otherwise need a GP visit for a prescription, which will

not only enhance the quality use of medicines but also provides significant benefits to both the public and the healthcare system.

Along with supporting the harmonisation with Australia and the reclassification of naratriptan from a prescription-only medicine to a restricted medicine, we also recommend:

- The reclassification, along with the associated requirements and controls, aligns with the pharmacist-only supply of sumatriptan and zolmitriptan, where the indication should be limited to the acute relief of migraine attacks, with or without aura, in patients who have a stable and well-established pattern of symptoms.
- The label should include clear, concise directions for consumers, highlighting the correct dosage, advising individuals not to exceed two tablets within a 24-hour period or take more than one dose for the same migraine attack (although another dose can be taken after four hours). The label should also stress that the recommended dose should not be surpassed and caution that the medicine may impair the ability to drive or operate machinery.
- The inclusion of appropriate contraindications on the label, particularly for potential cross-allergy to sulfonamides, use with irregular heartbeat, and interactions with other migraine medicines.
- Revising the Data Sheet and Consumer Medicine Information (CMI) leaflet to ensure the safe and appropriate use of naratriptan as a restricted medicine, including correct dosage, contraindications, interactions, side effects and advising clear guidance on managing overdose. Additionally, the CMI should encourage migraine sufferers to consult a doctor if their migraine persists longer than 24 hours, if they experience four or more attacks per month, if they do not fully recover between attacks, or if their symptoms worsen or change.
- Development of a screening protocol and Migraine Questionnaire to ensure appropriate patient selection for naratriptan treatment to assist pharmacists in confirming a migraine diagnosis, assessing treatment suitability, reducing the risk of misdiagnosis and inappropriate use, such as for cluster headaches or analgesic abuse headaches, and ensuring prompt referral to a GP for further evaluation. This questionnaire should also screen for contraindications based on the revised Data Sheet and provide clear guidance on when to recommend other treatments.
- Creation of a training and education programme designed specifically for pharmacists to ensure the safe and appropriate use of naratriptan, equipping them with the skills to identify contraindications, counsel patients on safe usage, and utilisation of the screening protocol and Migraine Questionnaire. The programme should also include guidance on referring patients to their GP if they are not suitable for treatment with naratriptan or other triptans.
- In addition to a clearly written CMI, pharmacies should have available a consumer leaflet on migraine and naratriptan to provide to consumers, which includes information on migraine, advice on management, and links to consumer support group websites. This consumer leaflet will help migraine sufferers better understand their condition, enabling them to self-diagnose more quickly and access appropriate treatment, ultimately improving their quality of life.

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](mailto:martin@pgnz.org.nz), 04 802 8218) or Cathy Martin ([cathy@pgnz.org.nz](mailto:cathy@pgnz.org.nz), 04 802 8214).

Yours sincerely,



**Nicole Rickman**  
**General Manager – Membership and Professional Services**