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

Dr Luke Bradford
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Medical Director | Mātanga Hauora

PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

16 January 2025

Medicines Classification Committee Secretary
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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*"

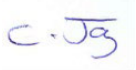
The value of the Owning my Gout (OMG) management programme has been independently evaluated by Synergia and demonstrated clinical success. The Community Pharmacy Gout Management Service Training has already been developed and is running in several Districts across the country. With a small amount of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

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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

[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
Chief Executive

PHARMACY GUILD OF NEW ZEALAND

16 January 2025

Medicines Classification Committee Secretary
Medsafe
Wellington

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

Dear Committee Members,

Re: Agenda for the 73rd meeting of the Medicines Classification Committee (MCC)

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

The Pharmacy Guild of New Zealand (Inc.) (the Guild) is a national membership organisation representing community pharmacy owners. We provide leadership on all issues affecting the sector and advocate for the business and professional interests of community pharmacy.

Our feedback covers the following agenda items:

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

6. Submissions for reclassification

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

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

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

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

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

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

- Pharmacist education and training: It is essential that pharmacists are equipped to effectively communicate the risks and proper use of lidocaine-containing oromucosal products to patients and caregivers, with training focusing on safe use, highlighting risks like excessive or prolonged use, and enhancing communication skills to ensure clear explanations for individuals with varying health literacy. Pharmacists should also be educated to identify high-risk patients, such as those with pre-existing conditions or potential drug interactions, so that they can provide tailored advice, and recognise signs of misuse or adverse reactions, enabling early intervention and appropriate referrals when necessary.

- Clinical tools: Clear guidelines and access to appropriate clinical tools, including updated training and dosing calculators, will be essential to equip pharmacists for their expanded role in overseeing the use of lidocaine-containing oromucosal products. These tools should include detailed age-based dosing recommendations, specific warnings about maximum doses, and guidance on the duration of use, particularly for children under 12 years of age, to ensure that pharmacists can make informed decisions and communicate effectively with patients and caregivers, reducing the risk of misuse or overdose.

- Revenue and access concerns: The proposed changes could inadvertently lead to supply chain restrictions, potentially impacting the availability of lidocaine-containing oromucosal products for patients who require them for legitimate medical needs and reducing revenue in community pharmacies, especially those that rely on these products as part of their regular offerings. While the restricted classification aims to improve safety, it will be crucial to ensure that these products remain readily available to those who need them, particularly for self-limiting conditions like mouth ulcers or teething pain.

- Enhanced communication from Medsafe: Clear communication from Medsafe about the specific dose forms affected by the reclassification is vital to ensure pharmacists, healthcare providers, and the public understand the reclassification changes and to facilitate a smooth transition with minimal disruptions. This communication should detail which lidocaine-containing oromucosal products are affected, any exceptions, and an implementation timeline to allow pharmacies time to adjust their inventory and procedures. A public awareness campaign, involving Plunket and other child health organisations, would also be beneficial to inform caregivers and the public about the new restrictions, potential dangers of misuse, and safe usage of these products, particularly for children under 12 years of age.

- Mandatory warning statements are easily understandable for the public: To maximise the effectiveness of the mandatory warning statements, they should be written in clear, simple language that is accessible to individuals with varying levels of health literacy and prominently displayed on the product. Caregivers, who may not have a healthcare background, should be

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

6.2 Tenofovir disoproxil and emtricitabine (Burnett Foundation)

The Guild strongly supports the proposal by the Burnett Foundation for the reclassification of disoproxil and emtricitabine to a prescription medicine, except when supplied for HIV prophylaxis to people who are over 18, are HIV negative, and meet the clinical and eligibility criteria of an approved training programme, when provided by a pharmacist who meets the requirements of the Pharmacy Council. This proposal aims to expand access to HIV PrEP in New Zealand, a proven option to reduce the risk of HIV transmission by up to 99%, through a pharmacist-led supply model to overcome current barriers to the access of this crucial treatment, increasing equitable access to HIV prevention, and reduction of individual and community risks.

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

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

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

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

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

6.3 Travel vaccines (Green Cross Health Limited)

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

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

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

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

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

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

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

However, we would like the proposed classification statement by GSK to be reworded to the following:
Prescription only except when administered for the prevention of herpes zoster (shingles) to a person 18 years or over by an authorised vaccinator or registered pharmacist who has successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who complies with the immunisation standards of the Ministry of Health (but excluding a vaccinator who has completed the Provisional Vaccinator Foundation Course).

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

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

- Enhancing access to vaccinations: Herpes zoster infection and its complications is a significant public health issue, particularly for older adults and immunocompromised individuals. The Recombinant Varicella Zoster Virus vaccine is highly effective in preventing this painful and potentially debilitating condition. However, the current prescription-only classification to those under the age of 50 years restricts access to the vaccine, especially for those who face barriers in visiting a general practitioner for a prescription. Allowing pharmacist vaccinators to administer the vaccine directly without the need for a prescription would significantly reduce cost and delays in vaccination, and this is particularly beneficial in underserved and rural areas or for high-risk patients who require timely immunisation to achieve optimal outcomes, where access to primary healthcare providers may be limited or overburdened.

- Promoting equity in immunisations: The reclassification of the Recombinant Varicella Zoster Virus vaccine supports New Zealand's commitment to health equity. Internationally, there is a growing recognition of the vital role pharmacists play in expanding access to immunisations. Countries like the United States, Canada, and the United Kingdom have seen significant success in increasing vaccine coverage and immunisation rates by leveraging pharmacists as accessible healthcare providers. By enabling pharmacist vaccinators in New Zealand to provide the Recombinant Varicella Zoster Virus vaccine to a broader patient population, we can similarly improve vaccine uptake, particularly among underserved populations or those at higher risk of complications from herpes zoster infection.

- The role of pharmacists in New Zealand: Pharmacists are among the most accessible primary healthcare professionals in New Zealand, offering extended hours, free consultations, and the convenience of walk-in vaccination services, often serving as the first point of contact for healthcare advice and services. Their successful role in administering vaccines, such as influenza and Covid-19 vaccines, has already demonstrated their capability and the trust the public places in them. Pharmacist vaccinators have been providing the Recombinant Varicella Zoster Virus vaccine to individuals aged 50 years and over for some time and expanding their ability to administer this vaccine without a prescription to a broader patient population is a logical and necessary step to ensure more New Zealanders are protected against shingles and its complications.

- Training of pharmacist vaccinators: Pharmacist vaccinators are highly trained to conduct comprehensive assessments and consultations before and after vaccination events, providing education and addressing concerns to support patients and caregivers in making informed decisions. Currently they undergo the same training as other healthcare professionals already administering vaccines in this field and have access to additional training resources, such as from IMAC and the Australasian College of Pharmacy, to further enhance their expertise. With advanced information technology systems and access to the Aotearoa Immunisation Register (AIR), pharmacist vaccinators can track and support individuals in adhering to vaccination schedules and recalls, contributing to overall public health. This is further supported by significant sector investments, including Healthpoint to guide patients to vaccination services and the Book My Vaccine platform for seamless booking.

- Health sector cost savings: The potential cost savings for the healthcare sector through pharmacist-administered vaccinations cannot be overstated. In addition to this, the educational services and support provided by pharmacists can enhance public awareness,

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

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

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

6.5 Allopurinol (Arthritis New Zealand Mateponapona Aotearoa, Green Cross Health, Dr Natalie Gauld, Associate Professor Peter Gow)
The Guild strongly supports the reclassification of allopurinol to a prescription medicine except when supplied for prophylaxis of gout to people who meet the clinical and eligibility criteria of an approved training programme, when provided by pharmacists who meet the requirements of the Pharmacy Council. This proposal, created in collaboration with experts and stakeholders, not only addresses critical barriers to effective gout management but also aims to improve gout treatment outcomes and promote health equity, ensuring that all individuals have equal access to high-quality care.

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

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

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

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

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

7. New medicines for classification

7.3 Cytisine

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

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

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

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

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

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

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

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

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

8. Harmonisation of the New Zealand and Australian Schedules

8.2.a Naratriptan

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

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

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

Naratriptan is a selective serotonin 5-HT1 receptor agonist used to treat acute migraine attacks. This medicine is most effective when taken at the onset of a headache, rather than during the aura phase or after the headache becomes more severe. Written submissions supporting the down-scheduling of naratriptan in Australia emphasises its effectiveness and tolerability for acute migraine relief, comparable to sumatriptan, and supports the reduction of the inappropriate use of simple analgesics. Since naratriptan is recommended in Australia and in the proposed reclassification in New Zealand only for acute relief in patients with a stable, well-established pattern of symptoms, its down-scheduling offers significant benefits with minimal risk of misuse.

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

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

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

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

Thank you for your consideration of our response. If you have any questions about our feedback, please contact our Senior Advisory Pharmacists, Martin Lowis (martin@pgnz.org.nz, 04 802 8218) or Cathy Martin (cathy@pgnz.org.nz, 04 802 8214).

Yours sincerely,

Nicole Rickman
General Manager – Membership and Professional Services

THE UNIVERSITY OF AUCKLAND
Te Whare Wānanga o Tāmaki Makaurau
NEW ZEALAND

MEDICAL AND HEALTH SCIENCES
SCHOOL OF POPULATION HEALTH

16th January 2025

Attn: Medicines Classification Committee

Building 507,
Floor 1, Park Road,
Grafton Campus,
Auckland, New Zealand
The University of Auckland
Private Bag 92019
Auckland 1142
New Zealand

Dear Medicines Classification Committee

We wish to make a submission regarding the following agenda item "New medicines for classification: 7.3 Cytisine". We are University academics and work primarily in the field of tobacco control and smoking cessation. We specialise in the conduct of pragmatic, community-based trials to inform practice and policy.

Cytisine is a plant-derived alkaloid and is one of the world's oldest smoking cessation medications, being available since the 1960s in Eastern and Central Europe.[1] Cytisine 'dampens down' feelings of nicotine withdrawal when people quit smoking; and reduces the pleasure people get from smoking.[1] These actions make it easier for people to quit smoking.

In an effort to help New Zealand reach its smokefree 2025 goal, we have for many years conducted clinical trials to identify effective, safe and acceptable interventions to help people quit smoking. This research has included three large, investigator-initiated community-based trials of cytisine for smoking cessation, with a total of 2,829 participants, including 1,323 Māori (47%).[2-4] Our research, and that of others around the world, has found the following:

- Cytisine is more effective than a placebo for smoking cessation.[1,5]
- Cytisine is more effective than combination nicotine replacement therapy (NRT) for smoking cessation.[2]
- Cytisine is at least as effective as varenicline (Champix) for smoking cessation, but has fewer side effects and is more acceptable to smokers wanting to quit.[3,5]
- Cytisine is lower cost than varenicline (Champix).[6]
- Modelling suggests cytisine may be more cost-effective than varenicline.[7-8]

- Cytisine has the lowest cost per quality-adjusted-life-year of all tobacco cessation medications.[9]

Given the above, the World Health Organisation recommends cytisine as an effective treatment for tobacco cessation.[10] Cytisine is available in many countries (e.g., Armenia, Australia, Austria, Azerbaijan, Belarus, Bulgaria, Canada, Czech Republic, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Moldova, Poland, Russia, Serbia, Tajikistan, Turkmenistan, UK, Ukraine, Uzbekistan).[1] However, cytisine is not yet approved for use in New Zealand.

Given the strong evidence base for cytisine (including NZ-specific evidence) we feel strongly that all New Zealanders who have a nicotine dependence would benefit greatly from having cytisine available and accessible. Furthermore, if cytisine was available at relatively low cost, given its appeal and wide margin of safety, cessation outcomes for tobacco users in New Zealand are likely to be equitable.

If cytisine was made widely available in NZ we would recommend it was pharmacy only (i.e., it can only be sold in a pharmacy but can be self-selected by customers, can be advertised, any staff member in the pharmacy can sell it, and name and address are not recorded), with an added statement of being available via health professionals, the national Quitline, and community-based smoking cessation providers.

We would also recommend that cytisine was approved in New Zealand for the treatment of nicotine dependence, thus enabling it to be not only available for people who wanted to stop smoking, but also those who want to stop use of other nicotine products, such as nicotine vapes, nicotine pouches, etc.

Yours sincerely

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January 2025

Submission to Medsafe in support of Cytisine to be available as a non-prescription medication for smoking cessation.

About ASH.

ASH is registered charity founded in 1984 with the mission to reduce death and disease caused by tobacco smoking.

Conflict of interest statement

ASH does not and has never received funding from tobacco companies or vape companies. We have no conflicts of interest and have also never received funding from pharmaceutical companies engaged in the manufacture of supply of smoking cessation medications. ASH is independently funded by member donations, charitable and research grants.

Key points

- ASH strongly supports cytisine to be accessible without prescription from pharmacies, and via accredited stop smoking practitioners.
- There is high certainty evidence that cytisine is an effective stop smoking treatment with higher acceptance, and lower adverse affects than similar treatments
- There is good clinical trial evidence that cytisine is effective, and well accepted by Māori
- There is good global precedent for minimising barriers to access
- A collapse in the supply of the only other similar acting smoking cessation drug treatment means there is a high unmet need for this type of partial nicotine agonist.
- Minimising barriers to access by allowing access via pharmacist and accredited stop smoking practitioners will contribute to reducing smoking rates and save lives.

Background

Cytisine is a natural product found in plants such as Golden Rain and New Zealand Kōwhai. It works as a partial nicotine agonist, partially blocking the effects of nicotine on the brain similar to the smoking cessation treatment Varenicline.

Cytisine has been used as a smoking cessation treatment in several European countries since the 1960s, is inexpensive compared to other cessation medications and has few significant effects.

Until relatively recently much of the literature showing cytisine's efficacy for smoking cessation was published in languages other than English and in Eastern Europe. Despite many decades of successful use this has resulted in cytisine often been overlooked as a treatment outside of a few countries.

More recent trial data using modern research standards have added to the existing literature and awareness of cytisine as a low cost efficacious option outside of a few European countries.

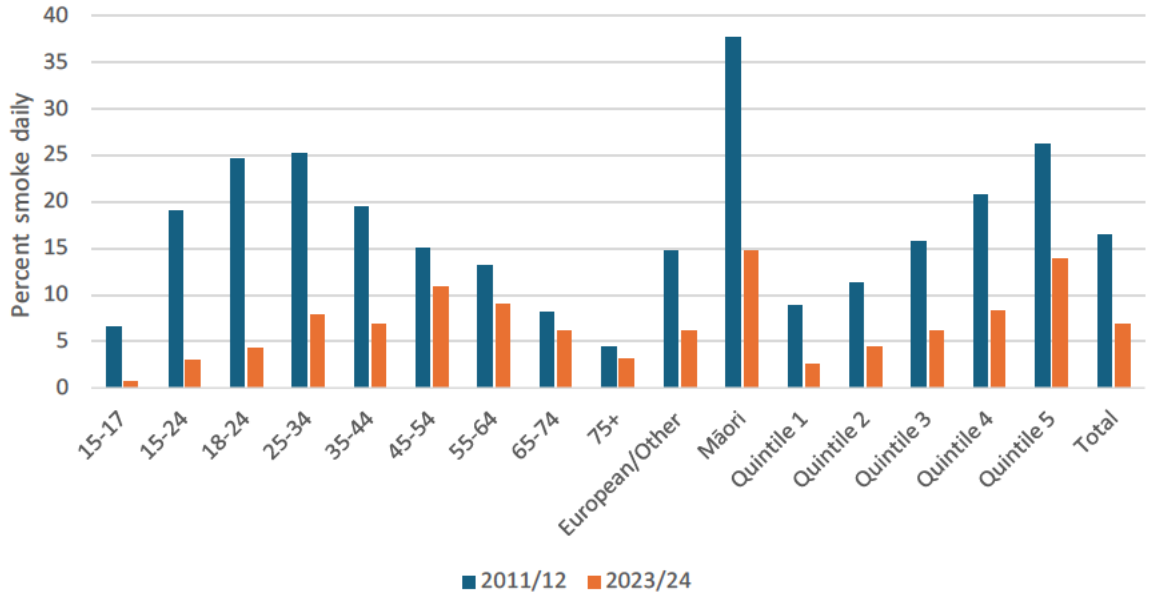
Notably, one of the first clinical trials of cytisine outside of Europe or low and middle income countries was conducted in Aotearoa New Zealand in 2014. Cytisine was found to be superior to nicotine-replacement therapy in helping smokers quit smoking and showed high efficacy and potential for Māori and Pacific populations[i].

Priority Population Benefit

Aotearoa New Zealand has seen rapid declines in smoking prevalence in the last five years, achieving an adult daily smoking rate of 6.9%. However, the most rapid decline has been in younger cohorts. Least progress has been made with populations over the age of 45[ii]. Most of these people who still smoke will have done so for decades, and will have tried to stop many times.

Whilst good progress has also been made reducing the smoking rates for Māori in the last 5 years, significant disparities remains with Māori daily smoking raters still 2.5 times higher than Europeans.

Figure 1. Daily smoking rates in 2011/12 and 2023/24 by age and ethnicity.



Source. New Zealand Health Survey[iii]

ASH believes that increasing access to safe, clinically trialled and proven medications will have significant net benefit to public health by increasing options available to help people stop smoking. We consider that those populations that have smoked for the longest time, and have lowest quit rates are most likely to benefit most from easy access to additional options.

This also includes lower income, rural, Māori and Pacific populations who still have higher rates of smoking than the general population. Having an additional pharmacotherapy option available through a pharmacist or accredited stop smoking provider significantly reduces barriers to is likely to have particular benefit to priority population groups.

Efficacy

The Cochrane collaboration published a meta-analysis of pharmacological and electronic cigarette interventions for smoking cessation in 2023 that included studies of cytisine. The review concluded the most effective interventions were nicotine e-cigarettes, varenicline and cytisine (all high certainty using the GRADE standard)[iv].

Cytisine had a predicted 6 month smokefree outcome of 13% compared to 14% for varenicline and 8-9% for nicotine replacement therapies.

A 2014 trial in Aotearoa New Zealand reported continuous 4 week abstinence from smoking of 40% in participants receiving cytisine compared to 31% of participants receiving nicotine-replacement therapy. The effectiveness of cytisine for continuous abstinence was superior to that of nicotine-replacement therapy at 1 week, 2 months, and 6 months[i].

A 2021 study investigated whether cytisine was at least as effective as varenicline in supporting smoking abstinence for ≥ 6 months in New Zealand indigenous Māori. It reported continuous abstinence rates at 6 months post-quit date were 12.1% (41 of 337) for cytisine versus 7.9% (27 of 342) for varenicline [risk difference 4.29%, 95% confidence interval (CI) = –0.22 to 8.79; relative risk 1.55; 95% CI = 0.97–2.46].

Cytisine was at least as effective as varenicline at supporting smoking abstinence for Māori, with significantly fewer adverse events. Eighty-eight per cent of participants allocated cytisine stated at 3 months that they would recommend their allocated treatment to others to help them quit smoking, compared to 74% allocated varenicline (P = 0.037)[v].

Dosage and use

Cytisine is typically taken over 25 days on a reduced dosing regime. Starting at six tablets a day and reducing to 2 per day 25. Although similar cessation outcomes have been observed for high dose tablet taken less frequently[vi]. This dosage regime is substantially shorter than for the similar acting (but currently unavailable) treatment varenicline that required a 12 week course.

Safety

In one form or another cytisine has been used in Europe by many millions of people for smoking cessation, mostly without prescription. To date there has been no evidence of any serious adverse events[vii]. The general safety profile of cytisine is likely to be similar to that of varenicline, but with fewer side effects.

The Cochrane review also looked at severe adverse effects (SAE) of cessation treatments in clinical trials. In the cases of cytisine, nicotine patch and nicotine electronic cigarettes, SAE rates were lower in the intervention arms than control.

Early trials of cytisine observed reactions including weight gain, irritability or appetite changes. However many of these symptoms could also be the result of smoking cessation, rather than

the use of Cytisine. Most adverse reactions occur when cytisine is started, and they usually resolve during treatment[iv].

Pharmacist access

Cytisine is currently available over-the-counter and/or on prescription as a smoking cessation treatment in more than 24 countries[viii]. We strongly support access via a pharmacist and there is precedent for this in several countries. Most recently countries outside of the EU including Australia and Canada have approved pharmacist access. It is currently under consideration by the FDA.

Cytisine has been sold in Canada as an over-the-counter herbal product for smoking cessation since 2017[ix]. The Australian TGA issued final approval of cytisine as a pharmacist only medication in October 2024[x].

The decision noted:

"the common adverse effects of cytisine use are rare and non-serious. Interactions and contraindications are known, identifiable and manageable by a pharmacist. I remain satisfied that pharmacist oversight can sufficiently mitigate the potential risks from cytisine. Further, cytisine has been used in many European countries for years as an over-the-counter medicine".

It concluded that:

"Access to cytisine products from a pharmacy will increase the options available to assist smokers to cease smoking."

As of late 2024, 24 countries have cytisine registered of which 15 classify it as an over the counter medication available from pharmacist without prescription[xi,vii,ix].

Table 1. Summary of registration status of cytisine by country as at January 2024[xi,vii,ix]

In a pharmacy with a prescription	In a pharmacy without a prescription	
Cote d'Ivoire	Austria	Uzbekistan
Germany	Australia	Latvia
Hungary	Azerbaijan	Lithuania
Italy	Bulgaria	Portugal
Spain	Canada	Russia
Sweden	Czechia	Serbia
Zambia	Georgia	Ukraine
United Kingdom	Kazakhstan	

Pharmacist access also has an important role to play in equitable access to treatments and Hauora Māori. A 2022 study of indigenous experiences of medications concluded that, for Māori, requiring a prescription is a barrier to medicines access and that having medicines available from a pharmacist without a prescription would eliminate this barrier[xii].

Cytisine is a treatment ideally suited to pharmacist access, especially for Māori. It treats the major preventable cause of premature mortality for Māori (smoking), and clinical trials have shown efficacy and high acceptance for this population[i,v].

Access via accredited stop smoking providers

Accredited stop smoking providers are well placed to coach people through the treatment and provide behavioural support that would maximise success. Health New Zealand accredited stop smoking providers are subject to rigorous training and standards and are required to develop high levels of professional competency. The National Training Service programme for cessation practitioners includes knowledge about stop smoking treatments and graduates must complete and pass an assessment on stop smoking medicines as part of the programme[xiii].

The training modules already cover cessation treatments, dose regimes, recognising side effects, and coaching and supporting use. This currently includes varenicline. The training on varenicline already includes information on cytisine as the drug on which varenicline is based[xiv]. Accredited stop smoking provers are trained to coach people on safe and effective use of prescription medications people access via a GP. Allowing people to access cytisine through providers would remove barriers to access, whilst still sustaining oversight of use at a higher level that GPs can realistically provide.

There is precedent for stop smoking providers to have limited rights to provide cessation medications. Aotearoa New Zealand was a pioneer in the mid 2000's with the 'Quitcard' scheme. A programme that allowed accredited providers to give people a voucher for funded nicotine replacement therapy. Providers had to complete a short online training module on the treatment to qualify as a quitcard provider.

There is a national database of graduates and access to continuous development. Updating the workforce does not present significant challenges. The national training service has the existing infrastructure to train and update and appropriately qualified specialist workforce to provide cytisine through stop smoking services.

Lack of access to comparative treatments

New Zealanders have had access by prescription to Champix (Varenicline), another partial nicotine agonist for more than 15 years. However, global supply issues have drastically affected access and almost eliminated use[xv]. Dispensing of varenicline has fallen by almost 100% since 2021 after steadily declining for a number of years. As of late 2024 there is no supply available to New Zealand[xvi].

Table 2. Dispensing and people using varenicline by year in Aotearoa New Zealand.

	2018	2019	2020	2021	2022
Dispensing	71321	44458	35982	20292	144
People	47578	34112	27390	15666	133

Source. Health New Zealand. Pharmaceutical web tool[xvii].

Increasing access to cytisine meets the needs of the many thousands of people who may benefit from this type of smoking cessation treatment but presently have no access to an

alternate. Prior to the global shortage, around 30,000 people a year used varenicline, a similar orally administered partial nicotine agonist. This clearly indicates a high demand. Given the efficacy of cytisine, there is clearly high potential to help many tens of thousands by having access to this type of treatment.

Cytisine can rapidly fill the gap left by ensuring people who smoke have access to a type of treatment that is otherwise unavailable. Furthermore, it is an option with lower rates of adverse reactions and a longer history of use dating back over 50 years. It also has a shorter treatment period than varenicline (25 days vs 12 weeks), something that may appeal to people. Trials of cytisine v varenicline have also shown a lower dropout rates for cytisine, possibly because of the shorter treatment period.

Summary

In summary ASH strongly supports and encourages access to cytisine via OTC pharmacy sales, and via stop smoking practitioners. Independent reviews of cytisine trials have concluded better efficacy than existing OTC medications, and lower rates of adverse reaction reporting. Given the abrupt end in the supply of varenicline there is also a significant gap in access to such cessation treatments.

We consider that OTC access, and provision by stop smoking services would be the most eDective way to ensure fair and equitable access. This strikes a good balance between maximising potential access and benefit and ensuring adequate oversight. The specialist nature of a stop smoking practitioner allows them to have more detailed knowledge than many general medical professionals are able to provide. Alongside pharmacist, this is ideal group to help people access cytisine, support them through the dosing regime, and monitor for adverse eDects.

Cytisine has been shown to have the potential for better outcomes than varenicline and NRT and with fewer adverse reactions. Notably, this includes better outcomes for Māori than existing pharmacotherapies.

Given the ongoing disparities in smoking rates, having access in communities where tobacco use is high, and health care access is low would significantly increase the potential population benefits of cytisine.

In conclusion, cytisine is effective, safe and we encourage New Zealand to join the 15 nations that already allow OTC access and extend this to allowing access via accredited stop smoking practitioners. We believe this would make a significant contribution to helping people stop smoking, contributing to reduced smoking rates and in turn saving many lives. In particular for the highest smoking populations.

Submission prepared by:

Ben Youdan
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ASH New Zealand
January 2025

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Submission [redacted] for the Medicines Classification Committee 73rd Meeting

7.3 Cytisine

Recommendation: Cytisine be classified as a non-prescription medicine in Aotearoa New Zealand (NZ) to maximise benefits to public health and to individuals who smoke, to reflect the favourable benefit-risk profile of cytisine, and to follow in the path of other countries including Canada, Australia, Austria and Poland. We recommend that Stop Smoking Practitioners can also supply this medicine without prescription and are included in the classification statement.

Non-prescription cytisine has the potential to provide an important impact for public health in NZ. This impact arises because tobacco is a significant risk factor for preventable illness in NZ, and NZ has an inequity both in terms of people who smoke tobacco and people harmed from smoking tobacco.

Over 4,500 people die prematurely in NZ each year of a smoking-related disease[1]. Smoking causes about three times the number of deaths as all non-medical causes combined (e.g. road accidents, drowning, suicide, murder). There is an ethnic disparity in harms from tobacco, e.g. Māori wahine lung cancer mortality is over four-fold higher than for non-Māori females.

NZ has had considerable success in reducing the overall smoking rates in the population. Of the adult population, in 2022/23 an estimated 7% were daily smokers, down from 8% the previous year and 16% in 2011/12[2]. This has happened through initiatives including legislation and supporting smoking cessation. However, Māori and Pacific peoples have higher smoking rates, with 20% for Māori and 18% for Pacific peoples.

Having a non-prescription classification for cytisine is in line with the long-standing NZ government policy of reducing smoking rates and aiding inequity of smoking incidence and harms.

The Smokefree 2025 Action Plan[3] has three stated outcomes. Two of these are relevant to having cytisine available without prescription and marketed as soon as possible:

Outcome 1: Eliminate inequities in smoking rates and smoking-related illnesses

This outcome particularly notes Te Tiriti o Waitangi obligations of achieving equitable health outcomes for Māori, as well as noting Pacific peoples and those living in high deprivation areas as also having inequities.

As a plant-based therapy, cytisine has good acceptability for Māori [4] and Pacific peoples [5]. Making cytisine available in NZ will help achieve equitable health outcomes for Māori and Pacific peoples, particularly if it has availability without prescription through pharmacies and Stop Smoking Practitioners who have completed the Stop Smoking Practitioner Programme in NZ[6], and has government funding. Although funding is not decided by Medsafe or the Medicines Classification Committee, cytisine is relatively low cost and funding to maximise the benefit in these groups and improve health outcomes would be likely given other smoking cessation medicines are funded and cytisine has advantages over existing medicines in terms of efficacy, duration of treatment and attractiveness (as a natural remedy) to the population as a choice to stop smoking[4, 5].

Outcome 3: Increase the number of people who successfully quit smoking

This outcome includes *"...removing the barriers that undermine quit attempts and ensuring the right quitting support is easy to access."*

Availability of cytisine through pharmacy and Stop Smoking Practitioners will help remove barriers to quit attempts and ensure a choice of effective smoking cessation support is available, particularly given that cytisine is more effective than nicotine replacement therapy[7, 8].

This is particularly important given that varenicline has not been available for some time in NZ and there may be a backlog of people who would prefer a tablet, ideally without a prescription barrier to access it.

General practice has become increasingly difficult to access in NZ. A 2024 survey from General Practice NZ[9] found that all responding PHOs (Primary Health Organisations) reported one or more general practices that were members of the PHO had restricted access. 57% of the PHOs reported 5 or more of their practices restricted access. 61% had practices in their network reducing services. It also reported that rural practices had particular issues recruiting general practitioners and nurse practitioners. Smoking cessation needs to use the accessibility of pharmacy with no appointment or enrolment needed and extended hours availability, and Stop Smoking Practitioners so that the moment someone wants to quit smoking they can.

About cytisine

Cytisine is a proven smoking cessation aid derived from plant alkaloids. As a partial agonist of nicotine acetylcholine receptors, it reduces nicotine withdrawal symptoms and makes nicotine less rewarding if smoking does occur. Cytisine allows for a gradual reduction in nicotine addiction and minimises symptoms of nicotine withdrawal.

Cytisine has been available for over 50 years, initially in countries in Eastern Europe, Central Europe and Central Asia. Cytisine inspired the development of varenicline which has a similar action[10]. Cytisine has more recently (from 2017 to 2023) become registered in many Western countries, including the United Kingdom (UK), Portugal, Belgium, Germany, Denmark, Sweden, Spain, Ireland and Austria, although it hasn't been launched in all of these yet.

Cytisine is an important option for smoking cessation. Leading academics in smoking cessation/tobacco control (including NZ and Australian academics) have called for more countries to have cytisine available noting its efficacy, safety and cost advantage [7, 11-14].

Cytisine 1.5 mg tablets are taken in a reducing course over a 25-day period, with 100 tablets per pack. This will be attractive to consumers because tablets are easy to take and the course is shorter than nicotine replacement therapy, but it has greater efficacy[7, 8].

Plant-based therapy and acceptability to Māori and Pacific peoples

Cytisine is a natural remedy derived from plants. Cytisine is found in seeds from kōwhai trees in NZ. That cytisine is plant-derived will be a benefit for some groups of smokers, for example qualitative research in Māori [4] and Pacific people in NZ [5] indicated acceptability because of their cultural practices of traditional medicine.

The randomised controlled trial by Walker et al[15] in Māori which compared cytisine and varenicline found 88% of cytisine users would recommend cytisine to others for smoking cessation, versus 74% of varenicline users.

Non-prescription status of cytisine

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Twenty-four leading academics in public health and tobacco control want non-prescription availability of cytisine and inclusion on the WHO Essential Medicines List (EML), stating:

> *"We support the addition of varenicline and bupropion to the WHO EML, but we also strongly recommend that cytisine should be added **and available OTC** to offer choice. If varenicline and bupropion are not added to the WHO EML, cytisine certainly should be."*

Signatories include Professors of Public Health, Pharmacology, Epidemiology, Medicine, Pharmacy and Health Psychology. Many have conducted smoking cessation studies including cytisine research and are leading academics from New Zealand, the UK, US, Switzerland and Australia [12]. Many have medical degrees and know cytisine well, so this recommendation provides confidence in the appropriateness of non-prescription availability.

Smoking cessation as a non-prescription category in NZ

Smoking cessation has been a non-prescription category in NZ for over three decades, with nicotine gum the first product available without a prescription. NZ was the first country in the world to classify nicotine replacement therapy patches as a non-prescription medicine in 1990 when it was launched as a pharmacy-only medicine[20], and it has since become a general sales medicine.

People are able to recognise themselves a desire to stop smoking, and can start themselves on a smoking cessation aid. Some will have additional help, e.g. with Quitline or health care professionals such as pharmacists, so availability through pharmacies and Stop Smoking Practitioners would be appropriate.

Nicotine replacement therapy is funded in New Zealand for people needing to stop smoking through Quitline, pharmacies and other health care professionals, recognising the importance of removing

barriers to access to smoking cessation aids, and the appropriateness of management by people with prescribing rights and those without.

Thus, the condition that cytisine is treating is clearly recognised as a self-management condition.

Efficacy and safety of cytisine

Independent well-designed studies and reviews confirm cytisine is more effective at achieving smoking abstinence than placebo [7, 8] and nicotine replacement therapy[7, 8] and has comparable efficacy to varenicline[7, 8]. Walker et al[15] found cytisine more effective than varenicline for smoking cessation in Māori, noting, however, that this particular study used the standard dosing of cytisine initially but then continued a low dose for a longer period than licensed cytisine products.

Adverse events are typically transient and mild-to-moderate [21]. The most common adverse events are gastrointestinal, e.g. nausea, dry mouth, dyspepsia and constipation, headache and abnormal dreams [7, 22]. Adverse events are more common with cytisine than nicotine replacement therapy, but are likely to be less common than with varenicline [7, 8]. Adverse events led to discontinuation in trials of 6-16% [7]. It is straight-forward for a person to stop the medicine if they desire to. Serious adverse events for cytisine are comparable in frequency to placebo and nicotine replacement therapy, and possibly less frequent than varenicline [8]. These adverse effects are no more likely without prescription than on prescription

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Dosage

Cytisine is taken as tablets in a reducing dose over 25 days as follows:

Cytisine should be taken according to the following schedule: Days of treatment	Recommended dosing	Maximum daily dose
From the 1st to the 3rd day	1 tablet every 2 hours	6 tablets
From the 4th to the 12th day	1 tablet every 2.5 hours	5 tablets
From the 13th to the 16th day	1 tablet every 3 hours	4 tablets
From the 17th to the 20th day	1 tablet every 5 hours	3 tablets
From the 21st to the 25th day	1-2 tablets a day	1 to 2 tablets

The product blister is labelled with the consecutive days of taking cytisine.

The person who smokes should stop smoking completely no later than on the 5th day of treatment. Smoking should not be continued during treatment as this may aggravate adverse reactions. The person who stopped smoking must not smoke even a single cigarette. In case of treatment failure, the treatment should be discontinued and may be resumed after 2 to 3 months

Contraindications and precautions

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Drug interactions

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Further information on safety

[redacted]

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Knowledge of providers of cytisine

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[redacted]

Registration

[redacted]

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Summary

Cytisine has a long history of availability, particularly in Eastern Europe, is more effective than nicotine replacement therapy for smoking cessation, is used for a condition appropriate for self-medication and has a safety profile consistent with non-prescription availability. It is available in a variety of markets without prescription, and is plant-based, which is likely to increase its acceptability as a smoking cessation option for some smokers, including some Māori and Pacific peoples. Non-prescription availability of cytisine in New Zealand would provide choice for consumers of a tablet taken for only 25 days with higher efficacy than nicotine replacement therapy.

The potential impact of getting cytisine on the market as a non-prescription medicine includes helping to achieve reduced tobacco use, reduced tobacco harm (and therefore reduced pressure on our health system) and, most importantly, helping to reduce the inequity of high rates of smoking in Māori and Pacific peoples and other disadvantaged groups, and tobacco harm in these groups.

Therefore, it is appropriate and desirable for cytisine to be available without prescription as a pharmacy-only or pharmacist-only medicine and through Stop Smoking Practitioners. This change is needed without delay to maximise the benefit to population health.

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