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*"

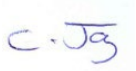
The value of the Owning my Gout (OMG) management programme has been independently evaluated by Synergia and demonstrated clinical success. The Community Pharmacy Gout Management Service Training has already been developed and is running in several Districts across the country. With a small amount of 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,

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17 January 2025

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Tēnā koe Jessica

Pharmacy Council submission on the Medicines Classification Committee (MCC) agenda 73rd meeting

Thank you for the opportunity to provide feedback on the agenda items for the 73rd meeting of the MCC.

The Pharmacy Council ("the Council") is a Responsible Authority established by the Health Practitioners Competence Assurance Act (HPCA Act) 2003. Our purpose is to protect the public by making sure pharmacists are competent and fit to practise. This submission is framed within the basis of this mandate. The Council's view is based on its responsibilities under the HPCA Act and the joint Medicine Reclassification framework[1] developed by the Pharmaceutical Society of New Zealand (Society) and Council. The Council has provided feedback on agenda items that involves medicines proposed to be reclassified and will have pharmacist involvement, such as "pharmacist-only" and "prescription medicines, except when provided by a pharmacist/ pharmacist vaccinator".

The framework has been used to determine whether a formal training programme, self-directed up-skilling, or no up-skilling is required by the Council and Society independently. The framework and this submission are not intended to provide specific details of a potential training programme or practical implementation of the proposal.

1. Agenda item 6.2 Tenofovir disoproxil and emtricitabine

Agenda item 6.2 is an application to MCC from the Burnett Foundation Aotearoa, previously the New Zealand AIDS Foundation to widen access to pre-exposure prophylaxis (PrEP) for HIV prevention. The Council notes that the Burnett Foundation Aotearoa has made available online learning modules freely for primary care health professionals.

The Council supports the reclassification of tenofovir disoproxil and emtricitabine to improve equity of access

The Council supports the reclassification of tenofovir disoproxil and emtricitabine, to improve equity of access to PrEP, with the proviso that pharmacists must have completed appropriate formal training to provide the service safely.

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[1] https://www.medsafe.govt.nz/consultations/LegalClassification/2d-Consultation-How-to-change-the-legal-classification-of-a-medicine-in-New-Zealand-Appendix-2-Pharmacy-Council.pdf Medicine Reclassification Framework

It is envisaged that pharmacists will complete formal training to gain better understanding about:

- culturally safe interactions with Rainbow and takatāpui communities,
- PrEP supply model,
- know how to search for drug interactions using New Zealand Formulary or the Liverpool HIV Drug Interactions Checker
- accessing and interpret laboratory results
- patient counselling and advice.

2. Agenda item 6.3 Travel vaccines

Agenda item 6.3 is an application to the MCC from Green Cross Health. It proposes to widen the classification for number of travel vaccines to allow pharmacist vaccinators to administer travel vaccines such as Hepatitis A, Hepatitis B, Japanese Encephalitis, Poliomyelitis, Typhoid and Yellow Fever.

The Council notes that current foundational pharmacist vaccinator training does not cover the complex consultation that is required when selecting appropriate travel vaccination. Yellow fever vaccination also requires additional authorisation[2] and needs to be administered from designated yellow fever vaccination centre. The Council agrees that relevant formal training in travel medicines and continuous professional development in this specialised field must be a core requirement. It is noted that postgraduate qualification in travel medicines is not currently funded for pharmacist vaccinators, which is a barrier to upskilling of the workforce.

The Council currently does not support the reclassification of travel vaccines, as we do not believe the current foundational pharmacist vaccinator training would provide sufficient knowledge or skills required to provide comprehensive travel consultation safely.

3. Agenda item 6.4 Recombinant Varicella Zoster

Agenda item 6.4 is an application to the MCC from GSK New Zealand. It proposes reclassification of recombinant varicella zoster vaccine to allow timely access for immunocompromised patients (adults 18 years of age and over). Pharmacist vaccinators currently cannot administer to eligible individuals 18 to 49 years without a prescription but can administer the vaccine to people over the age of 50 years.

The Council supports the reclassification of Recombinant Varicella Zoster vaccine

Pharmacist vaccinators are already familiar with the administration of the varicella zoster vaccine. The reclassification will reduce confusion in the health sector regarding who they can and cannot vaccinate. The vaccinator training applies to the preparation and administration of this vaccine. The reclassification will allow more equitable and timely access to immunisation against herpes zoster (shingles) to person 18 years or over.

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[2] Yellow fever training and authorisation – Health New Zealand | Te Whatu Ora

The Council recommend amending the suggested classification wording (in yellow) to the following for consistency with other vaccines:

"Prescription only except when administered for the prevention of herpes zoster (shingles) to a person 18 years or over by a 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)."

4. Agenda item 6.5 Allopurinol

The application proposes to make allopurinol more accessible to help overcome the low rate of long-term gout management. Trained pharmacists would be able to supply allopurinol to patients that meet specific criteria for non-prescription supply. Pharmacists are familiar with the use of allopurinol as a prescribed medicine. Insights[3] from Community Pharmacy Gout Management Service and Gout Stop Pilot Program[4] have identified critical success factors that included having access to additional training to provide a culturally safe approach to gout management.

The Council supports the reclassification of allopurinol to improve equity of access

With greater access to training (that focuses on patient assessment, point of care testing, supply guidelines/ guidance, and patient advice), the Council believes that pharmacists who have completed the additional training will be able to safely and effectively supply allopurinol as a prescription medicine with exceptions as outlined in the proposal.

5. Agenda item 7.3 Cytisine

Cytisine is a nicotine receptor partial agonist indicated for smoking cessation. The Council believes that pharmacists have the core competencies to provide smoking cessation advice and self-directed up-skilling on cytisine should be sufficient. Pharmacists have been providing smoking cessation services (such as nicotine replacement therapy) and health promotion messaging as part of their clinical services. The expansion of the range of products available will be beneficial to consumers who want to try new smoking cessation options.

The Council supports the proposed classification of cytisine to improve access to smoking cessation options for consumer

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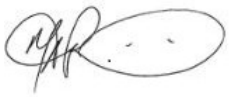
[3] HQSC https://www.hqsc.govt.nz/assets/Our-work/Improved-service-delivery/Patient-deterioration/Publications-resources/Presenter_slides_-_Equitable_approaches_to_gout_management_webinar_1_July_2020.pdf

[4] 91-day gout management programme provided by Mahitahi Hauora PHE and is now district wide across Northland (35 pharmacies and all general practice).

The proposed scheduling of cytisine as pharmacist-only medicine would provide another option available to support the smoking cessation goals of the consumer. The pharmacist will need to consider the patient's preferences, previous experience of smoking cessation aids and the likelihood to adhering to treatment. Improving access to more options to quit smoking will help support people to stay smokefree.

Yours sincerely



Michael A Pead
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13 January 2025

Medicines Classification Committee 73rd Meeting

Via email: committees@health.govt.nz

Tēnā koutou,

I am writing on behalf of Pharmac to support the submission for medicine reclassification for allopurinol for the prophylaxis of gout.

The classification sought is "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"

There are two proposed models:

1. Titration and continuation supply in a collaborative model designed particularly to work with the gout programmes around the country with Health New Zealand
2. Continuation supply (through pharmacies) outside of the existing gout programmes.

Pharmac has had an interest in gout through our Access Equity work and the identification of gout as a priority condition in our Achieving medicine access equity in Aotearoa New Zealand.2019 discussion document. Pharmac subsequently published our Gout Insights Impact on Māori in 2021 and our Pacific peoples health – Gout data insights 2022.

Findings from these reports showed that Māori and Pacific people had lower rates of 'possession' of preventive gout medicines compared to non-Māori, non-Pacific peoples, despite having higher rates of gout. Possession was defined as 'The average proportion of time that individuals with 'any dispensing' had medicine dispensed over the last two years. These findings aligned with the Health Quality and Safety Commission's/Te Tāhū Hauora Atlas of Healthcare Variation for Gout which showed that Māori and Pacific peoples were more likely to receive some urate-lowering therapy in a year, but less likely to receive it regularly. This is important because urate-lowering therapy needs to be used continuously long-term for people to benefit from it.

Furthermore, both our gout insights and the Commissions have shown that overall regular use of preventive gout medicines is low (approx. 30-40%). Low regular preventive medicine use may contribute to hospitalisations for gout, particularly to the high rates of hospitalisations we see among Māori and Pacific peoples compared to non-Māori, non-Pacific peoples.

Access issues contribute towards low preventive gout use. These include:

- Time off work or looking after children/elderly parents
- Difficulty seeing a doctor (eg unavailability of doctors, affordability geographic location opening hours, disability etc)

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- Stigma
- Communication difficulties
- Health Literacy

The current proposed model(s) for the titration and continuation of supply of allopurinol will not solve all the equity issues associated with accessing preventive gout medicine. It will however reduce barriers to access by:

1. Improving access to titration and continuation of supply of allopurinol within existing gout management programmes in Aotearoa New Zealand, including access for Māori and Pacific peoples.

2. Reducing the burden of standing orders to general practice for gout management programmes, freeing up general practice time

3. Increasing out-of-hours (and potentially) rural access for continuation of supply of allopurinol

4. Improving education around gout within community pharmacies

   Unfortunately the situation currently exists whereas people can access diclofenac (Voltaren^{Rx}) for gout flares through a pharmacist consultation but not the preventive long-term medicines for gout, including continuation of supply from a GP initiated prescription. As well as enabling continuation of supply, specifically trained pharmacists in gout may encourage more peoples who are buying NSAIDs for gout to go to their GP to initiate preventive treatment.

Allopurinol, in particular, is a low-cost preventive medicine which when used regularly helps to avoid long term sequelae of gout. This includes tophi, joint damage and renal damage, all of which places burden on individuals, whānau, caregivers and the health system. Māori and Pacific peoples are disproportionately affected.

Conversely well managed gout contributes to people reaching their full health potential. It also may contribute to the reduction of presentations with gout to emergency departments, the need for urgent appointments with the GP and hospitalisations.

For these reasons we support the reclassification bid for allopurinol.

Ngā mihi nui

Robyn Harris | Team Lead Implementation

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TOKELAU COMMUNITY GROUP INC

Medicines Classification Committee (MCC) Secretary
Medsafe New Zealand Medicines and Medical Devices Safety Authority
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Wellington 6145
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Sent via email to: committees@moh.govt.nz

Malo ni

Re Medicines Classification Committee 25 Feb 2025
Agenda item 6.5 Allopurinol Reclassification

We write in support of the submission by Arthritis New Zealand Mateponapona Aotearoa, Green Cross Health, Dr Natalie Gauld and Associate Professor Peter Gow, Rheumatologist to reclassify allopurinol to enable trained pharmacists to titrate and provide continuous supply of this preventive medication for patients with gout.

The Atafu Tokelau Community Group, based in Porirua, is seeking the reclassification of allopurinol to allow trained pharmacists to titrate and provide continuous supply of this preventive medication for individuals suffering from gout. Our group has noted a significantly high incidence of gout within the Porirua community, the largest population of Tokelau in the world live in Porirua.

Currently, the process for obtaining allopurinol is often cumbersome, requiring multiple healthcare visits and specialist consultations. By enabling trained pharmacists to titrate and dispense allopurinol, patients would benefit from more accessible and continuous care. Pharmacists, with appropriate training, can safely monitor uric acid levels, adjust dosages, and ensure patients are on an effective regimen, all while reducing the burden on primary care providers and specialists.

This initiative aligns with improving healthcare equity and accessibility, particularly for the Tokelau community in Porirua, where healthcare needs can be underserved. Allowing pharmacists to provide ongoing gout management would not only enhance patient outcomes but also reduce the strain on the healthcare system, making preventive care more accessible and effective for those in need.

Fakafetai lahi lele

Yours sincerely

Zechariah Reuelu
Project Lead
www.matauala.org

Medicines Classification Committee (MCC) Secretary
Medsafe New Zealand Medicines and Medical Devices Safety Authority
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New Zealand

16 January 2025

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

Re: Medicines Classification Committee 25th February 2025; Agenda item 6.5 Allopurinol Reclassification.

Kia ora Medicines Classification Committee,

I am writing to you to voice my very strong support for the submission prepared by Arthritis NZ Mateponapona Aotearoa, Green Cross Health, Dr Natalie Gauld and Associate Professor Peter Gow (Rheumatologist) to reclassify allopurinol to enable trained pharmacists to titrate and provide continuous supply of this preventive medication for patients with gout.

The proposed reclassification of allopurinol is particularly significant from my point of view for multiple reasons, both personal and professional.

First and foremost, I have gout myself. I am 50 years of age, identify as New Zealand European/Pakeha, and have been taking allopurinol since 2020 following a formal diagnosis of this disease after first experiencing gout flares approximately five years prior. My journey as a consumer with gout did not however start well. In addition to experiencing rather frequent flares and attending a medical centre where the GPs had very little knowledge of the condition, I was eventually admitted to the emergency department at my local hospital due to being unable to walk properly and in constant pain from the gout attacks. This visit to hospital was critical as I was seen by medical staff who were able to determine what was wrong and they subsequently helped set up a pathway which enabled me to finally get appropriate treatment for my condition.

There are many barriers to allopurinol use, including insufficient knowledge of the need for urate lowering therapy (ULT) and gout itself, not being able to work, and patients not being aware they even have gout in the first place. I experienced each of these barriers while having very little idea of what was happening to my body. If trained pharmacists were able to titrate allopurinol using point-of-care testing and play a more central role in the care of gout patients in tandem with GPs, I believe I may have been able to access treatment in a more timely way and enjoy better health outcomes than I did. Lastly, the effectiveness of allopurinol was startling: within 48 hours of first taking allopurinol, the level of pain I had been experiencing was dramatically reduced and I also quickly regained my mobility and no longer required crutches to walk.

Secondly, I am the Research Manager at Arthritis NZ and have been working in this role for approximately four years. Being able to draw on my own lived experience of gout, but also the research evidence base pertaining to the condition has been of vital importance when engaging with people who are part of our organisation's "consumer community". I have been able to discuss both the beneficial aspects associated with taking allopurinol, but also the numerous barriers that I have personally faced and other extremely well-documented barriers that lead to other people not having adequate access to treatment.

Additionally, I have also learnt many significant things relating to the health and wellbeing of Māori and Pasifika gout patients. Before working at Arthritis NZ I was unaware of how adversely gout can affect Māori and Pasifika patients in addition to NZ European/Pakeha with regards to various whānau, social, economic, and cultural needs. Barriers to appropriate treatment are even more challenging for many Māori and Pasifika consumers, and may include issues such as cost, the stigma or "whakamā" associated with the disease, and the ability to manage other long-term conditions. The proposal to enable trained pharmacists to be more involved in the care and support of gout patients through providing continuous supply of this vital medication, and ultimately better access to treatment while also seeing their GP annually will significantly improve health outcomes for Māori, Pasifika, and indeed all patients with gout.

Many thanks in advance for the opportunity to make a submission.

Yours sincerely | Ngā mihi nui | Kind regards

Dr Richard Griffiths
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18th December 2024

The Chair,
Medicines Classification Committee (MCC)
Medsafe

To the Chair,

Re: **Allopurinol – proposed change to the prescription classification statement**

I am a Rheumatologist and Professor of Medicine with 25 years' experience in gout management. I am writing in support of the application to change to the prescription classification statement for allopurinol.

Gout is a major form of musculoskeletal disability in New Zealand, affecting one in 20 adults. More than a quarter of older Māori men and one-third of older Pacific men have gout. Gout is also a common cause of work disability for young men.

Best practice for long-term gout management is the commencement and continuation of a urate-lowering medicine if the person has had two gout flares in the last 24 months. Allopurinol is by far the most used urate-lowering therapy in New Zealand. Treatment of gout flares is short term use of prednisone or nonsteroidal anti-inflammatory drugs (NSAIDS).

Data from the 2021 update of the HQSC Atlas of Healthcare Variation shows that only 41% of New Zealanders with gout receive continuous urate-lowering therapy such as allopurinol. Many people are started on allopurinol but do not get the benefit of this treatment without correct dosing and continuous use. This means that most people with gout continue to be treated with repeated courses of prednisone and NSAIDS, medications that can cause other important health problems such as chronic kidney disease, cardiovascular disease and diabetes.

Adopting strategies to reduce barriers to regular urate-lowering therapy is of central importance to improve gout management in New Zealand. This includes a process to increase access to regular allopurinol. Pharmacy-based gout management programmes have been demonstrated to be safe and superior to usual care, both overseas and in New Zealand. I am reassured that the proposal includes appropriate risk mitigation plans to ensure safe use of this medication.

Yours sincerely,

Professor Nicola Dalbeth, Rheumatologist and Head of Department,
Department of Medicine, University of Auckland

Professor Felicity Goodyear-Smith
MBChB, MD, FRNZCGP (Distinguished), FFFLM (RCP)

Department of General Practice & Primary Health Care
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Sent via email to: committees@moh.govt.nz

Kia ora

Re Medicines Classification Committee 25 Feb 2025
Agenda item 6.5 Allopurinol Reclassification

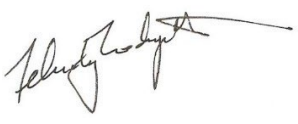
I write in strong support of the submission by Arthritis New Zealand Mateponapona Aotearoa, Green Cross Health, Dr Natalie Gauld and Associate Professor Peter Gow, Rheumatologist to reclassify allopurinol to enable trained pharmacists to titrate and provide continuous supply of this preventive medication for patients with gout.

I am a member of the Pacific Research Collective at the University of Auckland which is currently involved in HRC and Arthritis NZ-funded research projects to improve the uptake of allopurinol for Pacific people with gout. This research is being in conducted in partnership with the community-based Pacific Peoples Health Advisory Group (PPHAG), who have identified this as an important issue to address to improve the health outcomes of Pacific people from Sooth Auckland. Other members of the Research Collective include Pacific researchers Drs Malakai ‘Ofanoa, Dr Samuela ‘Ofanoa and Siobhan Tu’akoi, Pacific GPs Dr Maryann Nanette Anesi Heather and Hinamaha Lutui and members of PPHAG led by Ms Rose Lamont.

Barriers to allopurinol use have been identified as the time and cost of patients attending their GP for a prescription, going to the laboratory for blood tests, and then accessing the medication from the pharmacist, especially when the dose of the drug has to be titrated against the blood urate level. Having the pharmacist able to titrate the drug using point of care testing, provide flare control and use text messaging to remind the patients to get their prescriptions removes a significant barrier. It is agreed that collaboration between the pharmacist and the GP is necessary and the patients should see their GP annually.

Gout prophylaxis using allopurinol is under-treated, especially for Pacific people. Reclassification as proposed would go a long way to addressing this problem.

Ngā mihi nui
Yours sincerely



Prof Felicity Goodyear-Smith

Submission for the Reclassification of allopurinol

Thank you for the opportunity to make this submission.

My name is Susan Reid. My iwi is Te Rarawa. I am one of two directors of Health Literacy NZ Limited. I am also the honorary coordinator of Gout Action Aotearoa (GAA) a group of individuals (rheumatologists, GPs, nurses, researchers, health managers, pharmacists, and organisations such as PHOs, Arthritis New Zealand and Health Navigator who have an interest in improving gout treatment in Aotearoa. GAA meets quarterly to share research findings, project and programme updates and support each other's mahi. I am making this submission on my own behalf rather than on behalf of GAA. I am aware other members of GAA are making their own individual submissions. I do not have a clinical background. My background is in adult education and specifically adult literacy (defined in Aotearoa New Zealand as reading , writing, speaking , listening, numbers, interpreting measurement and shapes, and reasoning statically. (New Zealand Learning Progressions) . My current role is as a Health Literacy consultant and my primary mahi is the training of Health Coaches who are part of the Integrated Primary Mental Health and Addictions initiative.

Background to my work in gout

I was not at all aware of gout as a long-term condition until I started managing a workplace literacy programme at then Tasman Pulp and Paper in Kawerau. I worked there from 1994 to 2006. At the time I was employed by Workbase Education Trust the New Zealand Centre for workplace literacy.

At the time I worked at Tasman it employed over 1200 people most of them men. The workplace literacy programme I managed was based initially in the Wood Prep area where almost all of the employees were Māori men. Very shortly after I started working there I became aware of how many of these men suffered from acute gout attacks. None of the men took long term medicine for their gout. Instead they relied on using NSAIDs to manage the pain until the attack subsided. The men with gout explained that gout was their fault because they ate kaimoana and drank beer and that was what caused gout. They said that gout was a bit of a joke and they were teased when they had gout and they teased their fellow employees when they had gout. They explained how excruciating painful a gout attack was and how it impacted their lives and the lives of their whānau. Because the men had unlimited sick leave it did not impact of their income but the situation at Tasman Pulp and Paper was very unusual in relation to other employers.

Men with gout who were unable to work were referred to our Open Learning Centre Te Whare Ako while they were having a gout attack. This made me aware of how painful a gout attack was and how all the men could really do was rest as their cognition was impacted by the pain of their gout. Because of the detailed descriptions of the symptoms of gout attacks I was able to diagnose my own gout attack in 1998. When I talked to the GP on site who confirmed my self-diagnosis he advised me that there was a long-term medicine called allopurinol that in his words 'could cure my gout once and for all'. As this was my first (and luckily my only) gout attack I declined the long-term medicine. However this did start me on a journey of trying to find out

why the men who had been told about the medicine did not want to take it. Some men had tried allopurinol before and send it gave them gout, others said they didn't want to go on long term medicines as that meant they were unhealthy and others said it was their own fault because they drank beer and are kaimoana. There was a big focus on self-blame.

As part of wanting to learn more about gout I was very fortunate in 2011 to be invited by Dr Peter Gow, rheumatologist , to join the Maaori Gout Action Group (MGAG) based at then Counites Manukau DHB. MGAG is the predecessor to GAA. MGAG in 2011 was then chaired by Dr Karen Lindsay who was an English trained rheumatologist who when she arrived to work in South Auckland described it as the gout capital of the world as she had never seen such a prevalence of gout in a community. Other members of MGAG at that time included Professors Nicola Dalbeth, Tony Merriman and Bruce Arroll, Dr Doone Winnard, Dr Devi Ann Hall, Caran Barratt Boyes, representatives from Arthrtiis New Zealand and the CMDHB Pharmacy Managers.

In 2012 the then Māori Directorate of the Ministry of Health contracted my then employer Workbase to so a review of health education resources on gout medication. This was followed by a contract to research gout form a health literacy perspective. As a result of these projects we developed patient information resources about gout including To Stop Gout which became the national patient information resource.

In 2021 Pharmac contracted Health Literacy NZ to update and replace the To Stop Gout patient information resource and in 2022 the latest patient information resource Change your Life was printed and has been distributed widely throughout Aotearoa New Zealand.

In 2022 and 2023 Health Literacy NZ and Health Navigator Charitable Trust worked with five ProCare practices in a Gout Collaborative using quality improvement methodologies for better gout treatment and management for Māori whānau and Pacific peoples with gout. As a result of this project we developed the Gout Guide Welcome to the Gout Guide for health providers a comprehensive online guide for primary and community care providers which contains everything a health care team needs to better treat and manage gout. As part of the development of the Gout Guide a large number of new patient facing videos were developed and added to Healthify.

As a result of all these activities I have personally worked with and interviewed over a 1000 people with gout. Health Literacy NZ is now recognised as having significant expertise in gout and we continue to participate in gout research projects, host gout material and links on our website, and help connect individuals and organisations to people and places where they can get responses to questions about gout.

My submission

I wish to support rt the reclassification of allopurinol so it can be prescribed and up titrated for people with gout in both of these circumstances

1. Titration and continuation supply in a collaborative model. This is designed particularly to work with the gout programmes around the country with Health New Zealand.
2. The second is Continuation supply outside of the pharmacy gout programmes.

In both situations the pharmacist must successfully complete training endorsed by the Pharmacy Council of NZ, work within set parameters, refer if appropriate, keep appropriate records and inform the general practice of supply.

Both these approaches are necessary. Where gout programmes are currently being run in Aotearoa NZ it is unlikely funding will continue long term and so the second approach is necessary where a person with gout who may or may not have been involved in a previous gout programme but has been prescribed allopurinol before comes into a pharmacy looking for support to treat their gout.

Reclassification will take out the current road blocks around Standing Orders, and significant issues in relation to access to primary care – not just wait times but also opening hours.

Issues that the Committee needs to be aware of

- **Co-existing long-term conditions** – a number of people with gout also have Type 2 diabetes (about one third of the population with gout in Counties Manukau area) as well as high blood pressure, high cholesterol, kidney disease and other long-term conditions. Pacific researchers who are part of GAA have said people with gout will want a one stop shop where they can access repeats of all their medicines – not just allopurinol. So this might restrict people with gout who will access pharmacists, to those who only have gout (likely to be younger men who are a critical group). Otherwise those with other long term co-existing conditions may choose to access their primary care provider as they can then receive repeats for all their medicines and their primary care team may or may not prescribe allopurinol. This is the status quo for many Māori whānau and Pacific peoples with gout.
- **Workforce pressures** – like primary care teams (and other health professionals) pharmacists are being asked to do much more mahi and not receiving proper recompense for these extra activities e.g. infant vaccinations. Pharmacies are also having problems retaining staff and some pharmacies struggle to find space to do consultations with patients and/or are time limited in their approaches meaning a didactic approach to providing information rather than spending time with the person with gout and finding out about their concerns and motivation for taking allopurinol for the rest of their life. At this stage there is no funding for pharmacists and that concerns me in terms of the uptake by pharmacists. Apart from the pharmacists' valuable time, using Point of Care meters is essential for giving the person with gout instant feedback about their uric acid levels (and removing the barrier of having to go to a laboratory). There is a one-off cost to buy a Point of Care meter and ongoing costs for test strips which are expensive and expire quite quickly.

An issue that need to be addressed in this reclassification

- **Training needs to include behaviour change approaches** –. I have been involved in contributing to the content of current endorsed training and realise now it is not adequate and additional training needs to be added. Previously a lot of the training has focused on the pathophysiology of gout (very important) as well as the equity issues and the need to address biases.

  The reason gout is so poorly treated and managed in Aotearoa New Zealand is because of three key factors. The first is the very strong community beliefs that gout is the person's fault because it is caused by food and drink (in particular

kaimoana and beer) and is something to be suffered using if possible pain relief such as NSAIDs.

The second factor is clinical inertia on behalf of health professionals. In a time constricted environment it is much easier to prescribe NSAIDs rather than enter into a lengthy debate with someone who does not want to take life long medicines. I am still surprised to meet health professionals including GPs who either don't yet know the link between lowering uric acid and managing gout or who believe that just telling a person that you need to take allopurinol for the rest of their life is the way to get a person with gout to start and keep taking allopurinol.

The third factor is that getting a person with gout onto the appropriate dose of allopurinol takes time and effort on the part of the person with gout and the prescriber. People might experience gout attacks as their uric acid levels reduce and it might take a long time before the persons achieves the optimal dose of allopurinol to bring their uric acid level to achieve the appropriate treatment goal. So behaviour change involves the health care professionals being able to have person-centred, non-judgmental conversations which unpack a person's experiences with gout, their ambivalence about starting long term medicines and their motivations to get their gout under control and the somewhat tricky path to achieving that in terms of stating and up titration of allopurinol and the likelihood of a gout attack during this time.

For people with gout behaviour change involves developing new knowledge about gout, understanding how it is impacting on the person and their whānau and the reasons for the person to make the change and commit to taking a medicine every day for the rest of their life.

To my knowledge behaviour change approaches are not taught at Medical Schools or at Pharmacy Schools (motivation interviewing might be but this is only one small aspects of behaviour change). Behaviour change has been introduced to people with gout and their whanau on page 7 of the Change Your Life booklet in the context of deciding to take long term medicines but this introductory text need s to be supplemented with good conversations and discussion.

All pharmacists who are prescribing allopurinol to people with gout need to know and be able to use behavioural changes approaches which include recognising which stage of change the person is at and the appropriate questions to ask and then actions to take. It is an unreasonable assumption to make that everyone who comes into the pharmacy to talk about gout is in fact ready to commit to taking allopurinol for the rest of their life. Even if they say they are ready to make a change then at some stage they may slip back and stop taking their allopurinol and the pharmacist will need to find out what went wrong and then if the person wants to recommence taking allopurinol start on the lengthy titration process again.

Behavioural change approaches will also be needed in the second circumstance of reclassification where a person with gout who is not part of a gout programme comes in to see a pharmacist.

One off training will not be adequate for behaviour change approaches. Behaviour change is complex and it can be tricky initially to work out where people with gout are in terms of stages of change and the appropriate questions to ask. There will need to be access to other training such as webinars or online modules to reinforce this aspect of the required training. I would recommend that training in behaviour change approaches needs to be repeated every two years. Behavioural change approaches will also assist pharmacists when working with other patients around medicines or needing to improve their nutrition or be more active. I do not think the pathophysiology aspects of the training needs to be repeated and in any event resources to reinforce this could easily be made available.

Once again thank you for the opportunity to make a submission. The problems with the poor treatment and management of gout in Aotearoa will be partly (but not totally) resolved by this reclassification.

Dr Samuela ʻOfanoa
Research Fellow, Pacific Health, Pacific Research Collective

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13 Dec 2024

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Medicines Classification Committee (MCC) Secretary

Medsafe New Zealand Medicines and Medical Devices Safety Authority
PO Box 5013
Wellington 6145
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Sent via email to: committees@moh.govt.nz

Mālō e lelei

Re Medicines Classification Committee 25 Feb 2025
Agenda item 6.5 Allopurinol Reclassification

I am writing with full support of the submission by Arthritis New Zealand Mateponapona Aotearoa, Green Cross Health, Dr Natalie Gauld and Associate Professor Peter Gow, Rheumatologist to reclassify allopurinol to enable trained pharmacists to titrate and provide continuous supply of this preventive medication for patients with gout.

I am a member of the Pacific Research Collective at the University of Auckland. I am one of the Pacific co-investigators currently involved in HRC and Arthritis NZ-funded research projects to improve the uptake of allopurinol for Pacific people with gout. This research is being in conducted in partnership with the community-based Pacific Peoples Health Advisory Group (PPHAG) and the Pacific Practice Based Research Network (PPBRN) who have identified gout as an important issue to address to improve the health outcomes of Pacific people from South Auckland.

Pacific communities in our research reported barriers to allopurinol use such as time (inaccessible opening hours, limited appointment times), the cost of patients attending their GP for a prescription, and going to the laboratory for blood tests, and then accessing the medication from the pharmacist, especially when the dose of the drug has to be titrated against the blood urate level. In response to these barriers, community members highlighted the need for alternative points of access by utilising other health professionals. PPBRN general practitioner members agreed that the role of nurses, pharmacists and other health professionals has evolved over time and that they are capable of delivering gout management services. Thus, having the pharmacist able to titrate the drug using point of care testing, provide flare control and use text messaging to remind the patients to get their prescriptions can overcome the barriers highlighted by the community.

The uptake of allopurinol is low for Pacific gout patients in South Auckland. Reclassification as proposed would contribute considerably to improving access to and uptake of allopurinol.

Tuʻaʻofa atu
Yours sincerely

Dr Samuela ʻOfanoa

28 November 2024
Medicines Classification Committee Secretary
Medsafe
PO Box 5013
Wellington
6145
via email: committees@moh.govt.nz

Tēnā koe,

Thank you for the opportunity to submit comments on the agenda for the 73rd meeting of the Medicines Classification Committee. Regarding agenda item 6.5 for the above meeting of the Medicines Classification Committee I would like to note the below comments for consideration.

I have been involved in the Hawke's Bay Mate Taihā gout programme. The Mate Taihā gout programme allows community pharmacists to escalate allopurinol dose under standing orders. Pharmacies can deliver a patient centred service and have shown that they can be important members of the extended care team. Having to work under standing orders is a barrier for our pharmacist. Having to re-sign and audit standing orders is a burden to our General Practice prescribers as well. I believe reclassification of allopurinol is an important step to supporting patients with gout.

I support the proposed reclassification of allopurinol; however, I propose the below considerations:

Part B – Clinical context and implications:

- Risks will be managed as follows, point 2: *All gout patients where allopurinol is being provided or dose titrated by the pharmacist must have a consultation with their general practice at least once a year:* For patients who are not enrolled at a general practice this will not be practicable. There may be an inequitable number of young Māori or Pacific men who are unenrolled. Could this be extrapolated to Māori health providers, walk in clinics and urgent care providers?

- Risks will be managed as follows, point 4: *Maximum 600 mg/day of allopurinol.* The median dose of 450mg is required for the New Zealand population. While it is recommended that doses greater than 600mg should have specialist advice, there will be a group of patients who will have doses of over 600mg as their maintenance dose (as is also noted under Indication and dose, point 15). Are these patients excluded from continuation supply?

- Continuation supply, point 14: *eGFR is required annually and needs to be at least 60 mL/min.* I believe that this will add an unnecessary barrier to community pharmacists. While renal function dictates starting does and titration, dose reductions are not routinely required in patients with declining renal function who are already established on allopurinol. Therefore, an annual eGFR will not change management of the patient.

- Indication and dose, point 15: *What is the evidence that the proposed indication is an OTC indication, ie that the diagnosis and treatment can be understood by the consumer?* I tautoko the response to this question but would like to add that this is an opportunity for pharmacists to provide education to consumers on gout and the importance of long term treatment. Education programmes should include talking points.

Ngā mihi

Dear Medicines Classification Committee 17 January 2025

I act as Medical Director to Arthritis NZ in my capacity as a practising rheumatologist in Wellington.

The purpose of this project is to remove barriers to treatment, with a focus on younger patients who have normal baseline renal function.

The proportion of gout patients regularly receiving urate-lowering therapy is far lower for those aged 20-44 years (18.7%) than the older age groups and many young people with gout are being started on allopurinol but not continuing.

This submission will make it easier for patients with gout to receive long term allopurinol by removing barriers caused by the need for a doctor's prescription every three months.

I am happy to support the submission for medicine reclassification as presented.

Yours sincerely,

Andrew Harrison
Rheumatologist
Medical Director of Arthritis New Zealand

Kia ora koutou

Funded gout services have been provided through a small group of Porirua pharmacies serving high Māori Pacific communities since August 2019.

The service has enabled allopurinol to be more accessible to higher need communities through a structured programme by trained pharmacists under the oversight of the patient's medical practitioner.
Patient urate levels are monitored through point of care testing and results and changes to allopurinol dosing are reported to the patient's medical practitioner.
Pharmacists work with patients towards achieving therapeutic levels of allopurinol over a 6 month period, to reduce the incidence and the profoundly disabling impact of gout flares.
Patients who have not taken their medication for some time may be restarted at an appropriate dose.

The reclassification of allopurinol would remove the complexity of standing orders and save time. It could be prescribed by pharmacists as part of a structured pharmacy programme by suitably qualified pharmacists. Many of our communities are experiencing high wait times (typically several weeks) to see their medical practitioner. Enabling gout to be managed safely through structured pharmacy programmes will enable medical practitioners to spend time with patients on other conditions. It would also simplify the process for implementing pharmacy gout services.

Nga mihi
Keith

Keith Fraser
System Design Manager – Referred Services
Te Whatu Ora
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Kia Ora
Please see the submission from NZRA.

The New Zealand Rheumatology Association (NZRA) supports this initiative. The NZRA is very aware of the health burden of gout particularly for our Māori and Pasifika populations for whom gout (genetically) is more prevalent. We also acknowledge the extent to which gout is undertreated in Aotearoa , New Zealand, and understand the barriers to treatment for many individuals*

Gout is a treatable disease. Allopurinol is inexpensive and effective but requires dose titration, regular prescription renewal and monitoring.

This proposed new model of care has been designed to address some of these barriers and as such, we can anticipate improved treatment access and treatment continuation for vulnerable individuals.

***Dalbeth, N., et al., Gout in Aotearoa New Zealand: The equity crisis continues in plain sight. NZ Med J, 2018.131(1485):8-12.**

Kind Regards
Hugh de Lautour

Kia ora

Re: Proposed Model of allopurinol access - agenda item 6.5

Please be advised that the New Zealand Rheumatology Association (NZRA) supports this initiative. The NZRA is very aware of the health burden of gout particularly for our Māori and Pasifika populations for whom gout (genetically) is more prevalent. We also acknowledge the extent to which gout is undertreated in Aotearoa , New Zealand, and understand the barriers to treatment for many individuals*

Gout is a treatable disease. Allopurinol is inexpensive and effective but requires dose titration, regular prescription renewal and monitoring.

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Dalbeth, N., et al., Gout in Aotearoa New Zealand: The equity crisis continues in plain sight. NZ Med J, 2018.131(1485):8-12.

Ngā mihi nui

Dr Sarah Jordan
President NZRA

Tena koe,

I am writing in support of the application to reclassify Allopurinol as a pharmacist-prescribed medication for the purposes of prophylaxis of gout. I am a GP based in Te Tai Tokerau, where prevalence of gout is amongst the highest in the world. Uncontrolled gout is associated with many poor metabolic outcomes. Historically, it was thought of as a disease caused by poor food choices, leading to the sense of shame felt by many sufferers. We now understand the genetic heritage of this disease and the fact that diet alone will not control the disease and that long term medications should be offered and adequate monitoring take place to improve patient outcomes. I have recently audited our medical practice's patients with gout and note that there is a significant shortfall in patients of Maori descent seeking acute care for their gout. Furthermore, there is significant evidence of clinical inertia with re-prescribing of same dose Allopurinol despite urate levels still not to target. Discussion with colleagues and pharmacists have led us to hypothesise that many patients buy OTC NSAIDs rather than seek appropriate long term care for the management of their gout. This ultimately leads to even poorer outcomes for Maori and Pacific patients. Access to primary care is getting harder and harder, particularly for patients with lower means or lower health literacy. By enabling pharmacists to up titrate gout prophylaxis medications, it mitigates the clinical inertia that we currently see in practice. Through regular communication with the GP practice, it supports better team work within community teams. Furthermore, through the gout busters programme in South Auckland, patients were enabled to keep records of their own urate levels, enabling better self management of their own health. If reclassified, I believe that pharmacist-led titration of medications will free up primary care time to provide more proactive care.
Thank you for your time and consideration.