The Royal New Zealand College of General Practitioners
Te Whare Tohu Rata o Aotearoa

22 January 2025

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Tēnā koe

**MedSafe Medical Classifications Committee (MCC) 73rd Meeting**

Thank you for the opportunity to provide a submission on the MedSafe Medical Classifications Committee (MCC) 73rd Meeting.

**The Royal New Zealand College of General Practitioners** (the College) is the largest medical college in Aotearoa New Zealand. Our membership of 6,439 specialist GPs and rural hospital doctors comprises 40 percent of the specialist medical workforce. The Medical Council of New Zealand accredits the College to deliver vocational training to the specialist General Practitioner and Rural Hospital Doctor workforce. The College is committed to prioritising the reduction of health inequities experienced by Māori and honouring Te Tiriti o Waitangi and the Māori rights enshrined within. To do this we prioritise initiatives that support our members to develop cultural safety capabilities through our training, continuing professional development and quality programmes.[1]

Our members provide medical care in the community with 23 million[1] patient contacts recorded in 2023 showing the combined efforts of 1,077 general practice clinical teams providing first point of contact care to manage 90 percent of health concerns for whānau in Aotearoa New Zealand.

## The College's comments on the MCC 73rd meeting agenda items

## 6. Submissions for reclassification

### 6.1 Lidocaine (lignocaine): proposed up-scheduling of oromucosal lidocaine containing products (Medsafe)

Change is sought for the classification of external use medicines containing lidocaine that are intended for oromucosal use in children under 12 years of age (except for throat lozenges and throat sprays that contain lidocaine 2% or less).

- **The College supports the Medsafe proposal to up-schedule oromucosal lidocaine containing products to include a restricted (pharmacist only) entry specific to oromucosal dose forms and note that this item is the result of a review and recommendation from the Medicines Adverse Reactions Committee.**

***College considerations***

- The change would result in these products requiring a data sheet relating to potential toxicity when the medicine is administered incorrectly. This means information about the risks of accidental overdose in younger children and infants will be available for healthcare professionals to use to inform parents and caregivers.
- An additional safety consideration introduced by this change is that purchasing restricted medicines requires interaction with a pharmacist, who provides oversight for larger pack sizes of oromucosal lidocaine, and can give advice regarding suitability of the product, and dosage required to reduce the risk of medication errors in children, including safe storage advice.

**6.2 Tenofovir disoproxil and emtricitabine (Burnett Foundation) (PrEP medication)**

- **The College supports the <u>proposal</u> to change the classification of tenofovir disoproxil and emtricitabine to:**
  ***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.***

- **The College supports reducing barriers to prescribing HIV PrEP. Its classification will expand access to HIV prophylactic medicines through exemption of prescription status enabling pharmacists to supply HIV prophylactic medicines under certain conditions to ensure patient safety, i.e., that there are clear protocols for responsibility of blood ordering and results, with clear referral back to the medical practitioner (often sexual health clinics) protocols.**

***College considerations***
- We note that tenofovir disoproxil and emtricitabine are used for the treatment of HIV, and used as pre-exposure prophylaxis, with other safer sex practices to reduce the risk of sexually acquired HIV.
- The proposal is sound in terms of patient safety, quality, and equity of access as it is seeking to increase access to HIV Pre-exposure Prophylaxis (PrEP) medication.
- Sexual Health clinics and GP clinics cannot provide the accessibility levels that are needed for this medication, i.e., the nature of its opening hours, location, closed books, and time taken to get an appointment (generalised).
- We consider that continuity of care is the main issue for patient care, as this includes the opportunity to provide greater impact through information and advice on lifestyle aspects which are currently provided through the Team GP model of care and referral to sexual health services.

***In addition***
Protection from preventable disease provides immediate and health benefits for individuals, and economic benefits for the country, saving time and money in treating conditions. Pharmacist supply will be fully user-pays.
- We consider that Pharmacist/GP collaborative care could be utilised more effectively to increase equitable HIV prevention through better access to advice and administration of some travel vaccines.
- We seek clarity on the requirement for negative HIV tests for patients.
- We support advice as outlined in the guideline, as the indication and dosage are simple for pharmacists to educate patients.

***College considerations***
- Pharmacists must be suitably trained and utilise a supply checklist to ensure patients receive the correct information for safe use.
- When repeats are needed the pharmacist will ask about adherence and education needs.
- The College seeks clarity over who is responsible for the requesting of blood tests, the accountability for those tests and the escalation pathways for abnormal results.
- Clear protocols on regular sexual health checks need to be in place.

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

The Green Cross Health proposal minimises and commercialises the specialty of travel medicine. Picking off the proposed list in isolation will cause harm for some patients.

1. Hepatitis A Vaccine
2. Hepatitis B Vaccine
3. Hepatitis A and Hepatitis B vaccine
4. Hepatitis A and Typhoid
5. Japanese Encephalitis Vaccine
6. Poliomyelitis Vaccine
7. Typhoid Vaccine
8. Yellow Fever Vaccine

**Yellow fever vaccine:** *except when administered by registered pharmacists who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health), and who is authorised by the Director-General of Health or a Medical Officer of Health in accordance with this regulation to administer, for the purposes of an approved immunisation programme, a vaccine that is a prescription medicine, may, in carrying out that immunisation programme, administer that prescription medicine otherwise than pursuant to a prescription.*

The College notes that administering all travel medicines is a complex specialist area. The significance of the travel medicine consultation will have significance for some patients, and administering vaccination/s can be a complex encounter based on their health history, comorbidities, risk factors, etc. Other considerations, such as, sexual health, rabies, altitude and travel itinerary or the multitude of illness, infections, and risks depending on where a person is travelling to. GPs take a holistic view of health, travel and potential risk in specific environments. This is not able to be simplified and potentially poses harm if things are missed. A simple vaccination course will not capture the depth and breadth of skills and experience needed to ensure people are well protected in their travels.

- **The College does not support the Green Cross Health proposal for reclassification of yellow fever on the basis that it is a patient safety and quality concern.**
- **The College supports the application form for authorisation as a vaccinator to be for all travel vaccines, rather than singling out yellow fever, including: the applicant type: Medical Practitioner, Nurse Practitioner, Registered Nurse, and if the applicant is an existing vaccinator or if this is a new application.**
- **The College notes that travel medicine should not be diluted by being broken down into specific vaccines.**
- **The College does not support pharmacist prescribing for all travel medicine, as the risks with vaccines are more than minor.**

***College considerations***

**Yellow fever is a live vaccine**

Vaccination against yellow fever, exemption from vaccination and provision of approved international certificates of vaccination or prophylaxis, are responsibilities devolved by the World Health Organization (WHO) to national health authorities under the International Health Regulations (2005). Within the guidelines provided to New Zealand, the vaccine must be administered by an **authorised medical practitioner**, nurse practitioner or registered nurse. To our knowledge, no Pharmacist in Australia or New Zealand is currently permitted to administer the yellow fever vaccine as per the WHO guidelines.

- The GP travel medicine consultation is thorough examination which considers multiple variables for a patient and their itinerary and involves a considerable amount of extra training, including yellow

fever credentialling. There is no added benefit to the patient for having their travel consult done in a pharmacy.
- There are potential issues arising and potential harm for people with complex health problems. Reclassifying some travel medicines such as yellow fever may pose risks for patients who are also receiving care for a chronic disease from their GP.
- The College is concerned about the motivation behind this proposal as the applicant, Green Cross Health is a corporate owner of pharmacies and general practices across New Zealand, which will commercially benefit from the proposed reclassification changes, this could be compared to a pharmaceutical company seeking reclassification for a commercial benefit.

The Green Cross submission also identifies yellow fever as being more complex than other vaccines listed in this submission due to number of contraindications that need to be explored. We consider there is potential for harm to patients if the contraindications are not thoroughly investigated.

- To assess the applicability and suitability of the yellow fever vaccine, a relevant patient information and medical history is required.
- Community pharmacies do not have consistent access to the level of patient information required to safely determine eligibility, nor do they have experience to make this determination with confidence.
- There is a high level of clinical risk if things going wrong for people with complex co-morbidities.
- Peer support is not available by those with more experience in prescribing and administering.
- The College does not have confidence that the proposed training course alone would address the other more significant safety concerns.
- The current systems and infrastructure to determine the eligibility, safe prescribing, administration and monitoring of this vaccine is not set up to support it being given in a community pharmacy setting, for example in New Zealand, this vaccine can only be given by authorised yellow fever vaccinators working in an approved/certified yellow fever vaccination clinic. The College Foundation Standard programme certifies the 1,077 practices across New Zealand that meet the standard for their vaccination systems including authorised vaccinators.

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

The proposal for the classification of Recombinant Varicella Zoster Virus vaccines is to be:

*Prescription only except when administered for the prevention of herpes zoster (shingles) to a person **18 years** or over 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 College notes that the proposal would enable a wider range of vaccinators for these vaccines.**

**College considerations**

- New Zealand pharmacists are already vaccinating with SHINGRIX following reclassification in November 2022 for individuals 50 years and over (privately funded).
- Since enabling pharmacists to provide several National Immunisation Programme (NIP) vaccines from September 2023, approximately 50% of pharmacies (approximately 500 out of 1,068 pharmacies in New Zealand) have ordered SHINGRIX to administer the NIP for the 65year-old cohort.
- Funding was expanded from July 2024 to include immunocompromised individuals 18 years and over. However, pharmacists cannot currently administer to eligible individuals 18 to 49 years without a prescription but can administer SHINGRIX to an immunocompromised person over the age of 50 years.
- The management of immunocompromised individuals is complex and best done under a GP/physician who is aware of the history and current health status of the patient.

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

The proposal is to change the classification of allopurinol to:

*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.*

At the 66th meeting of the MCC on the 11th of August 2021, a reclassification of allopurinol was considered. The committee "agreed that the proposal could support addressing access issues to medical practices and improve continuity of care in remote areas", and that "there are favourable equity outcomes possible from this proposal".

The committee raised the following concerns:

- The risk of missing and/or undertreating the associated comorbidities of gout:
  - Duration for pharmacist follow-up with the patient before a follow-up with their doctor.
  - The absence of an electronic care plan that would allow management between community pharmacies and medical practice.
  - Processes around training and education for pharmacists.
- The meeting minutes stated that "The Committee were supportive of the joint submission and agreed there is an unmet clinical need however acknowledged that a change in classification alone will have limited impact on improving health outcomes and equity.
  - The Committee discussed their understanding that reclassification can enable a pathway for policy changes and programmatic development, however expressed reservations with the current proposal until the concerns identified are addressed.
  - The Committee concluded there should be engagement with the Pharmacy Council process for medicines reclassification as outlined in the guidance before a recommendation can be made.

- **The College supports pharmacist maintenance and titration of allopurinol, but initiation should be completed by a GP.**
- **The College supports pharmacists being able to titrate and repeat medications while working in conjunction with a GP/NP.**
- **The College supports the introduction of an annual check with a GP.**

***College Considerations***

- The new proposal addresses all previous concerns and has a significant body of New Zealand specific evidence to support the change – this is unique, as the issue has significant equity of access implications.
- We note that the training programme is to be delivered by the Pharmaceutical Society of New Zealand and was endorsed by the Pharmacy Council of New Zealand.
- Areas of concern previously identified by GPs:
  - In all cases the patient needs to have a consultation at their general practice at least once a year.
  - When a GP initiates allopurinol for a patient, they will then work with the pharmacist on titration this will be a collaborative exercise.
  - The prescriber will prescribe allopurinol for the patient to start on, and flare prophylaxis to cover the titration. It is likely that people will need a second prescription for flare prophylaxis at 3 months so will see the doctor then.
  - If the pharmacist is titrating the patient's dose, the pharmacist will inform the doctor of allopurinol dose changes and finger prick serum urate tests (if undertaken). This communication can be managed through software, automated, or manually by the pharmacist sending the GP an email.

## 7. New chemical entities for classification

### 7.3 Cytisine

Cytisine, also known as baptitoxine, cytisinicline, or sophorine, is an alkaloid that occurs naturally in several plant genera. Cytisine is schedule in Australia as:

*Pharmacist only: in divided oral and oromucosal preparations with a recommended daily dose of 9 mg or less of cysteine as an aid in withdrawal from tobacco smoking in adults.*

The College understands that cytisine is a new chemical to New Zealand so the safety mechanisms to guide its use, monitor effectiveness and establish its use and place in cessation, are yet to be established.

- **The College supports the initial rollout as specialist GP prescribing only until the efficacy and experience of use is well established in New Zealand, before including pharmacist prescribing.**

***College consideration***

- A randomised controlled trial found that cytisine was at least as effective as varenicline at supporting smoking abstinence in New Zealand indigenous Māori or whānau (extended family), with significantly fewer adverse events.

### 7.6 Glucagon-like peptide-1 receptor agonists (GPL-1 agonists)

They include Dulaglutide, Danuglipron, and Retratrutide, which are also on the agenda for this meeting. Semaglutide (a prescription medicine with products approved in New Zealand) is also a GLP-1 agonist. As further GLP-1 agonists will be developed over time, Medsafe proposes a group entry for GLP-1 agonists, as well as listing individual compounds as they arise, for clarity:

- **Dulaglutide** is used for the treatment of type 2 diabetes in combination with diet and exercise. It is a glucagon-like peptide-1 inhibitor.
- **Danuglipron** is being developed by Pfizer, for is type 2 diabetes in combination with diet and exercise. It is a glucagon-like peptide-1 inhibitor.
- **Retratrutide** is being developed by Eli Lili, for type 2 diabetes in combination with diet and exercise. It is a glucagon-like peptide-1 inhibitor.

### 7.7 Momelotinib dihydrochloride

Momelotinib dihydrochloride is used for the treatment of disease-related splenomegaly. It is an inhibitor of wild type Janus Kinase 1 and 2 (JAK1/JAK2) and mutant JAK2.

### 8.1 New chemical entities which are not yet classified in New Zealand

*22 May 2024 Scheduling Final Decisions Public Notice*

***College consideration***

The College notes that all the new chemical entities listed that are not yet classified in New Zealand have been classified as prescription medicine in Australia.

- **The College supports the harmonisation of the new chemical entities listed below that are not yet classified in New Zealand with Australia.**

From 1 June 2024 bulevirtude was classified as a Schedule 4 (prescription medicine) in Australia.

### 8.1c Erlanatamab

Erlanatamab-bcmm is a bispecific B cell maturation antigen (BCMA)-directed T-cell engaging antibody indicated for multiple myeloma under certain conditions. From 1 June 2024 erlanatamab was classified as a Schedule 4 (prescription medicine) in Australia.

### 8.1d Etranacogene dezaparvovec

Eyranacogene dezaparavovec-drlb indicated to treat adults with haemophilia B under certain conditions.

From 1 June 2024 estranacogene dezaparvovec was classified as a Schedule 4 (prescription medicine) in Australia.

### 8.1e Etrasimod

Etrasimod is a sphinosine 1-phosphate receptor modulator indicated for treatment of moderately to severely active ulcerative colitis in adults. From 1 June 2024 etrasimod was classified as a Schedule 4 (prescription medicine) in Australia.

### 8.1f Fezolinetant

Fezolinetant is indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.

From 1 June 2024 fezolinetant was classified as a Schedule 4 (prescription medicine) in Australia.

### 8.1g Lebrikizumab

Lebrikizumab is a humanized monoclonal antibody used for the treatment of atopic dermatitis.
From 1 June 2024 lebrikizumab was classified as a Schedule 4 (prescription medicine) in Australia.

### 8.1f Lecanemab

Lecanemab-irmb is indicated for the treatment of Alzheimer's disease. From 1 June 2024 lecanemab was classified as a Schedule 4 (prescription medicine) in Australia.

### 8.1h Maribavir

Maribavir is indicated for the treatment of adults and specified paediatric patients with post-transplant cytomegalovirus infection/ disease under certain conditions. From 1 June 2024 maribavir was classified as a Schedule 4 (prescription medicine) in Australia.

### 8.1i Nelarabine

Nelarabine is a nucleoside prodrug of 9-beta-D-arabinofuranosylguanine (ara-G). It is indicated for the treatment of patients with T-cell acute lymphoblastic leukaemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL) under certain conditions. From 1 June 2024 nelarabine was classified as a Schedule 4 (prescription medicine) in Australia.

### 8.1j Tebentafusp

Tebentafusp-tebn is indicated for the treatment of adult patients with HLA-A*02:01-positive unresectable or metastatic uveal melanoma. From 1 June 2024 tebentafusp was classified as a Schedule 4 (prescription medicine) in Australia.

### 8.1k Zilucoplan

Zilucoplan is indicated for the treatment of generalised myasthenia gravis in adults who are anti-acetylcholine receptor antibody positive. From 1 June 2024 tebentafusp was classified as a Schedule 4 (prescription medicine) in Australia

**8.2 Decisions by the Secretary to Department of Health and Aged Care Australia (or the Secretary's Delegate).**

**8.2a Naratriptan**

Naratriptan is serotonin-1 (5HT1) agonist indicated for the treatment of migraine headache with or without aura.

The TGA rescheduled naratriptan from schedule 4 (prescription only) to the following:

*Schedule 4 (prescription); except when included in schedule 3 (restricted)*

*Schedule 3 (restricted); when in divided oral preparations containing 2.5 mg or less of naratriptan per dosage unit and when sold in a pack containing not more than 2 dosage units for the acute relief of migraine in patients who have a stable, well-established pattern of symptoms.*

This scheduling change was implemented on the 1 June 2024.

***College consideration***

The College notes that:

Naratriptan was rescheduled in Australia from a prescription medicine to a restricted medicine on 1 June 2024 when in divided oral preparations containing 2.5 mg or less of naratriptan per dosage unit and then sold in a pack containing not more than 2 dosage units for the acute relief of migraine in patients who have a stable, well-established pattern of symptoms.

**The College supports the naratriptan is classification as a prescription only in New Zealand to harmonise with Australia.**

- This will result in up to two dose units containing 2.5mg or less of naratriptan being available as a pharmacist only medicine for the acute relief of migraine in patients who have a stable, well-established pattern of symptoms, i.e., without a prescription.
- A pharmacist only classification means that there is a consultation required with the pharmacist, medical history taken, name and supply recorded etc.
- Currently all the triptan products are only available on prescription and funded by Pharmac.
- This change would enable faster access for acute relief via pharmacists.

There is a question about whether patient safety concerns for a triptan to be accessible in New Zealand, as described above have been appropriately investigated.

If you require further clarification, please contact Maureen Gillon, Manager Policy, Advocacy, Insights – Maureen.Gillon@rnzcgp.org.nz

Nāku noa, nā

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Medical Director | Mātanga Hauora

PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

16 January 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 73rd MEETING AGENDA 26 February 2025**

Thank you for the opportunity to submit comments on the agenda for the 73rd 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:

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

The Society partly supports the introduction of a restricted classification for lidocaine use in medicines containing 10% or less for oromucosal use, except for use in adults and children 12 years of age and over, (except throat lozenges, except throat sprays 2% or less). This would meet the concerns raised by MARC. However, it is interesting to note that only 9 cases were documented between 2018 and 2023 in children under the age of 3. According to the applicant, four of these patients reached the level for a medical assessment but all were asymptomatic at the time of contact with the National Poisons Centre. It may be beneficial for the Medicines Classification Committee to explore relative versus absolute clinical risk before a reclassification occurs.

We are uncertain how the reclassification changes would work in practice and still enable adults who wish to self-select these medicines under the General Sale/Pharmacy Only classification, unless there are separate products available.

The Society would like to understand if any modelling has been completed around the impact of these changes on the supply chain and future access to these medicines in New Zealand, especially as the classification alignment will be different to the UK and Australia.

There will be a significant concern, if reclassifying these products results in product removal from the New Zealand market and consequently increases pressure on other parts of the health system (e.g. General Practice). If there are other ways to mitigate the identified risks this may be preferred.

## 6.2 Tenofovir disoproxil and emtricitabine – proposed down scheduling to include provision by pharmacists under certain conditions.

The Society supports the concept of widening 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] Pharmacists are medicines experts, and the proposed supply of PrEP is well within their scope of practice.

The Committee may wish to note that Paxlovid, was reclassified in 2022. This treatment includes ritonavir which has a very similar risk profile to tenofovir. Paxlovid has been available for pharmacists to provide for nearly 3 years. We are not aware of any clinical risks or harm that have occurred from pharmacists providing Paxlovid to suitable patients.[2] As a result, we are fully supportive of pharmacists providing PrEP to appropriate patent groups.

However, we are concerned that there are not sufficient resources available in community pharmacy to undertake the proposed model by the Burnett Foundation.

The application states that uptake of PrEP is lower outside of main urban centres. Unfortunately, pharmacies outside of urban areas are experiencing the highest levels of workplace pressures, identified in our 2024 Workforce Survey.[3]

Government funding decisions across community pharmacy settings has created financial and operational pressures. Increased funding would be required to enable pharmacists to support the relevant education and maintain consistent staffing levels to undertake the proposed model (including setting up patient management/recall systems, communicating with GPs, carrying out patient consultations, reviewing blood test results).

Without ongoing PHARMAC funding, at a subsidised price of $15.45 for 30 tablets (one month's supply) ex GST, this treatment will remain unaffordable for many consumers.

The 2022 SPOTS survey identified a lack of HIV prevention was higher among a range of sociodemographic characteristics, such as those without formal education qualifications, the unemployed or a beneficiary and those reporting financial need.[4] On top of the cost of medication, pharmacists will likely need to charge a significant consultation fee to patients to ensure any service is sustainable for all patients. As a result, we are concerned that those with the greatest need would struggle to pay.

The funding challenges are not a reason for the Medicines Classification Committee to be hesitant around reclassification of PrEP. Pharmacists have the expertise to deliver these medicines to appropriate patient groups. The Society does support the Burnetts Foundations application to increase access, but a lack of ongoing funding may impact on access to care, if not addressed in the longer term.

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

The Society supports the proposal to widen the classification of a number of travel vaccines to allow appropriately qualified vaccinators (those who have successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and hold the relevant postgraduate travel medicine qualification from an approved educational facility) to administer these prior to travel. We also support the requirement to complete any additional training identified by the Ministry of Health, for live vaccines, before pharmacists are

[1] National HIV Action Plan for Aotearoa New Zealand 2023-2030 | Ministry of Health NZ. URL [cited 6/1/25].
[2] Nirmatrelvir/Ritonavir (Paxlovid) What a pharmacist needs to know. PSNZ (2023). URL [cited 6/1/25]
[3] Pharmacy Workforce Survey, PSNZ (2024). URL [cited 6/1/25]
[4] Ludlam S.P. et al. Trends in combination HIV prevention and HIV testing 2002-2022. SPOTs (2024). URL [cited 6/1/25].

authorised to provide these treatments to the public. Any training must ensure that pharmacists are competent, and they remain up to date with current knowledge over the future years. In accordance with all vaccinations the vaccinator must also comply with the immunisation standards of the Ministry of Health to administer the proposed vaccines.

**6.4 Recombinant Varicella Zoster virus vaccine (GSK New Zealand)**
The Society supports the proposal to reclassify recombinant Varicella Zoster virus vaccine to people 18 years of age and over. We have some concerns regarding the opening up of the classification to any person who has completed the Vaccinator Foundation (or equivalent training courses approved by the Ministry of Health). We would like to suggest that the committee consider aligning the classification statement with the one that is used for influenza vaccine. This captures all appropriate vaccinators, along with pharmacists and intern pharmacists, rather than leaving it open to any person. There may not be a risk with the terminology proposed by the applicant, but we would suggest that the committee consider alignment, where possible to mitigate any potential risks.

**6.5 Allopurinol (Arthritis New Zealand Mateponapona Aotearoa, Green Cross Health, Dr Natalie Gauld, Associate Professor Peter Gow).**
The Society are fully supportive of the proposal to reclassify allopurinol to "*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*"

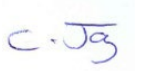
The value of the Owning my Gout (OMG) management programme has been independently evaluated by Synergia and demonstrated clinical success. The Community Pharmacy Gout Management Service Training has already been developed and is running in several Districts across the country. With a small amount of additional education built into this package, it could also deliver on the requirements outlined in this proposed reclassification. The Society are also ready to step in and provide the appropriate training and support required to ensure any reclassification is a success for both patients and pharmacists delivering care.

**7.3 Cytisine**
The Society are supportive of potentially aligning cytisine with the same classification (Pharmacist only) as Australia. There is some robust evidence to support the products use as an aid in withdrawal from tobacco smoking in adults. We are also aware that cytisine is potentially being investigated as a treatment to assist vaping cessation.[5] Currently there are no approved nicotine replacement treatment options for patients who wish to stop vaping.

As the committee are aware, there are no approved cytisine products available in New Zealand. If one does become available and follows a similar classification pathway to Australia, which could enable the approval to include vaping cessation, this would be significantly beneficial. It would increase access to approved over the counter treatments and help with the overall nicotine dependency, currently occurring through vaping.

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

Yours sincerely,



**Chris Jay**
**Manager Practice and Policy**

[5] D'Arrigo T. Cytisinicline Promising for Vaping Cessation. 2024 Psychiatric News Volume 59, Number 09 URL [cited 6/1/25].

PHARMACY GUILD OF NEW ZEALAND

16 January 2025

Medicines Classification Committee Secretary
Medsafe
Wellington

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

Dear Committee Members,

Re: Agenda for the 73rd 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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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 agreeance, 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 administered 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-HT1 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, 04 802 8218) or Cathy Martin (cathy@pgnz.org.nz, 04 802 8214).

Yours sincerely,

Nicole Rickman
General Manager – Membership and Professional Services

19 December 2024

Medicines Classification Committee Secretary
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**Attention: Matthew Spencer**
Manager, Product Regulation Branch
Medsafe
Ministry of Health

Dear Matthew,

**Re: Submission from the New Zealand Dental Association to the Agenda for the 73rd MCC Meeting**

Thank you for the opportunity to make a submission to the Agenda for the MCC's 73rd Meeting, about lidocaine-containing products; currently available and classified as non-prescription medicines (depending on the strength of lidocaine), where the product may be sold as a pharmacy only, or general sale medicine.

There are over 3000 dentists (including dental specialists) in New Zealand and the New Zealand Dental Association (NZDA) would like to be identified as an interested party for consultation. We advocate for more than 95% of dentists in New Zealand and also work cooperatively with other oral-health practitioners. We believe we are in an informed position to advocate for dentists and the public, as well as providing Government with valuable insight, to enable the efficient delivery of smooth processes and sensible regulations.

The NZDA submits that dentists have pharmacological, physiological and clinical knowledge, and must comply with the Health Practitioner's Competency Assurance Act, and Dental Council of New Zealand competency standards, to purchase and safely administer lignocaine-containing products, including by injection.

The NZDA can't easily find the proportion of adverse reactions linked to lidocaine-containing gels that have originated from Dentists, Dental Therapists, Dental Hygienists or other oral health workers such as specialist dental practitioners; compared to adverse reactions that have originated from members of the public, who may have inappropriately using lidocaine-containing products for infants — for example: over-use as a teething gel. The NZDA submits that this is an important consideration, before any regulations are imposed that could affect dentists' and dental teams' ability to procure and use lignocaine-containing products.

The NZDA has reviewed the Medicines Adverse Reactions Committee (MARC) report and summarizes it as follows:

**Regulatory Actions:**
Implement regulatory measures to minimize risks for all oral lidocaine-containing products, potentially varying based on the product's strength and intended use.
Include explicit warnings on labels for products not to be used for teething pain in children under 6 years unless specifically indicated.

**Labelling Updates:**
Improve clarity on package labels, including dosing instructions and frequency limits for children.
Add warnings about the risk of systemic toxicity, especially in children under 3 years.
Ensure that packaging clearly communicates that products are not recommended for prolonged use in young children.

**Dosing Guidance:**
Introduce stricter dosing guidelines for children, particularly for products used on the oral mucosa.
Highlight the importance of accurate dose measurement, recommending calibrated measuring devices where applicable.

**Educational Efforts:**
Educate healthcare professionals and caregivers about the risks of overdose, systemic toxicity, and administration errors.
Encourage prescribers to consider alternative pain relief methods before recommending lidocaine products for children.

**Restrictions on Indications:**
Limit the use of higher-strength lidocaine products (e.g., 10% sprays) to professional settings under healthcare supervision.
Emphasise that lower-strength products may still pose risks if misused.

**Monitoring and Reporting:**
Strengthen adverse reaction monitoring to better understand patterns of systemic toxicity.
Require reporting of adverse events associated with oral lidocaine use in children.

**Public Awareness:**
Disseminate warnings and educational materials about safe usage practices to prevent accidental ingestion and overuse.

The NZDA submits that the MARC report relates specifically to (see headings above) to oral lidocaine-containing products and risks of toxicity in younger children and infants if incorrectly used. The NZDA agrees that the proposed changes would increase safety around the uses of lignocaine-containing products by members of the public in particular, but also by health professionals, when such products are used in infants and young children.

The NZDA requests that careful consideration be made when drafting any potential legislation, so that any new regulations do not impact on dentists' ability to care for infants, young children, adolescents, young adults, adults, and older adults, or that there is an increased administrative or clinical burden that impacts on the way dentists currently practice.

The NZDA acknowledges the MCC has highlighted international regulatory authority safety communications of reports of serious adverse reactions with use of oral mucosal applications of lidocaine-containing products in infants and younger children.
The New Zealand Dental Association submits that oral lidocaine-containing products should continue to be readily available to dentists and other oral health practitioners for topical anaesthesia of the mouth for all patients that have clinical indications for its use across the age range from infants and younger children through to older adults.

The NZDA also submits that other topical local anaesthetic agents are available to dentists via registered suppliers and that this supply chain should continue, without undue burdensome restrictions to clinical or administrative processes for both the supplier and the end-user dentists who purchase the products. The MCC may find the following Q&A useful:

1. What lignocaine oral-mucosal products do dentists use?

   This depends on the dentist's preference and the availability from suppliers. In addition, topical anaesthetic agents used by dentists may be formulated with other anaesthetic agents. For example, topical gels may contain prilocaine, benzocaine, or other agents, and are not restricted just to lidocaine-containing agents.

2. Which companies could supply topical anaesthetic agents to dentists?

   In NZ there are at least 8 dental supply companies that may supply to dentists. Some or all of these companies could do so but at the time of writing, current inventories and supply chains of the companies are unknown. There may be other companies and dentists may obtain their own supplies via the internet):

   Aluro Healthcare: Supplies high-quality dental products and equipment exclusively to the New Zealand dental industry.

Oraltec: A leader in innovation, quality, and reliability within the dental supply industry across New Zealand and the Pacific Islands.

Independent Dental Supplies: A New Zealand-owned company offering a wide range of dental products and equipment.

DRC NZ: A 100% New Zealand-owned supplier to the dental and orthodontic industry, celebrating over 20 years in business.

Vecodent: Specializes in importing and distributing consumables and equipment for dental prosthetists and dental laboratories at competitive prices.

Health Care Essentials: Offers New Zealand dentists and laboratories restorative products and digital dental solutions from the world's leading brands.

Dentec: Provides premium branded dental equipment, ensuring seamless integration into any practice.

Henry Schein New Zealand: A dental supply company and fit-out specialist delivering renovations, expansions, and relocations for dental surgery setups.

NZDA submits that the present supply chain should remain unencumbered. According to the MedSafe website, commonly available products are: Lignocaine 2% Gel; Xylocaine Viscous 2% Oral Solution; Oraqix Periodontal Gel. A dentist could use a combination gel such as 18% benzocaine/2% tetracaine. Dental supply companies provide flavoured gels of various brands, and with various topical anaesthetic agents and concentrations, for example, "Ultracare Topical gel is 20% benzocaine.

The NZDA submits dentists should be able to continue to purchase topical anaesthetic agents of their choice as they are sold to registered dental practitioners with training in their pharmacology and clinical training for appropriate use.

3. How are these used (briefly)?

   A small pea-sized amount of anaesthetic-containing product is applied directly to the gum or oral mucosa using a cotton swab or applicator tip, immediately over a proposed local anaesthetic injection site. This is left in situ for about a minute and then the anaesthetic injection is given, usually without discomfort; the patient often rinses their mouth with water after the injection. Viscous solutions are used as a mouth rinse for about a minute and then expectorated. The anaesthetic effect typically occurs within a minute or two, providing relief of pain from generalised oral ulcers.

4. Who uses these agents? Currently dentists, dental specialists use the agents. Dental therapists, oral health therapists, and dental hygienists are able to use these products without a prescription from a dentist.

   The NZDA submits that dentists should be able to continue to use these products, because aligns with their scope of practice and training as accredited by the Dental Council of New Zealand. Other oral health workers should also be able to use the products as determined by their training, and all oral health workers including dentists are regulated by the Health Practitioners 'Competency Assurance Act (2003).

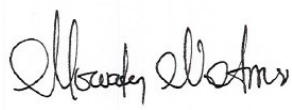
5. How are these distributed / sourced? Dentists either purchase directly from a pharmaceutical wholesaler, or by a specialist dental wholesaler. The suppliers are normally aware of any restrictions on the supply of these pharmaceutical products and so will only supply to a registered practitioner.

6. Should these healthcare professionals continue to have access? The NZDA strongly submits and advocates for continued access to all currently available topical anaesthetic agents, and any new future agents, available for dental use.

   The lignocaine-containing products in questions are used as a topical agent for short term mucosal anaesthesia of the mouth. Dental practitioners usually agree that these are not as effective as benzocaine-containing products. NZDA advises MedSafe that our experience with supply chain issues during COVID-19, where only lignocaine-containing products were available was, lignocaine-containing products weren't as good and much harder to control dose due to the presentation (more liquid gels). These would possibly be prescribed by some dentists for oral ulceration, but not commonly in very young children which is where the toxicity issues are greatest.

In summary: NZDA thanks the MCC for the opportunity to comment and submits that trained health practitioners including dentists, dental specialists, oral health therapists, and dental hygienists (we are not speaking for medical practitioners, nurse practitioners etc.), should continue to have current access to their topical anaesthetic agents of choice, from their current source of supply; and any regulatory changes should have little to no impact on current dental practice.

Kind regards,



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