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

22 January 2025

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Tēnā koe

MedSafe Medical Classifications Committee (MCC) 73rd Meeting

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

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

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

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

6. Submissions for reclassification

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

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

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

College considerations

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

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

- **The College supports the <u>proposal</u> to change the classification of tenofovir disoproxil and emtricitabine to:**
  Prescription medicine: except when supplied for HIV prophylaxis to people who are over 18, are HIV negative, and meet the clinical and eligibility criteria of an approved training programme, when provided by a pharmacist who meets the requirements of the Pharmacy Council.

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

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

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

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

6.3 Travel vaccines (Green Cross Health Limited)

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

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

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

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

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

College considerations

Yellow fever is a live vaccine

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

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

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

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

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

6.4 Recombinant Varicella Zoster Virus Vaccine (GSK New Zealand)

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

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

- **The College notes that the proposal would enable a wider range of vaccinators for these vaccines.**

College considerations

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

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

The proposal is to change the classification of allopurinol to:

Prescription medicine except when supplied for prophylaxis of gout to people who meet the clinical and eligibility criteria of an approved training programme, when provided by pharmacists who meet the requirements of the Pharmacy Council.

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

The committee raised the following concerns:

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

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

College Considerations

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

7. New chemical entities for classification

7.3 Cytisine

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

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

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

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

College consideration

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

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

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

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

7.7 Momelotinib dihydrochloride

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

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

22 May 2024 Scheduling Final Decisions Public Notice

College consideration

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

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

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

8.1c Erlanatamab

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

8.1d Etranacogene dezaparvovec

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

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

8.1e Etrasimod

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

8.1f Fezolinetant

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

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

8.1g Lebrikizumab

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

8.1f Lecanemab

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

8.1h Maribavir

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

8.1i Nelarabine

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

8.1j Tebentafusp

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

8.1k Zilucoplan

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

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

8.2a Naratriptan

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

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

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

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

This scheduling change was implemented on the 1 June 2024.

College consideration

The College notes that:

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

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

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

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

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

Nāku noa, nā

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Medical Director | Mātanga Hauora

PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

16 January 2025

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

Dear Medicines Classification Committee,

MEDICINES CLASSIFICATION COMMITTEE (MCC)
COMMENTS TO THE 73rd MEETING AGENDA 26 February 2025

Thank you for the opportunity to submit comments on the agenda for the 73rd meeting of the Medicines Classification Committee.

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

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

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

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

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

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

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

The Society supports the concept of widening access to HIV prophylaxis medication in New Zealand as a key step in the goal of eliminating local HIV transmission by 2030, set out in the National HIV Action Plan for Aotearoa 2023-2030.[1] Pharmacists are medicines experts, and the proposed supply of PrEP is well within their scope of practice.

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

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

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

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

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

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

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

6.3 Travel vaccines (Green Cross Health Limited)

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

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

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

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

6.5 Allopurinol (Arthritis New Zealand Mateponapona Aotearoa, Green Cross Health, Dr Natalie Gauld, Associate Professor Peter Gow).
The Society are fully supportive of the proposal to reclassify allopurinol to "*Prescription medicine except when supplied for prophylaxis of gout to people who meet the clinical and eligibility criteria of an approved training programme, when provided by pharmacists*"

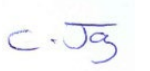
The value of the Owning my Gout (OMG) management programme has been independently evaluated by Synergia and demonstrated clinical success. The Community Pharmacy Gout Management Service Training has already been developed and is running in several Districts across the country. With a small amount of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

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

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

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

Yours sincerely,



Chris Jay
Manager Practice and Policy

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

PHARMACY GUILD OF NEW ZEALAND

16 January 2025

Medicines Classification Committee Secretary
Medsafe
Wellington

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

Dear Committee Members,

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

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

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

Our feedback covers the following agenda items:

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

6. Submissions for reclassification

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

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

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

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

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

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

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

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

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

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

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

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

6.2 Tenofovir disoproxil and emtricitabine (Burnett Foundation)

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

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

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

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

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

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

6.3 Travel vaccines (Green Cross Health Limited)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7. New medicines for classification

7.3 Cytisine

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

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

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

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

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

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

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

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

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

8. Harmonisation of the New Zealand and Australian Schedules

8.2.a Naratriptan

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

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

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

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

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

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

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

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

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

Yours sincerely,

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17 January 2025

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Tēnā koe Jessica

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

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

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

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

1. Agenda item 6.2 Tenofovir disoproxil and emtricitabine

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

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

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

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

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

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

2. Agenda item 6.3 Travel vaccines

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

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

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

3. Agenda item 6.4 Recombinant Varicella Zoster

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

The Council supports the reclassification of Recombinant Varicella Zoster vaccine

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

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

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

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

4. Agenda item 6.5 Allopurinol

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

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

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

5. Agenda item 7.3 Cytisine

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

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

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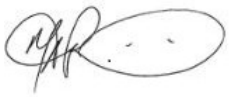
[3] HQSC https://www.hqsc.govt.nz/assets/Our-work/Improved-service-delivery/Patient-deterioration/Publications-resources/Presenter_slides_-_Equitable_approaches_to_gout_management_webinar_1_July_2020.pdf

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

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

Yours sincerely



Michael A Pead
Chief Executive

Tūmuaki Nēhi Aotearoa | HANGAIA NGĀ KAIĀRAHI NĒHI
Nurse Executives Aotearoa | DEVELOPING NEW ZEALAND'S NURSE LEADERS

Medsafe Classifications Committee
Medsafe
New Zealand Medicines and Medical Devices Safety Authority
PO Box 5013
Wellington 6140

Tēnā koe

Re: 73rd meeting, agenda item 6.2 Tenofovir disoproxil and emtricitabine (Burnett Foundation)

Thank you for the opportunity to comment on the Burnett Foundation's application to increase access to HIV Pre-exposure Prophylaxis (PrEP) through exemption to prescription status for pharmacists. Nurse Executives Aotearoa (NEA) strongly support this application and believe it will enhance access for those who would benefit from prophylactic treatment.

NEA also advocate for this exemption to extend to suitably trained registered nurses with appropriate knowledge and experience to provide PrEP to eligible people. As noted in the Burnett Foundation application, current mechanisms have yet to achieve high levels of equitable access to PrEP with Māori and Pacific peoples having lower rates of PrEP initiation and retention.

Registered nurses work in a range of diverse settings that support increased access to health care and medicines – for example Hauora Māori Partners, Pacific providers and youth health services. The ability to provide PrEP to people in these and other relevant settings through an exemption will increase access, improve coverage and support retention due to the ongoing relationships nurses in these settings maintain with clients.

NEA propose the following wording of the classification in line with that proposed by the Burnett Foundation:

> 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 or a registered nurse who meets the requirements of the Nursing Council of New Zealand.

PrEP HIV prophylaxis will be available from a duly trained and registered pharmacist or nurse. The training course for registered nurses will be created in collaboration with the community and relevant clinicians and meet the requirements of the Nursing Council of New Zealand. The training course and related collaborative work will need to be developed but this should not delay reclassification in line with the Burnett Foundation's proposal re pharmacists. Extending the reclassification to include registered nurses is logical and will save significant time and effort at a later date if specific reclassification for registered nurses is subsequently sought.

Once again, we thank you for the opportunity to comment on the proposed reclassification which we strongly support – particularly with the addition of registered nurses.

Tūmuaki Nēhi Aotearoa | HANGAIA NGĀ KAIĀRAHI NĒHI
Nurse Executives Aotearoa | DEVELOPING NEW ZEALAND'S NURSE LEADERS

Ngā mihi

Dr Jill Clendon RN PhD

Co-Chair

Bonnie Matehaere

Co-Chair

On behalf of Nurse Executives Aotearoa

Te Whatu Ora
Health New Zealand
Waitaha Canterbury

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3 January 2025

Medicines Classification Committee,
Ministry of Health
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Agenda item 6.2 Tenofovir disoproxil and emtricitabine (Burnett Foundation) **Due 17 January 2025**

Summary of proposal
Increasing access to HIV Pre-exposure Prophylaxis (PrEP) through exemption to prescription status for pharmacists.

Infection Management Service Christchurch Hospital response:

General comments:

Any initiative that reduces access barriers to HIV Pre-exposure Prophylaxis (PrEP) is a wonderful thing. New Zealand's decline in newly acquired local HIV infections for men who have sex with men (MSM) and increasing rates of PrEP uptake are clear evidence of the success and ongoing efforts internationally, and nationally to destigmatize PrEP. Both reflect the phenomenal amount of mahi already done, particularly by the Burnett Foundation Aotearoa (BFA), Positive Women (PW) and Body Positive (BP). The pivotal role of BFA in Pharmac approval of funded PrEP in 2017 cannot be disputed, their ongoing advocacy and efforts to widen eligibility and suitability criteria continue to reduce stigma, reduce locally acquired new infections, and support those living with HIV.

There are a multitude of factors which may impede a person's access to acceptable, affordable, culturally competent care, in this case HIV prevention by means of PrEP. Factors including geography, locality, cost, hours of service, wait times, and a person's comfort discussing this with a local provider. Providing people with a variety of options, from which they can then select the one they feel most comfortable with, and that is geographically/financially within reach, is essential for PrEP uptake to increase.

Broadly speaking we support any initiative which will increase people's access to PrEP. There is indisputable evidence that PrEP works, that the greater the access to it, and acceptance of it as a preventative tool the closer to elimination Aotearoa New Zealand will be. For this reason, our feedback is solely limited to the areas of the application related to the proposed Models of Care and their implementation.

PrEP is complex, provision is not as straightforward as providing a person with a supply of medication. Our reservations centre around the following areas, all of which could be rectified with a shared care model of care.

1. **Model of care**
    - The application identifies that two pathways currently exist in NZ for people to access PrEP, through a person's GP or sexual health clinics. In practice, there is also another readily available, low-cost option, notably the PrEP online service through BFA and MedOnline [1]. This provides a way for people to talk to a

[1] MedOnline. Available Preventing HIV with PrEP

clinician about PrEP without even leaving their house [2], and includes initiation of tasks such as STI testing and clinical oversight required for the safe and discrete provision of PrEP [3].

- The persons who would be eligible for the models proposed in this application would likely also benefit from access to DoxyPEP (Doxycycline Post-Exposure Prophylaxis) which is not currently available through a Pharmacy supply model. A shared care model would enable access to this for this population which would enhance non-HIV, STI prevention also.
- Increasing the number of options available for a person to access PrEP is helpful if a person's access barriers are related to geography, or an overwhelmed GP practice. However, if the barrier is around confidentiality and privacy in a small town, then enabling their local Pharmacist who also lives in their community may not negate that access issue.
- In 2023 there was a reclassification of hepatitis C treatment in New Zealand, which provided increased access through a novel collaborative nurse-pharmacist model of care in community settings [4]. In most cases, the pharmacist dispenses the medication, working with the nurse to ensure supply is appropriate and/or referring people as needed.

2. Pharmacy related

The following feedback is not intended to describe pharmacies as incapable, more about consideration of whether they have the capacity to provide an in-depth service.

- While seeing a local pharmacist may be more convenient and timesaving, not to mention free up Medical Centre appointments, there is already significant pressure on community pharmacies who have been struggling with numbers and quality of service [5]. Adding yet another service, particularly one as complex as HIV PrEP supply, could further compound these pressures and be negatively impactful for patients.
- Preparation to participate would need to include robust education.
- Many community pharmacists already have good links with secondary care, a shared model of care such as that utilised for Hepatitis C treatment, would capitalise on these.
- The appendices related to elevated risk includes overseas travel to a high HIV prevalence country. Is there a list of 'high prevalence' countries for pharmacists to review?
- While pharmacists can currently access laboratory results, in this situation it is not clear for the patient who has no GP, who the pharmacist can call for results that they can't interpret or require additional assessment or treatment.

3. Laboratory related

- Much of the feedback discussed within our team centered around processing and follow up of results (all). Specific concerns related to;
    - Follow-up of unexpected critical results (e.g. if a patient has a creatinine of 500)
    - Access of results – where to deposit them, and timely result review/signoff.
        - The positive HIV result not going back to pharmacist may be a problem as the pharmacist will be looking out for result, the patient expecting them to have it. The call with this result from a complete stranger is not ideal from a patient perspective. A shared model of care would facilitate appropriate/timely secondary specialist involvement and support the Pharmacist with providing a result if it was deemed the appropriate action.

- If a patient self-requests an investigation, currently they are charged for this. Self-requested tests may not be linked to a patients NHI which means they are invisible to clinicians.

[2] Burnett Foundation Aotearoa. Available Cheap Online PrEP Appointments
[3] MedOnline. Available at Book your MedOnline telemedicine appointments
[4] Health New Zealand Te Whatu Ora. Available Improving access to hepatitis C treatment in the community – Health New Zealand | Te Whatu Ora
[5] Pharmaceutical Society of New Zealand Inc. Available Press Statement for PSNZ 2024 Workforce Survey.pdf

- In this application it is unclear what the cost of investigations to the patient is. Will these somehow be subsidised, as the cost of these currently would certainly be a barrier for many.
    - Currently people accessing self-requested STI screening through Sexual Health 101[6] ($85 normally) can access a subsidy from Burnett Foundation, however the writer is unsure of how much the subsidy is and who exactly is eligible. Additionally the question arises as to whether the patient is left holding results (and therefore not pharmacist?).
        - A person who isn't eligible for subsidy through BFA can also access testing online through Awanui's online platform for self-request STI tests [7].

4. Clinical/Clinical oversight

- This application includes checking for lactic acidosis after 1 week. This is not a current part of clinical practice when commencing tenofovir/emtricitabine and is not included on the NZSHS PrEP & PEP Guidelines for Aotearoa New Zealand [8].
- The guidelines are unclear as to the frequency/requirement for screening.
    - Who ensures this is done prior to supply of PrEP? What happens if it isn't?
    - Who is responsible for the follow-up actions required for a positive result (contact notification, treatment, ESR notification [Redcap] and follow-up)?
- Hepatitis C co-infection is not a contraindication to PrEP, but its diagnosis should initiate a referral to ensure treatment offered.
- In regard to Hepatitis B, the Laboratory Investigation form in this application is only for HBV-S-antigen, so patient not tested for HBV-S-Antibody. If HBVs-S-antigen negative advice is to vaccinate, however if young the patient will probably already be vaccinated or could have had hepatitis B infection already and be immune. NZ Immunisation Handbook includes extensive information around serology interpretation and follow-up, and states that "most people with documented evidence of three HepB vaccinations will be immune for life" [9].

Recommendations:

1. Consider implementation of a shared-care model, such as the Hepatitis C Treatment Without Prescription [10]. This would provide clinical oversight, referral pathways, and utilise (in most cases) established primary and secondary care relationships.
2. A very clear referral tree needs to be included which addresses the secondary care considerations, and laboratory variables for the inevitable patients who will not fit inside the box.
3. Further engagement with laboratory providers to clearly identify pathways for abnormal result processing and follow-up.
4. Clarification of actual cost to people utilising the service; specifically, self-referred laboratory costs, and fees charged by the Pharmacy for a supply of PrEP service.

[6] Awanui. Available Self-requested testing — Awanui
[7] MyTests, Awanui. Available Contact - MyTests
[8] New Zealand Sexual Health Society. Available NZSHS PrEP tool final.pdf
[9] New Zealand Immunisation Handbook. Available 9. Hepatitis B – Health New Zealand | Te Whatu Ora
[10] This is already being applied using this model Hepatitis-C-Pharmacist-led-Collaborative-Model.pdf

Chemist Warehouse Group
318 Richmond Road
Grey Lynn 1021
Auckland

6 January 2025
Medicines Classification Committee Secretary
Medicines Classification Committee Secretary
Medsafe PO Box 5013

Dear Sir/Madam

MEDICINES CLASSIFICATION COMMITTEE (MCC) COMMENTS TO THE 73RD MEETING

AGENDA 6.2 Tenofovir Disoproxil and Emtricitabine (Burnett Foundation)

On behalf of Chemist Warehouse New Zealand (CW NZ), I am writing to express our full support on the proposal to reclassify Tenofovir Disoproxil and Emtricitabine (PrEP) from *Prescription Medicine* to *Pharmacist Only Medicine* (POM). CW NZ acknowledges the reclassification is based on the merits of the proposal by Burnett Foundation, where the benefits of doing so outweigh the risks. The objective of this proposal to broaden access to eligible individuals which aligns with our principles of equitable healthcare and with the National HIV Action Plan's goal to eliminate local HIV transmission by 2030. We have already observed an increase in customer inquiries about the possibility of obtaining PrEP from their regular pharmacists rather than arranging a visit to their GPs. One of the primary reasons given is the convenience of seeing their trusted pharmacists locally, which we believe would also help alleviate pressure on GPs.

Pharmacists in the community setting are already well equipped with providing services and consultations surrounding health concerns that are of sensitive nature, including those with perceived stigma. This is evident through the provision of Emergency Contraceptive Pill (ECP), Sildenafil for Erectile Dysfunction, and Nitrofurantoin for UTIs. We believe the reclassification to POM is a valuable first step towards cultivating a culture of openness, educating the community the importance of taking control of their health and breaking down the barriers related to the stigma associated with MSM, STIs and HIV.

CW NZ therefore supports the proposal to list PrEP as a restricted medicine, accessible through a pharmacist who has successfully completed an accredited training programme.

Thank you for your time.

Yours sincerely,

Edmund Yee
Pharmacist/ Professional Services Team CWNZ

PO Box 11-183
Ellerslie
Auckland 1542
New Zealand

16 January 2025

MCC Secretariat
MEDSAFE
PO Box 5013
WELLINGTON

Dear Sir / Madam

Re: Agenda item 6.2 (Tenofovir disoproxil and Emtricitabine) of the 73rd Medicines Classification Committee (MCC) meeting

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Viatris is pleased to provide comment on Agenda item 6.2 of the 73rd Medicines Classification Committee (MCC) meeting, with regard to the proposed reclassification of tenofovir disoproxil and emtricitabine. Notably, the proposal intends to change the classification to the following:

> *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.*

Viatris holds a registration for Tenofovir Disoproxil Emticitabine Viatris tablets and is the current holder of the PHARMAC sole supply tender for this product.

We are a leading supplier of medicines to the HIV/AIDS community, providing access to high-quality and affordable antiretrovirals in approximately 125 countries.[1] Globally, around 40% of the 23.31 million people on treatment for HIV use our products.

We confirm our support for the proposed change in classification, which seeks to widen access to HIV prophylaxis medication in New Zealand. This reclassification will broaden access to this medicine, aligning with the National HIV Action Plan for Aotearoa 2023-2030, to eliminate local HIV transmission by 2030.

Sincerely,
Viatris Limited

[redacted]

About Viatris
Viatris Inc. (NASDAQ: VTRS) is a global healthcare company uniquely positioned to bridge the traditional divide between generics and brands, combining the best of both to more holistically address healthcare needs globally. With a mission to empower people worldwide

[1] *See* 2023 Viatris Sustainability Report, here.

to live healthier at every stage of life, we provide access at scale, currently supplying high quality medicines to approximately 1 billion patients around the world annually and touching all of life's moments, from birth to the end of life, acute conditions to chronic diseases. With our exceptionally extensive and diverse portfolio of medicines, a one-of-a kind global supply chain designed to reach more people when and where they need them, and the scientific expertise to address some of the world's most enduring health challenges, access takes on deep meaning at Viatris. We are headquartered in the U.S., with global centers in Pittsburgh, Shanghai and Hyderabad, India. Learn more at viatris.com and investor.viatris.com, and connect with us on LinkedIn, Instagram, YouTube and X (formerly Twitter).

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To the Medicines Classification Committee,

We are writing in support of the Application to increase access to HIV Pre-exposure Prophylaxis (PrEP) through exemption to prescription status for pharmacists.

We know that when taken daily PrEP is 99% effective at preventing HIV infection, and as recommended by the World Health Organization, has been a vital and effective tool to reduce rates of HIV transmission. The US Food and Drug Administration approved TDF/FTC for PrEP in 2012, and many studies have established the safety and efficacy ofTDF/FTC in multiple populations. TDF/FTC is one ofthe most used, most studied biomedical HIV prevention tools available today. Oral PrEP has a side effect profile consistent with non-prescription availability and meets other criteria for non-prescription availability, such as low risk in overdose, low potential for misuse and abuse, an individual can determine whether they need HIV protection or not, and dosage is straight forward.

Despite having a very effective oral prophylaxis available fully funded within New Zealand since early 2018, barriers to access impede our ability to reach the 2030 target of elimination of local HIV transmission, and, particularly to ensure the most vulnerable members of our communities can access this prevention tool. The most recent IDI data shows only 44% of eligible people were accessing PrEP with the greatest MSM PrEP gap being within Maori and Pacifica. This reclassification seeks to help overcome some of these barriers and will make significant inroads in the equitable prevention and elimination of HIV infection (HIV Action Plan).

Widening access and removing barriers to enable equitable access are essential to address capacity issues that stifle uptake:

- The GP network in NZ is over-burdened. Appointments are difficult to obtain; many at risk individuals do not have a regular GP; Some GPs remain reluctant to engage due to the funding model that covers only 2 out of the 4 required regular visits; Many patients do not want to discuss their sexuality with their GP, Many GPS do not want to discuss sexual health (or meth use) with their patients.
- Similarly, the Sexual Health service is under heavy demand.
- Pharmacies provide increased accessibility and convenience and provide an alternate access pathway. Pharmacies typically have longer opening hours than GPs, convenient locations and provide a walk-in service without appointments or enrolment requirements.
- Oral PrEP has limited risk for harm or abuse and is easily managed within a pharmacist setting with a similar profile to Oral Contraceptives.

This proposal aligns with the healthcare provisions already in pharmacy, such as the supply of vaccines, hepatitis C testing and treatment, COVID antiretroviral medicines, and the oral contraceptive pill.

The risk/benefit profile of TDF/FTC recommends immediate provision of PrEP for the prevention of HIV infection. Waiting for kidney function or other test results should not delay initiation or continuation of oral PrEP. Multiple systematic reviews and meta-analyses of randomized controlled trials (RCTs) found that individuals taking TDF-based oral PrEP have, on average, a higher risk of experiencing kidney-related adverse events compared with individuals taking placebos but these adverse events tend to be mild, nonprogressive, and reversible after PrEP discontinuation. Severe kidney-related or other adverse events are very rare. Optional or reduced kidney function measurements for some populations may remove barriers to PrEP implementation and uptake. Testing requirements should not delay implementation at Pharmacist level with lab result review being available post dispensing.

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As noted in the application: Common reasons for discontinuation of Oral PrEP are cost, change in sexual behaviour and perceived risk or access to medication. Unemployed and younger men are more likely to discontinue use. Ongoing 3 monthly GP checkups are a high burden on PrEP users along with the ongoing requirement to disclose risk such as Meth use and sexual behaviour. The PrEP suitability criteria that are provided in the PrEP guidelines should not limit or deny access to PrEP to any person who seeks it. Instead, they should be used to help identify and actively recommend PrEP to people suitable.

In many countries, services have been demedlcalized, simplified, differentiated, digitalized, and integrated to increase uptake and effective use of PrEP. WHO, 2022. Wider and easier access to initiation and continuation of PrEP is vital if we are to succeed in our aim for elimination targeted in New Zealand's HIV Action Plan.

Sincerely

Mark Fisher

Executive Director

Introduction

The UNAIDS comments on the "**Application to increase access to HIV Pre-exposure Prophylaxis (PrEP) through an exemption to prescription status for pharmacists**" focuses on its potential for significant public health benefits. This application seeks to widen access to HIV prophylaxis medication in New Zealand by allowing suitably trained pharmacists with appropriate knowledge and experience to provide PrEP to those who are in need.

By providing more services and making PrEP more accessible within the community through trained pharmacists, New Zealand can address key barriers to PrEP access and enhance the overall effectiveness of HIV prevention services, thereby facilitating its commitment to eliminate local HIV transmission by 2030.

The structure of the UNAIDS comments is as follows:

1. Strengths of the Application: This section outlines the key strengths of the application, including the comprehensive framework for PrEP initiation, evidence-based approach, enhanced accessibility, integration of preventive services, public health benefits, and robust risk mitigation strategies.
2. Supporting Evidence, Global Guidance, Technical and Public Health Aspects of Differentiated Service Delivery (DSD) Models in Implementation of PrEP-Pharmacy: This section delves into the DSD models, emphasizing their client-centered approach, feasibility, acceptability, and risk mitigation strategies. It also highlights the importance of training and capacity building for pharmacists.
3. Advocacy and Mitigation Strategies: This section addresses potential concerns from clinicians regarding pharmacist-led PrEP delivery. It provides strategic solutions through DSD models, including pharmacist training, integration of standardized screening tools, and culturally sensitive outreach programs.

We believe that allowing pharmacists to prescribe PrEP will enhance the accessibility and availability of quality services within the community. We hope this initiative will serve as a steppingstone towards community-led services by providing an important option to bridge the gap and meet the diverse needs of our communities. UNAIDS fully supports this application and its potential to significantly and positively impact public health in New Zealand.

Section 1. Strengths of the Application

The application effectively addresses key barriers to PrEP access in New Zealand by introducing a pharmacist-led delivery model. This approach is well-aligned with global guidelines and demonstrates significant strengths, as outlined below:

- **Comprehensive Framework for PrEP Initiation**: The application provides detailed steps for initiating PrEP delivery through pharmacies, including pharmacist training, integration of standardized protocols, and procedures for HIV risk screening, adherence counseling, and dispensing PrEP. These clear guidelines enhance feasibility and accountability (Application, p. 34-42).
- **Evidence-Based Approach**: The model aligns with WHO guidance on Differentiated Service Delivery (DSD), which recommends decentralizing PrEP to non-traditional settings to improve accessibility (Application, p. 11-12; WHO 2022; WHO 2024).
- **Enhanced Accessibility**: By leveraging pharmacies as accessible healthcare touchpoints, the application addresses geographic and systemic barriers, particularly for underserved populations such as Māori, Pacific peoples, and rural residents (Application, p. 14-15; Kuo et al., 2022).
- **Integration of Preventive Services**: The integration of STI and HIV screening, along with adherence counseling, ensures a holistic approach to HIV prevention and fosters a greater public health impact (Application, p. 13-14; Ortblad et al., 2023).
- **Public Health Benefits**: Increased PrEP uptake is expected to reduce HIV incidence, improve STI prevention, and alleviate the burden on primary healthcare services (Application, p. 20; Roche et al., 2024).
- **Robust Risk Mitigation Strategies**: The application outlines risk management protocols to address potential concerns such as missed acute HIV diagnoses or ARV resistance through pharmacist training and consultation mechanisms (Application, p. 21-23).

Section 2. Supporting Evidence, Global Guidance, Technical and Public Health Aspects of DSD Models in Implementation of PrEP-Pharmacy

Differentiated Service Delivery (DSD) is a client-centered approach that simplifies and adapts HIV services to better suit the diverse needs of individuals and communities. DSD focuses on decentralizing care and providing services in accessible locations such as pharmacies, ensuring that healthcare delivery is both effective and equitable. Its application to pharmacy-based PrEP delivery showcases significant potential for addressing public health challenges:

- **Person-Centered Care**: Differentiated service models, such as those piloted in Kenya and sub-Saharan Africa, demonstrate that pharmacy-led PrEP delivery enhances patient convenience and privacy, reducing stigma associated with clinic-based models (Ortblad et al., 2023).
- **Training and Capacity Building**: Adequate training for pharmacists is critical to ensure competency in HIV risk screening, PrEP initiation, and adherence counseling. The application 's focus on this area aligns with global best practices (WHO 2024; Roche et al., 2024).
- **Feasibility and Acceptability**: Studies from LMICs (Lower-Middle-Income-Countries) highlight that pharmacy-delivered PrEP is feasible and acceptable to both clients and providers. High levels of client satisfaction and retention underscore the model's viability in diverse contexts (Kuo et al., 2022).
- **Risk Mitigation Through DSD**: Integration of standardized screening tools, pharmacy-driven adherence monitoring, and remote clinician support, as piloted in Kenya, demonstrates how technical solutions can address clinician concerns regarding missed acute HIV diagnoses and complex cases. The inclusion of pharmacy-specific strategies, such as dispensing protocols, inventory management, and pharmacist counseling for PrEP adherence, strengthens the role of pharmacies as critical nodes in differentiated service delivery (Ortblad et al., 2023).
- **Data Integration and Monitoring**: Centralized digital platforms for real-time data sharing between pharmacies and healthcare providers are essential for program success. The application 's emphasis on monitoring and evaluation is commendable and ensures program accountability (WHO 2022; Lalla-Edward et al., 2025).
- **Equity in Access**: Strategies such as subsidized PrEP for underserved populations, culturally sensitive outreach programs, and expanded pharmacy accessibility address systemic inequities and support greater public health impact. Specific pharmacy initiatives, such as training pharmacists in cultural competency and extending pharmacy hours in rural areas, further enhance equitable access to PrEP (Application, p. 23; WHO 2024).

Section 3. Advocacy and Mitigation Strategies

While clinicians may express concerns about pharmacist-led PrEP delivery, these apprehensions can be effectively addressed through the strategic implementation of Differentiated Service Delivery (DSD) models, as outlined in the section 2 above:

- Pharmacist training on standardized protocols, supported by remote consultation mechanisms, ensures complex cases are appropriately managed. As demonstrated in pilot models in Kenya and South Africa, these strategies **empower pharmacists to handle routine PrEP care effectively while ensuring referral pathways for complex cases** (Ortblad et al., 2023).
- The inclusion of provider-assisted HIV self-testing and structured screening tools ensures accurate diagnosis and adherence to safety protocols. These strategies empower pharmacists to effectively manage routine care while minimizing the risk of missed acute HIV diagnoses. As noted in pilot programs, **the integration of such tools strengthens the role of pharmacies in ensuring safe and reliable PrEP delivery** (Application, p. 22; Roche et al., 2024, Rousseau et al., 2021).
- The integration of STI and HIV testing into pharmacy services provides a more holistic approach to prevention, reducing the burden on primary care providers. This strategy **enhances the comprehensiveness of care by making pharmacies a one-stop point for preventive health services, thereby addressing potential gaps in continuity of care and optimizing public health outcomes** (Application, p. 13; Kuo et al., 2022).
- Culturally sensitive outreach programs and education campaigns can effectively address stigma, making pharmacy-based PrEP delivery more acceptable to communities. Routine monitoring and pharmacist-led counseling further mitigate concerns of misuse, ensuring adherence and safe use of PrEP. These integrated strategies **not only foster trust in pharmacy-based services but also strengthen their role as accessible and stigma-free points of care** (WHO 2022).

By situating these concerns within the robust framework of DSD's technical and public health benefits, the application emphasizes actionable solutions and underscores the pivotal role of pharmacists in expanding safe and equitable PrEP access.

References

1. World Health Organization, 2022. *WHO implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection. Module 13: Integrating STI services*. Geneva: World Health Organization.
2. World Health Organization, 2022. *Differentiated and simplified pre-exposure prophylaxis for HIV prevention: update to WHO implementation guidance. Technical Brief*. Geneva: World Health Organization.
3. World Health Organization, 2024. *WHO implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection: provider module for oral and long-acting PrEP*. Geneva: World Health Organization.
4. Rousseau, E., Julies, R.F., Madubela, N. & Kassim, S., 2021. Novel platforms for biomedical HIV prevention delivery to key populations: community mobile clinics, peer-supported, pharmacy-led PrEP delivery, and the use of telemedicine. *Current HIV/AIDS Reports*, 18(6), pp.500–507. Available at: https://doi.org/10.1007/s11904-021-00578-7.
5. Roche, S.D., Were, D., Crawford, N.D., Tembo, A., Pintye, J., Bukusi, E., Ngure, K. & Ortblad, K.F., 2024. Getting HIV Pre-exposure Prophylaxis (PrEP) into private pharmacies: Global delivery models and research directions. *Current HIV/AIDS Reports*, 21(116), pp.116–130. Available at: https://doi.org/10.1007/s11904-024-00696-y*)*.
6. Kuo, A.P., Roche, S.D., Mugambi, M.L., Pintye, J., Baeten, J.M., Bukusi, E., Ngure, K., Stergachis, A. & Ortblad, K.F. (2022) The effectiveness, feasibility and acceptability of HIV service delivery at private pharmacies in sub-Saharan Africa: A scoping review. *Journal of the International AIDS Society*, 25, e26027. Available at: https://doi.org/10.1002/jia2.26027.
7. Ortblad, K.F., Mogere, P., Omollo, V., Kuo, A.P., Asewe, M., Gakuo, S., Roche, S., Mugambi, M.L., Stergachis, A., Odoyo, J., Bukusi, E.A., Ngure, K. & Baeten, J.M. (2023) Stand-alone model for delivery of oral HIV pre-exposure prophylaxis in Kenya: a singl e-arm, prospective pilot evaluation. *Journal of the International AIDS Society*, 26, e26131. Available at: https://doi.org/10.1002/jia2.26131.
8. Lalla-Edward, S.T. and Venter, W.D.F., 2025. Feasibility and impact of community pharmacy and novel pick-up points for antiretroviral therapy pre-exposure prophylaxis initiation and continuation in low and middle-income countries. Current HIV/AIDS Reports, 22(2). Available at: https://doi.org/10.1007/s11904-024-00710-3.

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30 January 2025

Medicines Classification Committee 73rd Meeting

Re: submission in support of widening access to HIV prophylaxis medication PrEP

Submitted via email: committees@health.govt.nz

Tēnā koutou,

I am writing on behalf of Pharmac | Te Pātaka Whaioranga, to support the submission to widen access to the HIV prophylaxis medication PrEP (Pre-Exposure Prophylaxis). Tenofovir disoproxil, and emtricitabine are used for the treatment of HIV, and also used as pre-exposure prophylaxis, with other safer sex practices, to reduce the risk of sexually acquired HIV.

The classification sought is

"Prescription medicine except when supplied for HIV prophylaxis to people who are aged over 18, are HIV negative, and meet the clinical and eligibility criteria of an approved training programme when provided by pharmacists who meet the requirements of the Pharmacy Council".

The purpose of PrEP treatment is to prevent HIV transmission. PrEP has shown to have high efficacy (up to 99%) for prevention of HIV. Despite this, Māori and Pacific men who have sex with men (MSM) have lower rates of PrEP initiation, retention, and uptake. Currently 27% of Māori, and 26% of Pacific peoples are not using PrEP treatment. (Leakey et al., 2023 # 134)

Since records began with the AIDS epidemiology group, researchers have identified that Māori are consistently over-represented in HIV diagnoses. Māori are more likely to be diagnosed in the later stages of HIV (AIDS) and experience conditions associated with Acquired Immune Deficiency Syndrome (AIDS).
https://www.otago.ac.nz/__data/assets/pdf_file/0019/570610/83.-AIDS-NZ-May-2024.pdf

Additionally, PrEP initiation, retention and persistence is lower for people living in rural areas. Contributing factors include accessibility to primary care providers, clinician education

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and bias, and patient confidentiality and privacy concerns especially in a small, rural community. (HIV pre-exposure prophylaxis uptake suitability and gaps, 2022. University of Auckland 2024 Saxon et al)

There are two proposed models:

1. *Initiation at pharmacy, for men not accessing PrEP already.*
2. *Collaborative model between GP and Pharmacist, for continuation of supply via pharmacist*.

We are supportive of both models. We have reviewed Appendix 1 of the submission and given the information provided at this stage, we believe that both models will align with our responsible use functions under Pae Ora (Healthy Futures) Act 2022 to promote the responsible use of pharmaceuticals.

Further to this, we note that pharmacies may be open longer hours than primary care centres and sexual health clinics. Additionally, there are pharmacies in more geographical locations than sexual health clinics. Therefore, being able to access this medication at a pharmacy could improve a person's physical ability to access medicines

Improved access to PrEP would likely improve the general health of this population by reducing the transmission of HIV, preventing infections and AIDS related illnesses and cases as well as supporting regular testing for other sexually transmitted infections in collaboration with pharmacy, sexual health, and primary care.

For these reasons we support the reclassification of this prescription medicine; tenofovir disoproxil and emtricitabine. Thank you for your consideration and please let us know if you require anything further from Pharmac | Te Pātaka Whaioranga.

Ngā mihi nui

Anna Owles | Senior Advisor Lead Implementation

17th January 2025

To whom it may concern,

On behalf of ASHM I would like to express our support for the Burnett Foundation Aotearoa Submission to MCC regarding HIV PrEP pharmacy prescribing.

As outlined in the Australian HIV Taskforce Report (November 2023), diversifying the professions who are eligible to prescribe HIV PrEP has the potential to increase access to HIV PrEP, and may reduce the burden of HIV PrEP prescribing on primary care and publicly funded sexual health clinics. The importance of increasing access to HIV PrEP cannot be overstated if we are to reach HIV elimination targets by 2030.

Thank you for your consideration.

Kind regards,

Jessica Michaels
Deputy CEO
ASHM Health

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MSHC
MELBOURNE SEXUAL HEALTH CENTRE

MONASH University

[redacted]

2nd January 2025

To Whom It May Concern,

I am writing as an Australian Sexual Health Physician and Professor of Medicine to express my strong support for the proposed initiative. I am the Vice-President of ASHM (the peak professional organisation for the HIV workforce in Australia and Aotearoa New Zealand), Advisor to the World Health Organization for HIV since 2019, and the in-coming Director of Melbourne Sexual Health Centre (starting February 2025), the largest public sexual health clinic in Australia.

To allow pharmacist supply of PrEP represents a pivotal step toward increasing equitable access to HIV prevention and addressing disparities in health outcomes for vulnerable populations.

Pre-exposure prophylaxis (PrEP) for HIV is a game-changer in controlling HIV. PrEP is highly effective, with up to 99% efficacy in preventing HIV transmission. Despite its proven benefits, access remains a significant barrier for many individuals, particularly those who are young, reside in rural or remote areas, or belong to historically underserved communities, such as Indigenous populations and culturally diverse groups. Expanding the range of access points to include trained pharmacists would reduce structural barriers and normalise the uptake of this vital preventive tool.

Benefits of Pharmacist Supply of PrEP:

1. **Increased Accessibility:** Pharmacists are often more geographically distributed and have extended operating hours compared to general practitioners and sexual health clinics. This accessibility can reduce delays in PrEP initiation and refill, addressing a critical need for continuity in HIV prevention.
2. **Enhanced Equity:** Allowing pharmacist supply will support equitable access for populations that experience systemic barriers to healthcare, such as those in rural areas, young individuals, and people who may feel stigma or discomfort accessing PrEP through traditional clinical settings.
3. **Complementary to Existing Services:** Pharmacist-initiated PrEP supply can complement existing medical pathways by improving entry points for prevention while maintaining connections with broader healthcare services, such as general practitioners for ongoing care and specialist referrals.
4. **Support for Routine Testing:** The pharmacist supply model integrates necessary HIV and STI testing protocols into the process, encouraging consistent engagement with healthcare systems and improving early detection and treatment rates for other conditions.
5. **Value for money:** Expanding PrEP access reduces long-term healthcare costs by preventing new HIV infections, thereby avoiding the lifelong costs associated with antiretroviral therapy and HIV-related complications.

MSHC
MELBOURNE SEXUAL HEALTH CENTRE

MONASH University

I am encouraged to see the proposed framework includes robust safety measures to ensure that pharmacist supply of PrEP adheres to best practices and clinical standards:

- Mandatory completion of an approved pharmacist training program covering PrEP use, clinical eligibility, and appropriate patient education.
- Comprehensive checklists for patient eligibility, including HIV-negative status confirmed by recent testing, renal function assessments, and screening for contraindications.
- Structured patient education on adherence, potential side effects, and the importance of regular follow-up testing.
- Clear referral pathways to general practitioners or sexual health clinics for cases requiring further evaluation or management.

The pharmacist supply model aligns with global public health strategies promoting differentiated service delivery to enhance PrEP uptake and persistence.[1] Evidence from international pilots and studies demonstrates that pharmacist-led PrEP initiatives are safe, effective, and highly acceptable to users.[2,3] Implementing this model in Aotearoa New Zealand would bring us closer to the national goal of ending HIV transmission while addressing persistent inequities in healthcare access.

As a clinician deeply committed to the prevention of HIV and the promotion of sexual health, I strongly endorse this initiative and encourage its adoption. Pharmacist supply of PrEP is a practical, equitable, and impactful approach to strengthening our public health response to HIV.

Thank you for considering this crucial advancement in HIV prevention.

Yours sincerely,

[redacted]

1. Roche SD, Were D, Crawford ND, et al. Getting HIV Pre-exposure Prophylaxis (PrEP) into Private Pharmacies: Global Delivery Models and Research Directions. *Curr HIV/AIDS Rep* 2024; **21**(3): 116-30.
2. Lee LC, Pollak BA, Coffey CP. Implementing a collaborative practice agreement for HIV pre-exposure prophylaxis in the primary care setting. *J Am Pharm Assoc (2003)* 2023; **63**(1): 383-8.
3. Lutz S, Heberling M, Goodlet KJ. Patient perspectives of pharmacists prescribing HIV pre-exposure prophylaxis: A survey of patients receiving antiretroviral therapy. *Journal of the American Pharmacists Association* 2021; **61**(2): e75-e9.

To: committees@health.govt.nz

From: Gay Men's Sexual Health (GMSH) research group, School of Population Health, Faculty of Medical and Health Sciences, University of Auckland

Date: 17 Jan 2025

Submission to Pharmac to support proposal to widen access to HIV pre-exposure prophylaxis (PrEP) via pharmacist supply

Who we are

I am the Director of the Gay Men's Sexual Health (GMSH) research group and Associate Professor at the School of Population Health, University of Auckland. We conduct research on HIV prevention and sexual health among gay, bisexual and other men who have sex with men (GBM). We have led most of NZ's research on PrEP. I am also adjunct A/Prof at the AIDS Epidemiology Group, Otago.

Disclosures and funding

We receive research funding from agencies such as HRC, MoH, Pharmac and NZ AIDS Foundation (now Burnett Foundation Aotearoa). In 2017 I was co-PI on the NZPrEP study that received funding from Gilead, however my time leading the behavioural arm was funded by NZAF and Pharmac. Subsequently I was PI on a $1.4m HRC grant #20/887 to investigate biomedical HIV prevention among GBM, and have recently been funded by Te Whatu Ora $1.6m to lead NZ's HIV behavioural surveillance programme 2024-28 (SPOTS – Sex and Prevention of Transmission Study) to inform NZ's HIV response. I am an expert advisor to the Ministry of Health's HIV Action Plan, HIV Monitoring Plan, Mpox response and I also receive a fellowship from Burnett Foundation Aotearoa to provide independent advice and analyses. I was on the NZ Sexual Health Society Exec for 10 years 2014-2024 including time as Vice President. I was coauthor on the updated 2024 PrEP Prescribing Guidelines.

Executive summary

- We support the proposal to expand access to PrEP without prescription via select pharmacies
- PrEP is a crucial component of modern combination HIV prevention approaches. PrEP uptake in NZ is suboptimal and inequitably accessed by those who would benefit from it
- Unless we expand access to PrEP in ways that are both acceptable to key populations and also clinically safe, NZ is unlikely to meet its goal of eliminating HIV transmission by 2030 outlined in the govt's HIV Action Plan
- The longer NZ takes to eliminate new HIV infections, the more it will cost Pharmac in lifetime HIV treatments that could have been averted by effective primary prevention, such as via expanded PrEP access
- The proposal has broad support from the HIV sector and from a number of STI professionals
- The proposal is consistent with updated WHO Guidelines for differentiated delivery of HIV prevention tools
- We endorse the framework developed by Burnett Foundation Aotearoa in collaboration with the pharmacy sector that sets out careful and responsible processes to supply PrEP via pharmacies.

PrEP is crucial to achieving HIV control

1. Experts regard the appropriate uptake of PrEP, in addition to condoms, testing and timely diagnosis and treatment of people living with HIV to render them sexually non-infectious, as crucial to achieving virtual elimination of HIV transmission in Aotearoa.[1] We refer to this as "**combination HIV prevention**."

2. Furthermore, the HIV and sexual health sector views PrEP uptake *at sufficient scale* to be key in achieving HIV control in populations. In other words, the overall prevention coverage including all combination HIV prevention tools (condoms, PrEP, viral suppression) must be high enough to interrupt chains of transmission and reduce the reproductive rate of HIV to below 1. We refer to this as "**comprehensive HIV prevention**".[2]

3. A multi-disciplinary group representing HIV and STI specialists, epidemiologists, NGOs and policy analysts praised Pharmac's public funding of PrEP in 2018, but also pointed to **implementation challenges that might stymie PrEP uptake** and prevent Aotearoa from realising PrEP's potential. These included barriers to access and prescribing.[3]

Early experiences of GBM benefitting from PrEP

4. In 2018 under the original PrEP criteria we estimated that 18% of HIV negative GBM in Aotearoa would be eligible for PrEP, equating to 5816 GBM (being 99% of all eligible people).[4] This is a **small fraction of all GBM who could potentially benefit from PrEP and lead to reduced HIV incidence**.

5. In 2023 the PrEP prescribing guidelines broadened from PrEP eligibility to "suitability". Estimates of PrEP suitable GBM were then updated to 16,700.[5] This includes a number of GBM with more moderate levels of sexual partnering than the original narrow criteria, but who are **engaging in condomless casual sex and consequently are at risk of acquiring HIV**. The new criteria also increased the number of GBM newly PrEP-suitable who live outside the main centres or who are Māori or Pacific, who face barriers accessing primary care (due to cost) or specialist STI clinics (due to distance).

6. Among PrEP early adopters in the NZPrEP prospective cohort study in 2017, we found that GBM eligible under the original criteria were interested in and motivated to take PrEP, and had high HIV and STI risk profiles prior to initiating PrEP, indicating **high potential benefit**. GBM who were recommended into PrEP (as opposed to self-referrals) had lower education, lived less centrally and had higher STI prevalence, signalling potential inequities in PrEP awareness despite similar needs.[6]

7. After following GBM on PrEP for 12 months in the NZPrEP cohort, we found that risk behaviours did not increase over time, that STIs were high but stable and some STIs even had declining incidence (perhaps due to more timely diagnosis and treatment in sexual networks). Most GBM were adherent to PrEP at levels that provided protection. **No participant acquired HIV** in the trial despite high behavioural risk profiles.[7]

8. On the other hand, we found that Māori and Pacific GBM were less adherent, more likely to take breaks from PrEP, and described lower self-efficacy about taking the pills.[7] This highlights **potential inequities in taking PrEP for Māori and Pacific GBM**, similar to those seen among Māori and Pacific communities accessing clinical care for other conditions.

9. Qualitative research among NZPrEP participants "pre-PrEP" revealed that while many GBM were motivated to take PrEP to reduce their own HIV risk, many were also motivated by altruism, wanted to feel less anxious about HIV every time they had sex, and wished to **play their part in helping control HIV in their community**.[8]

10. Qualitative research among GBM "on-PrEP" showed that the regular sexual health screening was appreciated by many GBM, whereas others experienced negative experiences with GPs or sexual health staff (e.g. judgementalism, stigma).[9] This signals **opportunities to improve** delivery for GBM needing PrEP.

Early evidence of PrEP uptake and impact on HIV epidemic

11. Epidemiological and behavioural data suggests PrEP is **reducing HIV transmission at the community level** in Aotearoa. Focusing on Auckland, where PrEP was first available via the NZPrEP study in 2017, diagnoses of incident locally acquired HIV among GBM declined 65% between 2014-2016 and 2017-2019.[10]

12. Behavioural data from the same analysis showed that while PrEP use rose from 2% in 2016 to 30% in 2019 among HIV-negative Auckland GBM having anal intercourse with casual partners, 49% in 2019 were still engaging in condomless anal intercourse with no HIV prevention coverage (condoms or PrEP). This showed the **potential unmet needs** that more optimal PrEP settings could address.[10]

13. Importantly, PrEP was acceptable to GBM with higher numbers of sexual partners (49%) compared to those with fewer sexual partners (21%). GBM with high numbers of sexual partners are strategically important in HIV transmission networks, but have traditionally been a harder subpopulation to achieve consistent condom use among. This means PrEP is **achieving high HIV prevention coverage among this critical group better than earlier efforts**.[10]

14. Comparative research provided by our joint Flux study with the Kirby Institute at UNSW in 2019 indicated PrEP use was lower among GBM in NZ (18% of all non-HIV positive respondents) than GBM in Australia (46%) at the time.[11] This suggests that **when PrEP is more accessible, more GBM opt to take it**.

15. The epidemiology of HIV in Aotearoa continues to show that transmission is concentrated among GBM, revealing significant health inequities for GBM compared to non-GBM. For instance, we demonstrated that GBM are 348 times more likely to contract HIV locally than heterosexual men and women.[12] These data strongly support focusing effective HIV prevention efforts on this small population, such as with PrEP, that will have **substantial and disproportionate impacts on NZ's overall HIV epidemic control.**

Progress on HIV elimination is now stalling

16. Recent data from the AIDS Epidemiology Group at the University of Otago show that new HIV diagnoses continue to decline. These have largely been driven by a substantial reduction among GBM in Auckland and who are NZ European.[13] This suggests that prevention is working, but to achieve elimination, it **must continue to reach those remaining pockets with unmet need**.

17. It is a concern that new diagnoses of locally acquired HIV have risen in the last two years, suggesting **progress may have stalled**.[13] New HIV diagnoses are also not declining among GBM who are Māori or Pacific, suggesting these groups are not enjoying the benefits PrEP can offer

(i.e. the distribution of benefits is uneven). Recent modelling by the AIDS Epidemiology Group also estimates that at the current trajectory, NZ will overshoot the HIV transmission elimination target by 2030, even under the most optimistic scenario.[14] The AIDS Epidemiology Group argue that greater innovation is needed to get back on track.

Current PrEP uptake, gaps and inequities

18. Data from the SPOTS study, NZ's bio-behavioural surveillance programme of n=3838 GBM in 2022 reveal that 25.6% of non-HIV positive participants had taken PrEP in the previous six months.[15] Of those who had taken PrEP, three quarters (74.8%) had taken it daily or most days, 16.9% had taken it around the time of sex (so-called "on demand", "event-driven" or "2-1-1" dosing), and 8.0% had taken it daily for a limited time (so-called "intermittent" dosing). **This suggests GBM themselves are already innovating and taking PrEP in diverse ways**.

19. Despite almost a quarter of participants using PrEP, coverage is short of where it needs to be. **Approximately one in six participants (18.9%) were in the "PrEP gap"**.[15] In other words, these GBM reported risk behaviours that identified them as suitable candidates to be prescribed PrEP - based on the NZ clinical guidelines[16] - and they were also willing to take PrEP, but they were not using PrEP. The authors state: "This represents a critical gap to close in the next few years. Clearly, **it should be an important target for all agencies involved in the HIV response**, if NZ is to meet the goal of virtually eliminating HIV transmission by 2030."[15]

20. The PrEP gap is also patterned by demographic characteristics, **pointing to inequities in PrEP implementation as it is currently delivered in NZ**. The PrEP gap was larger for Māori (27.4%) and for Pacific (26.1%) GBM. It was also larger for GBM living outside the main centres (23.0%), that includes rural GBM and GBM living in regions not well-served by publicly funded sexual health clinics, or by GPs specialising in PrEP prescribing.[15]

21. The PrEP gap was also larger for some GBM reporting specific HIV risk behaviours. For example, the PrEP gap was almost a third (34.6%) among GBM who reported a history of injecting drug use, and was up to 44.4% among GBM who had engaged in chemsex in the previous six months.[15] **Such GBM may find it more acceptable to enquire about PrEP through alternative providers than GPs or sexual health clinics**. Alternative providers such as pharmacies are trained to support customers presenting with stigmatised or embarrassing behaviours. For such GBM, there may be a perception that disclosing behaviours like chemsex or injecting drug use (or other PrEP-suitable but stigmatised behaviours) to a pharmacist, instead of their usual GP, would avoid compromising their relationship with the latter.

22. This **use of alternative providers is already evident among current PrEP users**. In SPOTS, the most common place for participants to be prescribed PrEP in 2022 was "my regular GP" (56.2%), followed by a sexual health clinic (37.0%), **with 7.2% stating "a different GP"** (a small proportion were also from other sources).

23. Moreover, evidence from HIV testing also suggests that **GBM in NZ are quick to utilise more convenient approaches to their sexual health**. As non-government organisations rolled out new models of HIV testing such as home-based testing, self-screening and point-of-care testing, the proportion of HIV tests that were conducted in these "other" settings increased from 5.7% in 2011 to 23.4% in 2022 (i.e. as distinct from tests conducted via a GP or sexual health clinic).[17]

24. **Greater choice in HIV testing delivery modes over this period was ecologically associated with an increase in HIV testing among GBM**. For example, the proportion reporting recent testing in

the previous 12 months increased from 47.2% in 2011 to 59.6% in 2022, the highest ever testing levels recorded among GBM in NZ.[17]

Structural barriers to PrEP initiation in NZ

25. **Ongoing structural barriers to high quality, respectful and sensitive health care for GBM in NZ are impeding PrEP uptake among those who need it**. To qualify for PrEP, GBM must disclose their sexual behaviour and essentially "come out" to a healthcare provider. Although a number of GPs and many sexual health clinicians support GBM well when their sexuality is disclosed to them, many do not.

26. **Less than two-thirds (63.5%) of GBM sampled in SPOTS 2022 stated their GP knew about their sexuality**. Almost a quarter (23.1%) stated they felt "very" or "somewhat" uncomfortable discussing issues related to their sexuality with their GP or doctor. One in five (20.3%) reported that "a healthcare provider had ever reacted negatively to things you've asked them about your sexuality or sexual health needs".[18]

27. **Qualitative research highlights unacceptable experiences by GBM seeking sexual healthcare in NZ**. One SPOTS participant reported "*once I came out, [Dr] refused to have me as a patient"*. Another stated [Dr was] *"having a laugh at me being gay, while diagnosing depression"*. Comments specifically related to sexual health and PrEP included: *"asked for an HIV test and told I should consider making different life choices"*, *"doctor… told me I was 'doing that gay nonsense too much'"*, and [Dr] *"clearly had very little understanding about bisexuality and PrEP"*.[19]

28. **Suboptimal care within the current PrEP delivery model is affecting PrEP uptake**. Just 6.8% of GBM categorised as "uncomfortable non-disclosers" (i.e. they had not disclosed their sexuality and were not comfortable discussing their sexual health needs with their GP) had taken PrEP in the last six months, compared to 35.4% of "comfortable disclosers" (i.e. they had disclosed their sexuality and were comfortable discussing their sexual health needs with their GP).[20]

29. The "PrEP gap" (i.e. those suitable and willing but not on PrEP) was also wide among GBM who were not out to their GP (27.2%). Importantly, it was also wide among GBM who did not have a GP at the time (24.2%).[15] Not having a GP was more common among GBM who were aged under 30, of an "other" ethnicity (including Middle Eastern, Latin American and African GBM), and those on temporary visas.[21] **This further points to inequities in the current PrEP delivery model for some of the most vulnerable GBM**.

Cost-effectiveness for Pharmac

30. **Improving HIV prevention is cost-effective**. PWC has recently estimated the lifetime cost of a person diagnosed with HIV in NZ to be $1,170,000 or $550,000 in present value terms (Appended to this submission). The estimates include antiretroviral treatment (ART) costs, costs of non-ART drugs for opportunistic infections, outpatient costs, inpatient care and loss of quality of life. The cost estimate for a complex patient ranges from $540,000 to $784,000 in present value terms.[22] Each new HIV transmission averted by improving HIV prevention delivery saves scarce health resources.[23]

31. **Expanding the PrEP delivery model to include pharmacies is a low-cost regulatory option to improve PrEP uptake and effective HIV prevention coverage.** This is a relatively straightforward policy lever to pull. Much of the detail regarding patient pathways has already been developed. The HIV and pharmacy sectors have demonstrated a commitment to collaboration, patient safety and pragmatic and innovative solutions.

The strategic lens

32. The proposal to expand PrEP provision to select pharmacies is consistent with the government's HIV Action Plan 2023-2030. Specifically, the government has called to *"Investigate new models to increase access to PrEP and PEP delivery. This could include establishing models for nurse-led PrEP and PEP delivery (including nurse prescribers in primary health care services) and piloting new models for delivery, such as telehealth, community-led and delivered initiatives,* ***and provision in pharmacies****. Representatives from priority groups should be involved in the process"* (p.26).

33. Expanding PrEP access to pharmacies is consistent with WHO's guidance on differentiated and simplified PrEP provision in 2022. This states: *"Pharmacies can be more accessible, acceptable and convenient for clients than health care facilities…providing PrEP through pharmacies may present an opportunity to expand access to PrEP."* [24]

34. Since then, **a number of jurisdictions similar to NZ with a strong focus on patient safety have approved PrEP delivery in pharmacies**. These include Canada and several US States.[25] NZ would not be the first country to approve pharmacy-delivered PrEP. There are existing models to support the development and refinement of NZ pathways.

35. The **NZ HIV and pharmacy sectors agree that PrEP can be delivered safely via select pharmacies**. They have already demonstrated effective partnerships by developing proposed pathways.

36. There is **broad agreement among the HIV sector, GBM advocacy organisations and public health experts that PrEP provision via select pharmacies is needed if NZ is to control HIV**. The PrEP Symposium held in 2024 provided a mechanism for the sector to identify barriers, debate the issues, reach consensus and foster relationships with key stakeholders. Now such networks are in place, they can be activated to adapt, refine and improve delivery models in future.

37. The current proposal should also be seen in light of **NZ's proud history of effective HIV responses** that have engineered a smaller epidemic than in comparable countries. Our successes have been driven by timely, evidence-based, pragmatic responses, often led by key affected populations and conducted in collaboration with policymakers, health agencies, regulators and community organisations.[26] It is still possible for NZ to be one of the first countries globally to achieve elimination.

38. Notwithstanding these successes, it is clear that NZ's current HIV prevention and testing delivery pathways are insufficient to eliminate HIV transmission by 2030. **The potential gains from the current proposal are significant and the risks are minimal**. All stakeholders are committed to formulating pathways that are safe for patients.

39. The **concept of proportionality** is important here. There is no such thing a zero risk with innovations. However, we argue that this must be considered in context of the much greater challenge of currently inadequate PrEP uptake, that will, all things remaining the same, result in avertable HIV transmissions. In other words, the real costs of every avoidable new HIV transmission event to individuals and to the government outweigh the minimal and largely hypothetical risks of harm occurring. For most people, PrEP is a safe drug and the key patient populations are typically healthy young men.

40. In summary, we support the proposal to expand access to PrEP without prescription via select pharmacies.

Thank you for the opportunity to provide feedback.

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School of Population Health, University of Auckland
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[1] Saxton PJ, Hughes A, Giola M. HIV prevention today: with coordinated action, we can end transmission. NZ Med J. 2015 Dec 4;128(1426):8-15.
[2] https://hivconsensus.org.nz/
[3] Saxton PJ, Giola M, Coughlan E, Rich J, Azariah S, Ludlam A, O'Toole C, Pohl M, Myers J. Implementing HIV pre-exposure prophylaxis (PrEP): let's not get caught with our pants down. NZ Med J. 2018 Aug 31;131(1481):64-73.
[4] Saxton PJ, McAllister SM. Enumerating the population eligible for funded HIV pre-exposure prophylaxis (PrEP) in New Zealand. Sexual Health. 2019;16(1):63-9.
[5] Leakey C. HIV Pre-exposure prophylaxis (PrEP) cascades for Aotearoa New Zealand: Monitoring engagement with PrEP to inform HIV prevention. Master of Health Sciences thesis. University of Auckland: Auckland, 2023.
[6] Saxton PJ, Azariah S, Franklin RA, Forster RF, Werder SF, Jenkins R, Myers JM, Rich JG, Te Wake WP, Fisher MD. Baseline characteristics of gay and bisexual men in a HIV pre-exposure prophylaxis demonstration project with equity quotas in Auckland, New Zealand. Sexual Health. 2018;16(1):47-55.
[7] Saxton PJ, Azariah S, Cavadino A, Forster RF, Jenkins R, Werder SF, Southey K, Rich JG. Adherence, Sexual Behavior and Sexually Transmitted Infections in a New Zealand Prospective PrEP Cohort: 12 Months Follow-up and Ethnic Disparities. AIDS and Behavior. 2022:1-5.
[8] Punchihewa T, Saxton P, Wiles J. P421 'The promise of PrEP': motivations for taking PrEP among early-adopting new zealand gay and bisexual men. Sexually Transmitted Infections. 2019 Jul 1;95(Suppl 1):A201.
[9] Punchihewa TM, Wiles J, Saxton PJ. More than prevention: early adoption of HIV pre-exposure prophylaxis (PrEP) by gay and bisexual men in New Zealand. Culture, Health & Sexuality. 2024;26(2):222-35.
[10] Saxton P, McAllister S, Ludlam A, Bateman J. Declining HIV diagnoses and rising PrEP uptake in Auckland, New Zealand: successes and challenges. Paper presented at 2020 Australasian Joint HIV and Sexual Health Virtual Conference 2020, Nov 16-20.
[11] Saxton P, Hammoud M, Andrews S, Newcombe D, Prestage G. Combination HIV prevention, STI testing and STI diagnosis in NZ and Australia compared: Flux study. Presented at New Zealand HIV Clinical Update, 28 May 2021, Auckland.
[12] Saxton PJ, McAllister SM, Thirkell CE, Ludlam AH, Bateman JP, Anglemyer AT, Priest PC, Sonder GJ. Population rates of HIV, gonorrhoea and syphilis diagnoses by sexual orientation in New Zealand. Sexually Transmitted Infections. 2022;98(5):376-9..
[13] AIDS Epidemiology Group. AIDS – New Zealand. Issue 83 May 2024. Dunedin: University of Otago.
[14] Priest P, McAllister S, Bateman J, de Grouw A, Saxton P, Anglemyer A. HIV transmission in Aotearoa New Zealand: Are we on track to meet the 2030 target? Paper presented at Te Niwha Pandemic Preparedness Conference, Wellington, Nov 12-14, 2024.
[15] Saxton P, Leakey C, Ludlam A, Paynter J, McAllister S, Haunui K, Sriamporn KT, Hollingshead B, Fisher M, Ritchie S, Rich J, Priest P. HIV pre-exposure prophylaxis uptake, suitability and gaps 2022. Research brief. Auckland: University of Auckland; 2024 link
[16] New Zealand Sexual Health Society. PrEP and PEP Guidelines for Aotearoa New Zealand. Auckland, NZ: New Zealand Sexual Health Society; 2023.

[17] Saxton P, Ludlam A, Paynter J, McAllister S, Haunui K, Sriamporn KT, Leakey C, Hollingshead B, Fisher M, Ritchie S, Rich J, Priest P. Trends in combination HIV prevention and HIV testing 2002- 2022: Research brief. Auckland: University of Auckland; 2024. Link

[18] Saxton P, Ludlam A, McAllister S, Ritchie S, Paynter J, Haunui K, Sriamporn KT, Leakey C, Fisher M, Rich J, Priest P. HIV behavioural surveillance in Aotearoa New Zealand 2002-2022: Summary tables. Auckland: University of Auckland, 2024. Link

[19] Swinburn T, Saxton P, Lyndon M. Out in health: gay, bisexual, and other men who have sex with men's negative experiences discussing sexuality and sexual health with healthcare providers in New Zealand. Poster presented for the International AIDS Conference 2024, Munich Jul 22-26, 2024.

[20] Swinburn T, Saxton P, Lyndon M. Out in health: sexual orientation disclosure to healthcare providers among gay, bisexual and other men who have sex with men in New Zealand. Poster presented at the International AIDS Conference 2024, Munich Jul 22-26, 2024.

[21] Swinburn T. Out in Health: Gay, bisexual and other men who have sex with men's disclosure of sexual orientation to general practitioners in Aotearoa New Zealand. BMedSci Hons thesis. Auckland: University of Auckland, 2023.

[22] PricewaterhouseCoopers (PwC) Consulting. The lifetime cost of HIV: A report for the Burnett Foundation Aotearoa. Auckland: PwC, 2024.

[23] The Lever Room. Delivering value for New Zealand: Demonstrating the social and economic impact of a community-led HIV response. The Lever Room, Factsheet, 2024.

[24] World Health Organization. Differentiated and simplified pre-exposure prophylaxis for HIV prevention: update to WHO implementation guidance. Technical Brief. Geneva: World Health Organization; 2022.

[25] Canadian Pharmacists Association. Prescribing Authority of Pharmacists Across Canada 2023 [Available from: https://www.pharmacists.ca/cpha-ca/assets/File/pharmacy-in-canada/PharmacistPrescribingAuthority_Oct23_EN.pdf]

[26] Saxton P. Eliminating HIV is within our grasp. Opinion piece, Newsroom. 6 Aug 2022 Link.

The lifetime cost of HIV

A report for the Burnett Foundation Aotearoa

December 2024

pwc

Joe Rich
Chief Executive
Burnett Foundation Aotearoa
31 Hargreaves street
St Marys Bay
Auckland 1011

10 December 2024

Lifetime cost of HIV in New Zealand

Dear Joe,

Please find enclosed our report, containing our estimates of the lifetime costs of a patient being diagnosed with human immunodeficiency virus (HIV) in New Zealand.

This report is provided in accordance with the terms of our letter of engagement dated 3 May 2024, and is subject to the restrictions set out in Appendix A.

If you have any queries, please do not hesitate to contact us.

Yours sincerely,

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Costing approach

The purpose of our work is to estimate the cost of contracting HIV over a patient's lifetime, including both healthcare costs and other societal costs.

Key elements of our approach

The key elements of our approach are as follows:

- We have estimated the cost for a 'typical' patient, as well as a number of other patient types (see next page).
- Our main estimates of the lifetime cost are shown in present value (PV) terms, reflecting the discounted sum of total costs over a patient's lifetime. We also show the undiscounted total values. We use a discount rate of 3% for our main figures (see page 7).
- We include costs to the health system, as well as other costs to the patient and society.
- We use today's treatment approaches and costs to derive our cost estimates. This means that our estimates reflect the lifetime cost of a patient who is diagnosed today, assuming that treatment methods are unchanged in the future.

This approach is broadly consistent with that adopted by recent international analyses of the lifetime cost of HIV. It is also broadly consistent with Covec's 2013 analysis of the lifetime cost of HIV in New Zealand[1] which was prepared for the New Zealand AIDS Foundation.

Cost items included

We include the following cost items in our estimates of lifetime cost:

- Antiretroviral treatment (ART) costs
- Costs of non-ART drugs, for various opportunistic infections
- Outpatient care costs (eg tests, clinic visits, HIV specialist consultations)
- Inpatient care costs
- Loss of quality of life (estimate of the monetary value of this).

We note that Covec also included a loss of productivity in its 2013 estimate. Due to improvements in HIV treatment over time, productivity loss is now very small. We have therefore excluded it from our analysis on the basis that it is immaterial.

Sources of information

We have used Pharmac data for the ART costs, and publicly available data for other healthcare costs. This data is complemented by a number of assumptions, which are based on assumptions adopted by other HIV cost analyses.

More detailed information is provided later in this report.

1. Covec Ltd, "Cost Benefit Analysis of HIV Prevention Programmes", 2013.

Costing approach (cont.)

The purpose of our work is to estimate the cost of contracting HIV over a patient's lifetime, including both healthcare costs and other societal costs.

Patient characteristics

We have estimated the cost for a 'typical' patient, the characteristics of which are described in the table below.

We have also estimated the cost for six alternative patient types, which differ from the typical patient in terms of one characteristic, as well as the cost for a 'combined' patient type reflecting the highest cost type from each characteristic.

Patient characteristics	Typical patient	Included in other patient types	Combined patient type
Sex	**Male**	Female	Female
Age at infection	**30**	20	20
CD4 severity at diagnosis	**>350**	<200	<200
ART treatment failure	**No failure**	Failure of first and second lines	Failure of first and second lines
Ethnicity	**NZ European**	Māori	NZ European
Location	**Urban**	Regional	Regional

Estimates of lifetime costs - a typical patient

Our 'typical' patient incurs an estimated lifetime cost of $1,170,000, or $550,000 in present value terms.

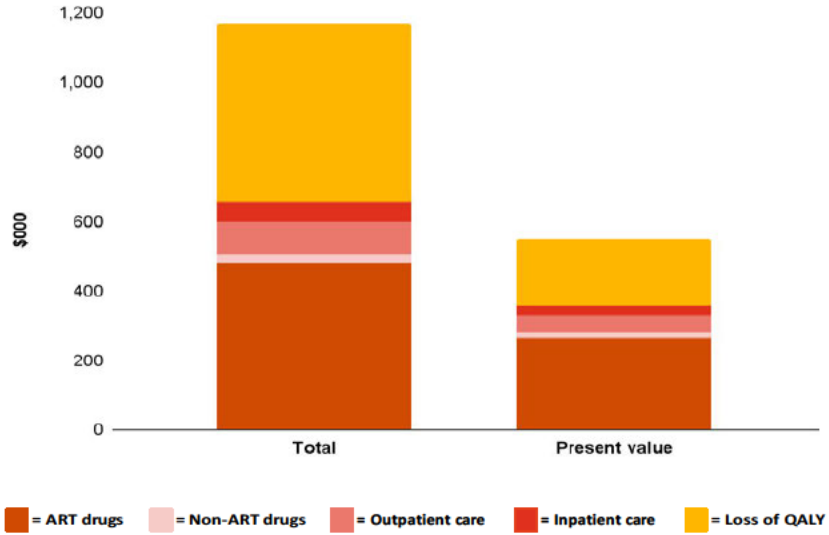
This page sets out our estimates of the lifetime cost of HIV for a typical patient (as defined on the previous page). Both the total value and PV (using a 3% discount rate) are shown.

Table 1: Lifetime cost estimates, for a typical patient, by cost item ($000)

Patient type	Total	Present value
Direct costs		
ART drugs	483	265
Non-ART drugs	25	14
Outpatient care	93	51
Inpatient care	53	29
Total direct	**654**	**359**
Indirect costs		
Loss of QALY	516	191
Total indirect	**516**	**191**
Total cost	**1,170**	**550**

Source: PwC analysis

Figure 1: Lifetime cost estimates, for a typical patient, by cost item



Source: PwC analysis

Estimates of lifetime costs - other patient types

Alternative patient types have estimated lifetime costs of $540,000 to $784,000 (PV terms).

This page sets out our estimates of the lifetime cost of HIV for a number of alternative patient types, in PV terms (using a 3% discount rate).

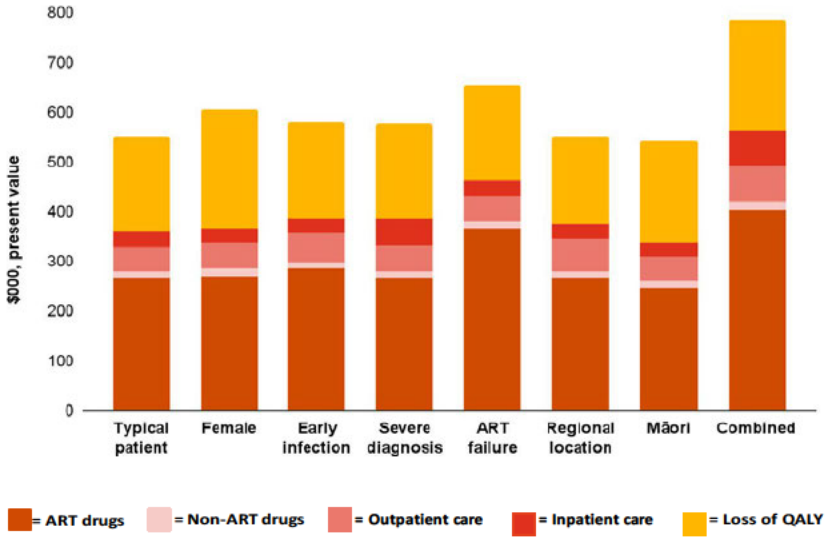
Six patient types differ from the typical patient in terms of a single characteristic, which demonstrates the sensitivity of the cost estimate to each characteristic. We also show a 'combined' patient type, which reflects the highest cost type from each characteristic.

Table 2: Lifetime cost estimates, by patient type and cost item ($000, PV)

Patient type	Typical patient	Female	Early infection	Severe diagnosis	ART failure	Regional location	Māori	Combined
Direct costs								
ART drugs	265	270	285	265	367	265	248	402
Non-ART drugs	14	14	15	15	14	14	14	18
Outpatient care	51	52	55	51	51	67	48	72
Inpatient care	29	30	31	55	31	29	28	72
Total direct	**359**	**366**	**387**	**386**	**463**	**374**	**338**	**564**
Indirect costs								
Loss of QALY	191	240	194	191	191	175	203	220
Total indirect	**191**	**240**	**194**	**191**	**191**	**175**	**203**	**220**
Total cost	**550**	**605**	**581**	**577**	**655**	**549**	**540**	**784**

Source: PwC analysis

Figure 2: Lifetime cost estimates, by patient type and cost item



Source: PwC analysis

Estimates of lifetime costs - discounting

The estimated cost for a typical patient reduces to $380,000 (PV terms) if a larger discount rate is adopted.

The PV values on the previous pages are derived using a 3% discount rate, which is the rate used for a number of recent international analyses of lifetime costs.

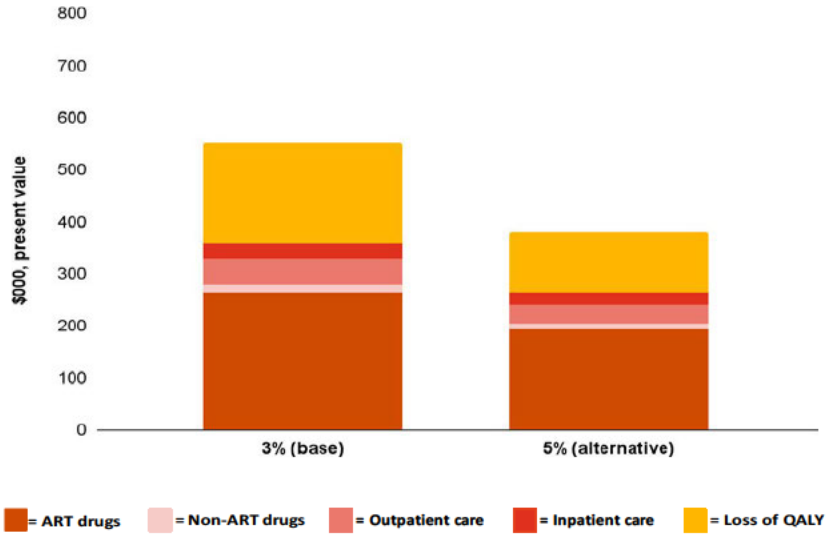
On this page we show the impact on the lifetime cost estimate of using an alternative discount rate of 5%, which is the New Zealand Treasury's default rate for most social sector projects and consistent with what the Covec 2013 analysis used.

Table 3: Lifetime cost estimates, for a typical patient, by cost item ($000, PV)

Discount rate	3% (base)	5% (alternative)
Direct costs		
ART drugs	265	194
Non-ART drugs	14	10
Outpatient care	51	38
Inpatient care	29	22
Total direct	**359**	**263**
Indirect costs		
Loss of QALY	191	116
Total indirect	**191**	**116**
Total cost	**550**	**380**

Source: PwC analysis

Figure 3: Lifetime cost estimates, for a typical patient, by cost item



Source: PwC analysis

Estimates of lifetime costs - annual values over time

The estimated lifetime cost reflects a series of annual costs.

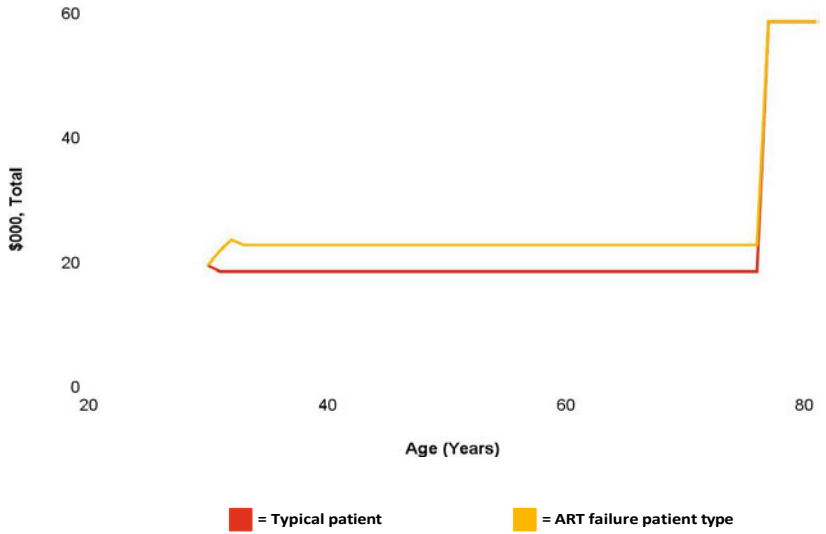
The chart to the right shows how our lifetime cost estimates are built up from annual cost values. It shows the annual cost estimates for our typical patient, as well as the 'ART failure' patient type.

The majority of our cost estimates are constant over a patient's lifetime. The key changes happen in the early years, as patients respond (or not) to treatment.

Our main cost estimates in this report reflect the cost if a patient was diagnosed today. But this time series information can help consider the remaining lifetime cost of a patient who was diagnosed in the past.

- A patient born in 1964 and diagnosed in 1994 would be 60 years old today. Their remaining lifetime cost would incorporate the right-most part of the line.
- If that patient diagnosed in 1994 received less effective treatment than a similar patient today, they may be in worse overall health and have higher ongoing treatment costs. Even if they were a typical patient in 1994, their costs may be similar to a high-cost patient today, and hence the higher line of the two shown right may be more applicable.

Figure 4: Annual cost estimates, over a patient's lifetime



Source: PwC analysis

Key data sources and assumptions

We have used Pharmac data, complemented by cost information from publicly available sources, and assumptions based on other studies.

ART drugs

We have derived an annual ART cost per patient, for each of first, second and third line treatments, using:

- Pharmac-supplied data on the total annual ART cost and total patient numbers for FY23
- academic data on the relative cost and patient numbers between each treatment line (Solem et al., 2014).

The formula we have used is:

$$\frac{Total\ FY23\ costs\ for\ ART\ treatment}{(\#\ of\ patients\ FY23\ start \times \sum line\ multiples) + (new\ patients\ in\ FY23 \times average\ proportion\ of\ year\ treated)}$$

Non-ART drugs, inpatient care, outpatient care

Our estimates of non-ART direct costs are sourced from a Canadian study, Krentz, Vu and Gill (2020), which estimated the HIV per patient healthcare costs in Canada between 2006-2017, grouped by CD4 counts.

Patients with relatively low CD4 counts typically require more inpatient care and non-ART drugs, as a result of opportunistic infections (OIs) taking advantage of their weak immune systems.

We have cross-checked the cost values from this study against estimates for a number of other sources. Values have been converted to 2024 NZD.

Loss of QALY

Values for the loss of quality-adjusted life years (QALYs) reflect two elements:

- loss of quality of life (QoL)
- reduced life expectancy.

Our estimates are sourced from surveys of the QoL and life expectancy for HIV patients (McAllister et al., 2022; Trickey et al., 2023) and the general population (Quality of Life Project, 2022, Stats NZ, 2024).

The value of a QALY is assumed to be New Zealand's GDP per capita.

Life expectancy

Different life expectancy is a key factor in the different lifetime cost estimates across our patient types.

Life expectancy estimates for the general population, including by characteristic (eg ethnicity, gender, age today) are sourced from Stats NZ.

Life expectancy estimates for HIV patients are sourced from Trickey, et al. (2023). This includes estimates for each gender, by North American and European patients, aged 20 and 40.

As noted earlier, we have assumed that the 'typical patient' is 30 when they acquire HIV, and the 'early infection' patient is 20. We have assumed that both have a similar reduction in life expectancy as a result of infection. This means that the 'early infection' patient has more years of treatment, and hence a greater treatment cost. This assumption reflects an average over the wide range of actual experiences patients have.

Key data sources and assumptions (cont.)

We have used Pharmac data, complemented by cost information from publicly available sources, and assumptions based on other studies.

Other assumptions

Other assumptions include the following:

ART treatment

- All patients eventually respond to a line of treatment (ie patients that fail first and second line treatment respond to third line).
- Patients progress through the CD4 severity levels at a rate consistent with that documented by Loka et al., 2011.

Life expectancy

- Relative life expectancy between HIV patients and the general population in New Zealand is similar to that in North America and Europe.
- Relative life expectancy between HIV patients and the general population is proportionally the same for Māori as for all patients.
- Relative life expectancy for 30 year old patients with HIV, can be extrapolated from the estimates for 20 and 40 year olds.

Other health costs

- A comorbidity multiplier of 1.04 is applied to Māori patients for relevant cost items (based on Reid et al., 2022).
- The additional annual cost for patients in rural locations is $540, to attend clinic visits (based on Krentz, Vu & Gill, 2020; Fearnley, Kerse & Nixon, 2016).

Quality of life

- Māori, female, and urban HIV patients experience worse QoL (ie more QoL loss) than the average HIV patient (based on McAllister et al., 2022).
- We note that patients with ART failure and/or a severe diagnosis may experience worse QoL than typical patients (Farnham et al., 2013; Lo et al., 2024), but our primary data source for QoL inputs did not contain data on this aspect. Such an assumption was not included in the modelling.

Other

- Productivity loss for patients diagnosed today is very small (based on Verbooy et al., 2018; Ritchwood, Bishu & Egede, 2017)

Appendices

Appendix A: Restrictions

This report has been prepared for the Burnett Foundation Aotearoa, to present estimates of the lifetime costs of HIV patients in New Zealand. This report has been prepared solely for this purpose and should not be relied upon for any other purpose. We accept no liability to any party should it used for any purpose other than that for which it was prepared. This report has been prepared solely for use by the Burnett Foundation Aotearoa.

To the fullest extent permitted by law, PwC accepts no duty of care to any third party in connection with the provision of this report and/or any related information or explanation (together, the "Information"). Accordingly, regardless of the form of action, whether in contract, tort (including without limitation, negligence) or otherwise, and to the extent permitted by applicable law, PwC accepts no liability of any kind to any third party and disclaims all responsibility for the consequences of any third party acting or refraining to act in reliance on the Information.

We have not independently verified the accuracy of information provided to us. We express no opinion on the reliability, accuracy, or completeness of the information provided to us and upon which we have relied. The statements and opinions expressed herein have been made in good faith, and on the basis that all information relied upon is true and accurate in all material respects, and not misleading by reason of omission or otherwise. The statements and opinions expressed in this report are based on information available as at the date of the report. We reserve the right, but will be under no obligation, to review or amend our report, if any additional information, which was in existence on the date of this report, was not brought to our attention, or subsequently comes to light.

This report is issued pursuant to the terms and conditions set out in our engagement letter dated 3 May 2024.

Appendix B: Cost estimates

Undiscounted values

Table 4: Lifetime cost estimates, by patient type and by cost item ($000, undiscounted)

Patient type	Typical patient	Female	Early infection	Severe diagnosis	ART failure	Regional location	Māori	Combined
Direct costs								
ART drugs	483	503	575	483	675	483	421	834
Non-ART drugs	25	26	30	27	25	25	23	34
Outpatient care	93	97	111	93	94	121	81	149
Inpatient care	53	55	62	80	54	53	48	108
Total direct	**654**	**682**	**779**	**682**	**848**	**682**	**573**	**1,125**
Indirect costs								
Loss of QALY	516	693	618	516	516	486	498	766
Total indirect	**516**	**693**	**618**	**516**	**516**	**486**	**498**	**766**
Total cost	**1,170**	**1,375**	**1,397**	**1,199**	**1,364**	**1,168**	**1,072**	**1,891**

Appendix B: Cost estimates

Present values, 3% discount rate

Table 5: Lifetime cost estimates, by patient type and by cost item ($000, PV, 3% discount rate)

Patient type	Typical patient	Female	Early infection	Severe diagnosis	ART failure	Regional location	Māori	Combined
Direct costs								
ART drugs	265	270	285	265	367	265	248	402
Non-ART drugs	14	14	15	15	14	14	14	18
Outpatient care	51	52	55	51	51	67	48	72
Inpatient care	29	30	31	55	31	29	28	72
Total direct	**359**	**366**	**387**	**386**	**463**	**374**	**338**	**564**
Indirect costs								
Loss of QALY	191	240	194	191	191	175	203	220
Total indirect	**191**	**240**	**194**	**191**	**191**	**175**	**203**	**220**
Total cost	**550**	**605**	**581**	**577**	**655**	**549**	**540**	**784**

Appendix B: Cost estimates

Present values, 5% discount rate

Table 6: Lifetime cost estimates, by patient type and by cost item ($000, PV, 5% discount rate)

Patient type	Typical patient	Female	Early infection	Severe diagnosis	ART failure	Regional location	Māori	Combined
Direct costs								
ART drugs	194	196	202	194	267	194	186	280
Non-ART drugs	10	10	11	12	10	10	10	13
Outpatient care	38	38	39	37	38	49	36	50
Inpatient care	22	22	22	47	23	22	22	62
Total direct	**263**	**266**	**274**	**290**	**339**	**274**	**254**	**405**
Indirect costs								
Loss of QALY	116	142	113	116	116	104	127	124
Total indirect	**116**	**142**	**113**	**116**	**116**	**104**	**127**	**124**
Total cost	**380**	**408**	**387**	**406**	**455**	**379**	**381**	**530**

Appendix C: Sources of information

Sources

In developing our estimates of the lifetime cost of HIV, and as described above in this report, we have utilised information from a range of sources. These sources are set out below. Some of these sources are our primary basis for certain inputs and assumptions, while others were used as cross-checks and other contextual information.

Information provided to us by the Burnett Foundation Aotearoa

- Pharmac information on ART costs - 'Pharmac up to June 2023.xlsm' (provided 6/03/2024)
- Additional Pharmac information on ART costs - 'Updated treatment costs.pdf' (provided 8/07/2024)
- 2013 Covec analysis of the lifetime cost of HIV in NZ - 'Final Covec Report 120713.pdf' (provided 7/05/2024)

Academic articles

- AIDS Epidemiology Group. (2024). *HIV & AIDS in New Zealand: Issue 83 - May 2024*. University of Otago.
- Bachmann, P., Kretzschmar, M., & Bruggmann, P. (2022). Economic evaluations of HIV/STI prevention interventions: A scoping review. *AIDS and Behavior, 26(7)*, 2279-2298. https://doi.org/10.1007/s10461-022-03583-y
- Farnham, P. G., Holtgrave, D. R., Gopalappa, C., Hutchinson, A. B., & Sansom, S. L. (2013). Lifetime costs and quality-adjusted life years saved from HIV prevention in the test and treat era. Journal of Acquired Immune Deficiency Syndromes, 64(2), e15. https://doi.org/10.1097/QAI.0b013e3182a5c8d4
- Jacobsen, M. M., & Walensky, R. P. (2016). The critical role of cost-effectiveness and modeling analyses in HIV prevention.
- Lim, M., Devine, A., Gray, R. T., Kwon, J. A., Hutchinson, J. L., & Ong, J. J. (2022). Lifetime cost of HIV management in Australia: An economic model. *Sexual Health, 19*(6), 523-524. https://doi.org/10.1071/SH21250
- Lo, T., Fang, C.-T., Lee, Y.-Y., Shih, C.-C., Chu, F.-Y., & Wang, J.-D. (2024). Early HIV diagnosis enhances quality-adjusted life expectancy of men who have sex with men living with HIV: A population-based cohort study in Taiwan. Journal of Microbiology, Immunology and Infection, 57, 85-96. https://doi.org/10.1016/j.jmii.2023.11.004
- Lok, J. J., Bosch, R. J., Benson, C. A., Collier, A. C., Robbins, G. K., Shafer, R. W., & Hughes, M. D. (2011). Long-term increase in CD4+ T-cell counts during combination antiretroviral therapy for HIV-1 infection. *AIDS*, 25(9), 1207-1215. https://doi.org/10.1097/QAD.0b013e328347fa13
- McAllister, S., Iosua, E., Hollingshead, B., Bruning, J., Fisher, M., Olin, R., Mukakayange, J., Greenwood, C., de Gouw, A., & Priest, P. (2022). Quality of life in people living with HIV in Aotearoa New Zealand: An exploratory cross-sectional study. AIDS Care, https://doi.org/10.1080/09540121.2022.2082359
- Nakagawa, F., Miners, A., Smith, C. J., Simmons, R., Lodwick, R. K., Cambiano, V., Lundgren, J. D., Delpech, V., & Phillips, A. N. (2015). Projected lifetime healthcare costs associated with HIV infection. *PLOS ONE, 10*(4), e0125018. https://doi.org/10.1371/journal.pone.0125018

Appendix C: Sources of information (cont.)

Academic articles (cont.)

- Nielsen IQ. (2022). *2022 Quality of Life Survey: Topline Report for Eight New Zealand Cities*.
- Ritchwood, T. G., Bishu, K. G., & Egede L. E. (2017). Trends in healthcare expenditure among people living with HIV/AIDS in the United States: evidence from 10 Years of nationally representative data. *International Journal for Equity in Heath, 16*(1), 188. https://doi.org/10.1186/s12939-017-0683-0
- Rankin, S. L., Hughes-Anderson, W., House, A. K., et al. (2016). The price of free: Quantifying the costs incurred by rural residents attending outpatient clinics. *Journal of Primary Health Care, 8*(3), 205-209. https://doi.org/10.1046/j.1440-1622.2001.02188.x
- Reid, A. L., Bailey, M., Harwood, M., Moore, J. E., & Young, P. J. (2022). Outcomes for Māori and European patients admitted to New Zealand intensive care units between 2009 and 2018. *New Zealand Medical Journal, 135*(1550). Retrieved from https://www.nzma.org.nz/journal-articles/outcomes-for-maori-and-european-patients-admitted-to-new-zealand-intensive-care-units-between-2009-and-2018
- Schackman, B. R., Fleishman, J. A., Su, A. E., Berkowitz, B. K., Moore, R. D., Walensky, R. P., Becker, J. E., Voss, C., Paltier, D. A., Weinstein, M. C., Freedberg, K. A., Gebo, K. A., & Losina, E. (2015). The lifetime medical cost savings from preventing HIV in the United States. *Medical Care, 53*(4), 293-301. https://doi.org/10.1097/MLR.0000000000000308
- Solem, C. T., Snedecor, S. J., Khachatryan, A., Nedrow, K., Tawadrous, M., Chambers, R., Haider, H., Simpson, K. (2014). Cost of Treatment in a US Commercially Insured, HIV-1-Infected Population. *PLOS ONE, 9*(5), e98152. https://doi.org/10.1371/journal.pone.0098152
- Trickey, A., et al. (2023). Life expectancy and comorbidities among people with HIV on antiretroviral therapy in high-income countries: A longitudinal cohort study. *Lancet HIV*. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1234567/
- Verbooy, K., Wagener, M., Kaddouri, M., Brouwer, W., Roelofs, P., Miedema, H., van Gorp, E., Brouwer, W., & van Exel, J. (2018). Are people living with HIV less productive at work? *AIDS Care, 30*(6), 728-736. https://doi.org/10.1080/09540121.2018.1426827

Websites

- https://www.stats.govt.nz/information-releases/national-and-subnational-period-life-tables-2017-2019
- https://www.taxtechnical.ird.govt.nz/operational-statements/2024/os-19-04-km-2024
- https://www.stats.govt.nz/news/average-hourly-earnings-up-5-2-percent-annually/
- https://www.rbnz.govt.nz/monetary-policy/about-monetary-policy/inflation-calculator
- https://www.exchange-rates.org/exchange-rate-history/cad-nzd-2017-12-21
- https://www.stats.govt.nz/information-releases/consumers-price-index-june-2024-quarter/#:~:text=Annual%20change,home%20ownership%20(up%203.0%20percent)

Aotearoa New Zealand Sexual Health Physicians Network

We are an informal alliance of vocationally trained sexual health physicians working in specialist sexual health services across the motu. We are all fellows of the Australasian Chapter of Sexual Health Medicine (AChSHM) which is a chapter of the Royal Australasian College of Physicians (RACP). Sexual health medicine is the specialised area of practice concerned with healthy sexual relationships. Sexual Health Medicine Physicians work collaboratively with a multidisciplinary team to improve the sexual health outcomes of the individual and the community by identifying and minimising sexual health issues through education, behaviour change, advocacy, screening, clinical service provision, surveillance and research. Our members have a wide range of expertise including the management of sexually transmitted infections and HIV, vulvovaginal conditions, genital dermatology, chronic genital pain, gender affirming health care, sexual assault medicine and public health. We provide education for other health professionals and are involved in advocacy and research in the field of sexual health medicine.

We have led the development of the following national guidelines in collaboration with the New Zealand Sexual Health Society: The Aotearoa New Zealand STI management guidelines for Primary Care, the New Zealand Syphilis in Pregnancy guideline, the HIV PEP and PrEP guidelines for Aotearoa New Zealand and the DoxyPEP interim prescribing guidelines. (www.nzshs.org) Our members were also involved in development of the Aotearoa New Zealand STBBI strategy.

Our aim is to provide expert advice and information to governmental and non-governmental organisations on matters related to sexual health. We believe that all New Zealanders regardless of their gender, sexual identity, ethnicity or geographical location have the right to access healthcare that is safe and respectful in order to enhance their health and wellbeing. We therefore endorse the Aotearoa statement in

closing the STI and BBV gaps between indigenous and non-indigenous peoples in Australasia. www.nzshs.org

Members of the Alliance

Wellington Sexual Health Service
Dr Jenny Hayward
Dr Julia Scott
Dr Dilmini Mendis
Dr Jane Morgan

Auckland Sexual Health Regional Service
Dr Jeannie Oliphant
Dr Rose Forster
Dr Sunita Azariah
Dr Nicky Perkins

Waikato Sexual Health Service
Dr Susan Bray
Dr Karen Benattar
Dr Natalie Renaud

Tauranga Sexual Health Service
Dr Massimo Giola

Palmerston North Sexual Health Clinic
Dr Anne Robertson

Christchurch Sexual Health Service
Dr Edward Coughlan
Dr Heather Young
Dr Jane Kennedy

Auckland
Dr Teena Mathew
Dr Min Lo

8th January 2025

Chair of Medicines Classification Committee

Re: Application to increase access to HIV Pre-exposure Prophylaxis (PrEP) through exemption to prescription status for pharmacists.

Dear Committee members

Thank you for the opportunity to make a submission regarding this proposal. This letter comes from the Aotearoa New Zealand Sexual Health Physicians Network which represents vocationally registered sexual health medicine specialists. Our specialty focus is on the management of sexually transmitted infections and HIV at personal and population health levels. (Please refer to attached document for information regarding our members). A member of this group (Dr Sunita Azariah) was the lead investigator of the NZ PrEP demonstration project and collectively we have extensive experience in the early roll-out of HIV PrEP in New Zealand.[1]

We fully support improving access to PrEP as part of a combination prevention and health promotion approach with the aim of eliminating HIV in Aotearoa, New Zealand as outlined in the HIV action plan.[2] We are deeply concerned regarding current inequities in access for Māori and Pacific peoples which has been high-lighted in recent research referred to in the application to the committee. Even more concerning is recent data from the AIDS Epidemiology group that has demonstrated that whilst rates of new HIV infections acquired in Aotearoa New Zealand are declining in non-Māori; this has not been the case for Māori and Pacific peoples. There is no question that this inequity needs to be addressed however the application has not provided any evidence to support that this pharmacy-led model will improve PrEP access for Māori and Pacific people. Although we accept that consultation may have taken place, there is no reference in the application to partnership or collaboration with Iwi or Pacific heath organisations to identify and address current barriers.

We support implementation of new models for provision of care particularly as clinical services are stretched and many people do not have easy access to a GP or a sexual health clinic. Stigma and discrimination towards Rainbow communities are further barriers to seeking care, particularly in rural and remote communities and we agree that pharmacies

have an important role to play in improving access to care. Pharmacists are well placed to have discussions about PrEP under appropriate conditions and there is data from the United States to support that people would be willing to discuss PrEP with a pharmacist[3]. However, the significant level of stigma around HIV and PrEP means that people in rural and remote communities may still hesitate to discuss this with their local pharmacist.

Clinical Safety Concerns

The application refers to the SB-159 legislation in California that allowed pharmacists to dispense under a 'collaborative care model'.[4] It is important to note that this legislation allows only for a limited amount of medication to be dispensed as '*initiation only'* and that *'the patient must be seen by a primary care provider to receive subsequent prescriptions for pre-exposure prophylaxis and that a pharmacist may not furnish a 60-day supply of pre-exposure prophylaxis to a single patient more than once every two years'*. The United States model however does require follow-up by a primary care clinician for on-going care.
We are concerned that potential clinical risks of PrEP have been minimised in this submission with the inclusion of incorrect information. E.g. *'bone effects' from tenofovir have only been observed in animals',* when tenofovir is well known to lower bone density in humans.[5]

Our main concern about this proposal is regarding clinical monitoring. When PrEP is prescribed appropriately with proper clinical monitoring there are usually few medical complications. However, the applicants have not addressed the importance of appropriate clinical monitoring as outlined in the New Zealand PrEP prescribing guidelines,[6] and have not clearly explained the process for test requesting, review and follow-up of any abnormal test results. There is no mention of in the submission of any consultation with primary care and sexual health services regarding implementation of referral pathways for those people that need clinical care and follow-up. E.g. For abnormal renal function tests, positive STI tests, or for the management of people newly diagnosed with HIV.
We do not support self-requested laboratory testing without clinical oversight of results.

How do the costs stack up for this model compared to other modes of delivery?

There is no mention of cost in this application particularly in comparison to other models of care, for example a face to face or telehealth consultation with a nurse specialist or nurse practitioner. The committee will need to carefully consider what the financial implications will

be for the individual patient and to Te Whatu Ora. *'Pharmacists will provide education about PrEP, including how to take it, potential side effects, and adherence and direct users to appropriate info sources on sexual health topics'.* What will be the cost of the pharmacy consultations? Will the patient or Te Whatu Ora be required to pay for the consultation? Will the patient have to pay for the medication as is the case for other pharmacy dispensed medications? (For example urinary tract infections and emergency contraception) What service will be billed for the laboratory tests? What about re-imbursement for additional pharmacy workload for ordering, reviewing and follow-up of laboratory results?

For these reasons, we are currently unable to endorse this application. We would prefer an alternative model that would enable nurse prescribers to prescribe PrEP as we consider it would be more clinically safe. We would advocate for setting up a national nurse-led telehealth service (in a similar model to provision of abortion services) to improve PrEP access for those in rural or remote areas.[7] This would allow for appropriate clinical over-sight and referral to primary care and sexual health clinical services if needed.

Short term pharmacy provision of PrEP may be appropriate for repeat prescriptions when people cannot access it from their usual provider, for example if away from home and if results were accessible through Manage my Health or test safe to check that they were up to date with HIV serology and other recommended tests such as renal function monitoring.

H**IV Post-exposure Prophylaxis**

We would support enabling pharmacists to prescribe HIV post-exposure prophylaxis (PEP) due to the short time frame for effective intervention (as it must be started within 72 hours of exposure) and because the medication is only prescribed for a limited time. This would reduce current barriers to PEP access, and pharmacists could then facilitate referral to clinical services for follow-up and initiation of PrEP if indicated.

We also recommend increasing access to a wider range of condoms (including internal condoms) as an integral part of a national HIV strategy as they are very effective at preventing HIV when used correctly and consistently and have no clinical safety issues. Pharmacies could have an important role in facilitating better access to condoms if a wide range could be dispensed free from pharmacies.

We thank you for your time intaking time in considering this submission.

Dr Sunita Azariah (on behalf of the Aotearoa New Zealand Sexual Health Physicians Network)

Sexual Health Physician

Auckland Sexual health Service

Te Toka Tumai

References

1. Azariah S, Saxton P, Franklin R, *et al*. NZPrEP. Demonstration Project: protocol for an open-label, single-arm trial of HIV pre-exposure prophylaxis (PrEP) to determine feasibility, acceptability, adverse and behavioural effects of PrEP provision to gay and bisexual men in publicly funded sexual health clinics in Auckland, New Zealand. *BMJ Open* 2019;9:e026363. doi:10.1136/bmjopen-2018-026363
2. https://www.health.govt.nz/publications/national-hiv-action-plan-for-aotearoa-new-zealand-2023-2030
3. J Pharm Pract. 2020 Feb 18;34(5):734–740. doi: 10.1177/0897190020904590
4. Bill Text - SB-159 HIV: preexposure and postexposure prophylaxis. (ca.gov)
5. The Effect of Tenofovir Disoproxil Fumarate on Bone Mineral Density: A Systematic Review and Meta-Analysis - Benjamin Baranek, Shaoyuan Wang, Angela M Cheung, Sharmistha Mishra, Darrell HS Tan, 2020 (sagepub.com)
6. NZSHS PrEP tool final.pdf (rocketspark.co.nz)
7. Decide

14th December 2024

Dear Medicines Classifications Committee – 73rd Meeting

Re: 6.2 Tenofovir disoproxil and emtricitabine (Burnett Foundation)

I am a New Zealand trained medical practitioner who commonly prescribes tenofovir disoproxil and emtricitabine (TDE) for HIV pre-exposure prophylaxis. I am writing to support the reclassification of TDE as outlined by The Burnett Foundation submission. As a general practitioner who delivers primary care for people living with HIV and those who face an elevated HIV exposure risk, I commonly navigate the human face of our ongoing HIV public health challenge. I hear how access to HIV prevention tools - such as TDE - does not always meet our communities' expectations, hopes, and immediate need.

I have reviewed the Burnett Foundation's submission in detail and feel the population and individual benefits significantly outweigh the well-considered and mitigated risks.

We are privileged in New Zealand to have highly trained pharmacists who have demonstrated the clinical acumen required to extend their scope – nirmatrelvir/ritonavir dispensing comes to mind. In my view, empowering our pharmacist community remains an exciting opportunity to innovate and meet New Zealand's urgent demand for healthcare. I consider this evidence based, safe-guarded, implementation framework for TDE HIV pre-exposure prophylaxis to be an exemplary opportunity to meet demonstrable need through our pharmacist resource.

New Zealand can wait for the rest of the world to lead the way, or we can do what we did with pavlova – be the first to do it the best.

I wish to thank you for considering the submission.

Kind regards,

Dr [redacted]

15 January 2025

Tēnā koutou,

I am writing to fully support of the application titled Increase access to HIV Pre-exposure prophylaxis (PrEP) through exemption to prescription status for pharmacists.

As outlined in the excellent application, pharmacists are already embedded as part of the primary health team, working alongside medical prescribers, nurses, and other health care professionals, working in collaborative partnership, providing their own expertise. They are located across the country, in rural and urban areas both within the 'bricks and mortar' of the pharmacy and there are increasing roles in an online and mobile settings. Therefore, have the potential for reach those who have disengaged, or have been unable to access existing health providers.

Community based pharmacists are an important and valuable member of the team, who are in the most part, accessible without an appointment, and have drug therapy expertise. These health care professionals have a long-standing track record of being able to provide safe and effective care with pharmacist only medicines, such as sildenafil for erectile dysfunction, and more recently UTI treatment and COVID vaccination. Community based pharmacists have recently been involved in point of care testing, for example, providing INR testing and interpretation for warfarin treatment, and HbA1c and blood glucose testing for Type 2 Diabetes Mellitus monitoring. Community based pharmacists routinely review online laboratory results, for example, WBC and neutrophil counts for clozapine, and serum creatinine for ritonavir and nirmatrelvir (Paxlovid).

Pharmacists think about health holistically, and when consulting on the use of PrEP, community based pharmacists will be able to use this approach to provide holistic sexual health care (e.g., screening for STIs, providing condoms). Community based pharmacists are well placed to contribute to the goal of zero transmission of HIV in Aotearoa New Zealand, as outlined by the National HIV Action Plan.

Having PrEP available as a pharmacist only medicine will provide an *additional* pathway to accessing PrEP. This is highly likely to be welcomed by the MSM community, and with an equity-based implementation plan, is likely to contribute to equitable health outcomes for Māori, Pacific Peoples, those living rurally, and other underrepresented and marginalised people. The case made in the application has sufficient evidence to demonstrate community need.

Safe treatment with PrEP, for the people indicated in the eligibility criteria, will be easily maintained due to the relatively few contraindications and these can be easily identified with a robust checklist (e.g., HIV-1 status, concomitant use of tenofovir disoproxil). The warnings and precautions of lactic acidosis and renal impairment are precautions pharmacists understand well due to their knowledge of renally cleared medicines and ability to review renal function from recent laboratory test results (e.g., serum creatinine, BUN). Pharmacists are also capable of calculating Creatine Clearance using the Cockcroft Gault formula, or interpreting the eGFR to identify the risk of nephrotoxicity, and therefore whether the person needs to be referred to a medical prescriber. Pharmacists are well aware of their scope of practice, and will be able to follow the checklist in addition to their good clinical practice, and refer to a medical prescriber when appropriate.

Regarding Hepatitis B, some community based pharmacists are already engaged in providing Hepatitis C testing and treatment, and are therefore will be able to bring an established skill set in Hep C testing and treatment to the Hep B training.

Pharmacists are already familiar with the pharmacist-initiated supply of ritonavir and nirmatrelvir (Paxlovid) for COVID and are experienced with using existing good clinical decision making skills and knowledge alongside additional clinical training and robust checklists. Therefore, approving PrEP for pharmacist only supply will be a relatively easy transition for most pharmacists who choose to undertake additional training to provide this to the community they work alongside.

It is standard of care to provide advice on adverse effects for pharmacist only medicines, and therefore this advice on PrEP will be thoroughly discussed with the person. This will form an important part of the monitoring plan, as will creatinine clearance.

In summary, the community based pharmacist workforce have the skills and knowledge to safely and effectively provide another pathway for people to access PrEP. This will be an important contribution to the overall healthcare team to achieve the goal of Aotearoa New Zealand having zero transmission of HIV by 2030. All aspects of the healthcare team and system need to be leveraged to achieve this goal.

I look forward to hearing the outcome from the committee on this application. I am happy to be contacted should the committee have any questions for me.

Kā mihi maioha,

Dr Lisa Kremer (Kāi Tahu, Kāti Māmoe, Waitaha)

Associate Dean Māori, Senior Lecturer in Clinical Pharmacy

He Rau Kawakawa (School of Pharmacy), Ōtākou Whakaihu Waka (University of Otago)

Kia ora koutou

I would appreciate it if the Chair of the MCC and secretariat could accept this email as a submission in support of the proposal to reclassify PrEP medicines to be available without requiring a prescription.

I'll keep my comments brief and hope that my reflections will be considered with my extensive experience in pharmacy practice, task shifting policy, medicines reclassification and innovative pharmacy service policy and implementation in mind.

Pharmacists and their teams have beyond proven themselves competent and safe in the provision of many pharmacist only medicines and 'prescription except when' medicines. Recent examples of note are their outstanding contribution safely improving access to Covid-19 antivirals and the growing contribution they are making to improving access to Hepatitis C medicines across the motu.

I see provision of PrEP as a natural extension of this valuable role in supporting safe, easier and equitable access to these essential medicines for HIV related therapeutics. In fact in my studies here at Johns Hopkins I am involved with a team that is underway with their third piece of research looking to publish evidence on successful implementation strategies for this exact approach to PrEP access, which is available from pharmacies already in California.

I do hope that this submission will be received favourably by the committee, and would happily provide any further comment as required.

Ngā mihi nui

Andi

Andi Shirtcliffe (she/her)
Fulbright Scholar
Johns Hopkins Bloomberg Public Health & Dean's Scholar
MPH - Health Behaviour Change Candidate JHU
Graduate Implementation Science Policy Certificate Candidate JHU
Honorary Fellow (Otago) Pharmacy
Assoc. Prof (Auckland) hon, B.PHarm, PG Dip (Clin) Pharm, FPS
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Ko te oranga o te tangata, he hapori!
The wellbeing of the people is community!

E rere ana te mihi maioha ki a koe, e te rangatira. Tuku atu he mihi ka tika ki te mana whenua o te rohe ahakoa no hea koe.

Ko Kapowai te maunga, ko Waikare te awa, ko Ngātokimatawhaorua te waka. He uri ahau nō te Whare Tapu o Ngāpuhi. Ko Te Kapotai me Te Popoto ōku hapū, ko Benjamin Doyle tōku nei ingoa.

I am writing this submission to Medsafe in support of the reclassification of PrEP. I speak as a representative and MP of the Green Party of Aotearoa.

In caucus I am the spokesperson for Sexual & Reproductive Health and Takatāpui & Rainbow Communities. Prior to entering parliament I worked as Senior Māori Advisor at Burnett Foundation Aotearoa and a public health, education, and Māori rights researcher at both Waikato and Auckland Universities. I am Māori, I am a parent, I am non binary, I am takatāpui, and I live with a chronic autoimmune disease. It is my positionality and lived experience which informs this submission.

I believe that reclassifying PrEP as a pharmacist medicine is a crucial step to achieving the New Zealand HIV Action Plan goal to eliminate local transmission of HIV and end stigma by 2030. In fact, without this step, I do not think it possible to achieve elimination or equitable health outcomes for rainbow Māori populations.

Takatāpui - alongside Pacific peoples - experience worse sexual health outcomes than any other community in Aotearoa. A range of well documented and intersecting factors compound to disproportionately affect rainbow Māori communities, including the ongoing effects of colonisation, medical distrust, health education, poverty, geographic proximity to services, systemic and institutional racism, homophobia and transphobia, and stigma.

This experience of the healthcare system is acutely and uniquely felt by Takatāpui. In the context of STI and HIV prevention and treatment, where cultural expectations and shame combine with external barriers to access which mean that rainbow Māori are less likely to know about, test for, seek combined prevention methods, or undergo treatment for sexually transmitted infections. By reclassifying PrEP as a drug which is able to be supplied by pharmacists, a significant barrier to accessing a key HIV prevention method is removed not only for Māori, but all people at risk of exposure to HIV.

Without the necessary move of reclassification, the uptake of prep by at-risk populations will continue to slow down. Eventually, the most hard to reach communities will be unserviceable with the status quo prescribing approach, and this risks not only future outbreaks of HIV transmission but a widening in existing inequities between rainbow Māori and other population groups. It is in the best interests of all communities to avoid this scenario.

Once again, I wish to express my emphatic support of reclassifying PrEP as a pharmacist-prescribed drug in Aotearoa. We have a chance to become the first country to eliminate local transmission of HIV, and this is a pivotal step in achieving this ambitious and utterly necessary goal, for the benefit of all New Zealanders in generations to come.

Kia tau ai te mauri tū, te mauri tau, te mauri ora ki a koe.

Nā, Benjamin Doyle

Green Party MP, spokesperson for Sexual & Reproductive Health, Takatāpui & Rainbow Communities, ECE & Māori Education, ACC, and Internal Affairs.