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
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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*"

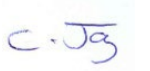
The value of the Owning my Gout (OMG) management programme has been independently evaluated by Synergia and demonstrated clinical success. The Community Pharmacy Gout Management Service Training has already been developed and is running in several Districts across the country. With a small amount of 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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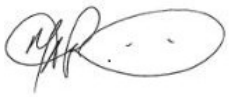
[3] HQSC https://www.hqsc.govt.nz/assets/Our-work/Improved-service-delivery/Patient-deterioration/Publications-resources/Presenter_slides_-_Equitable_approaches_to_gout_management_webinar_1_July_2020.pdf

[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

Immunisation Advisory Centre

13th January 2025

Secretary
Medsafe - Medicines Classification Committee
Ministry of Health
via email: committees@health.govt.nz

Kia ora koutou

Agenda of 73rd Meeting of the Medicines Classification Committee (MCC)

The Immunisation Advisory Centre (IMAC) welcomes the opportunity to comment on the agenda items for the 73rd meeting of the Medicines Classification Committee (MCC).

IMAC is a nationwide organisation that provides independent, evidence-based advice, education and training on the safe, effective and equitable delivery of immunisation services in New Zealand. In general, we support all work to improve and expand access to effective vaccinations with good safety profiles that protect New Zealanders from vaccine-preventable diseases.

We feel that addressing equity of access issues for National Immunisation Schedule (NIS) vaccines should be a primary focus of any vaccine reclassification and the safety and quality of vaccination services must also not be compromised by efforts to expand access.

Summary of our submission

IMAC does not support agenda item 6.3 (Travel Vaccines - Green Cross Health Limited)
We are not convinced that there are compelling equity or public health reasons to justify this change and the "health system" and "economic benefits" have been overstated by the submission. Travel vaccines target very specific diseases, with limited geographical indications for use and protection primarily aimed at the individual who travels to environments that have a different disease risk profile than in New Zealand. Additionally, we have strong concerns about the potential for this change to degrade the overall quality of general vaccination and health services that New Zealanders should receive when preparing for overseas travel. There are no clinical systems or reference tools in place to support pharmacists in offering these vaccines, which require highly specialised and up-to-date knowledge to inform their use.

Vaccination is only one component of travel medicine, and we are not confident that pharmacists have the capacity to provide other aspects of essential comprehensive travel advice and access to medications that are necessary to protect New Zealanders when travelling overseas. We believe that the safety and protection of New Zealanders travelling overseas would be better protected by accessing these vaccines as part of more holistic travel health advice.

IMAC is overall supportive of agenda item 6.4 (Recombinant Varicella Zoster Virus Vaccine - GSK New Zealand*)* which would enable SHINGRIX to be given by pharmacists to high-risk individuals who are 18 years of age and over. However, we do not think it is necessary to extend this reclassification to authorised vaccinators (AV) and this could create legal confusion around the AV scope.

We expand on these points more fully in our submission below.

IMAC does not support agenda item 6.3 (Travel Vaccines - Green Cross Health Limited)

There is no compelling case for proposed reclassification of travel vaccines

IMAC supports efforts to improve vaccine access, however we are not convinced that there are compelling equity or public health reasons to justify the proposed reclassification. These vaccines target specific diseases with limited geographical relevance and with minimal, or no importation risk to New Zealand. They are private-market vaccines, typically only offered following a very careful individually based risk assessment, rather than being funded for routine use. It is inappropriate that the application quotes the huge impact of the expanded programme of immunisation, delivering childhood vaccines globally in an application for travel vaccines to be delivered only to a specific subset of travellers from high income countries.

Green Cross claims reclassification of these travel vaccines could yield broader "economic benefits" and reduce healthcare burdens. However, such benefits are overstated. Vaccine-preventable diseases (VPDs) account for a very small proportion of illnesses in travellers. In a large cohort of American travellers to developing countries, diarrhoea was the most common health problem followed by upper respiratory tract symptoms, fever (mainly currently non-vaccine-preventable sources such as malaria), skin disorders, altitude sickness, motion sickness, accidents and injuries (1). Among 37,542 ill returned travellers seen at GeoSentinel Surveillance network clinics only 1.5% had VPDs (2). The commonest VPDs seen in travellers currently are COVID-19, influenza, dengue and animal bite with a risk of rabies (3). The application does not seek reclassification of vaccines for these commonest VPDs among travellers.

The reclassification claims the increased access to travel vaccines would reduce the spread of infection from person to person. VPDs that travellers have been clearly shown to spread include polio, meningococcal disease, measles and influenza (4). The reclassification will not impact any of these apart from polio which is a very low risk to our country.

Additionally, we remain unconvinced about the extent to which the current classification is resulting in unreasonable barriers to the access of these vaccines. The submission cites increasing travel amongst New Zealanders and the fact that there are 'only' 601 travel doctor health centres but provides no detailed evidence on geographical distribution of these centres, wait times, access challenges or sale volumes that could suggest suboptimal delivery of these vaccines. Such data is necessary to substantiate that access issues exist and that they are sufficiently serious to justify reclassification and the potential for this to reduce service quality.

We note that international supply shortages, for example for Hepatitis A, Typhoid, and Japanese Encephalitis vaccines, have been the primary barrier to access in recent years. Spreading available vaccine supply across a broader range of providers - who may administer vaccines unnecessarily - could exacerbate these shortages and in fact lead to a reduction in access for those who need them most.

Travel vaccines should be administered as part of a comprehensive travel consultation by fully trained clinicians with expertise in all aspects of travel medicine and access to all preventive measures.

Vaccine administration is only a small part of preparing individuals for overseas travel.

More significant and common health risks for New Zealand travellers include non-vaccine-preventable illnesses such as traveller's diarrhoea, altitude sickness, malaria, and dengue fever. We are not convinced that pharmacists operating at cross purposes in community settings have the right level of experience and time to provide all the other essential advice required to manage and minimise these broader travel risks. They do not have sufficient knowledge to assess and appreciate all aspects of a traveller's health and the impacts of underlying health conditions such as chronic conditions e.g. diabetes or immunocompromise on potential health risks during travel. Pharmacists also do not have the prescribing authority to supply critical travel medications, such as malaria and altitude sickness prophylaxis and would not be able to give other travel vaccines like rabies, Imojev or oral typhoid vaccine as these have not been included in this reclassification. An animal bite with a risk of rabies poses a greater risk to travellers than diseases like Hepatitis B or Typhoid.

This feels a piecemeal partialist approach. A traveller who visits a pharmacist may believe they are fully prepared for their travel and not be aware that rabies preexposure vaccination would offer them important protection. The proposed reclassification would result in fragmentation of services, with the risk that those accessing travel services from pharmacies would miss out on essential medications and advice or alternatively would have to pay twice to access these from another location such as their general practice or a travel clinic.

Insufficient clinical support for pharmacists to administer travel vaccines would degrade service quality

There are no services in place to provide the necessary clinical support that pharmacists need to offer these vaccines in the community. Travel medicine is a complex and dynamic field. Travel vaccines are expensive and the decision to offer a travel vaccine must involve a carefully conducted individual based risk assessment, which includes reviews of travel itineraries, applying up-to-date knowledge of the diseases and risks in specified geographical locations and consideration of any high-risk conditions. Vaccinators and doctors who work in general practices and dedicated travel care settings have the benefit of collegial and clinical support at hand, whereas pharmacists will be making these decisions in isolation.

In the UK, US and Canada, there are well developed support systems in place for travel vaccination services, these include clinical reference tools like national travel medicine guidelines and dedicated phone and email advisory services. New Zealand does not offer comparable support services. IMAC's clinical advisory service (including the 0800 IMMUNE service) are not currently funded to provide travel vaccine advice, and the New Zealand Immunisation Handbook covers only three of the proposed vaccines (Polio, Hepatitis A, and Hepatitis B) with very brief recommendations for their travel related use. The absence of ongoing clinical support has the potential to negatively impact on the quality of travel vaccination services provided in pharmacy, with practical (i.e. consumers paying for vaccines that they don't need) as well are more serious implications for individuals (under vaccination, receiving vaccines that are contraindicated, incorrect management of adverse vaccine events).

Yellow fever vaccines are subject to International Health Regulations and utilisation of existing MoH pathways for the provision of this vaccine would better ensure consistency with these regulations

Rather than pursuing reclassification for this vaccine, we believe it would be more appropriate for pharmacist vaccinators to seek authorisation as Yellow Fever vaccinators through the existing MoH pathways which are consistent with International Health Regulations.

This would involve an amendment to the current policy to allow pharmacists to apply under this pathway and would achieve the same objective as reclassification by enabling them to administer the vaccine without a prescription. It would have the added benefit of ensuring pharmacists meet the same level of competence and meet the ongoing training and education and service provider requirements as other authorised Yellow Fever vaccinators.

IMAC is supportive of agenda item 6.4 (Recombinant Varicella Zoster Virus Vaccine - GSK New Zealand*)*

IMAC supports agenda item 6.4 to enable SHINGRIX to be given by pharmacists and authorised vaccinators to high-risk individuals who are 18 years of age and over

This is an essential vaccine for high-risk immunocompromised peoples across all age groups. Pharmacists are well experienced and trained in its administration including screening for funded and non-funded indications. They have access to clinical support via IMAC clinical advisory services and the Immunisation Handbook to guide them in its use and the management of adverse events. For these reasons we agree that pharmacist access should not be unduly restricted to those over 50 years and over and feel confident that this will not degrade the quality and safety of vaccine services. Notwithstanding our general support we wish to make the following comments regarding its effective and safe use, which have not been discussed in GSK's submission.

- **Effective screening by pharmacies is essential to ensure its use is justified in all instances**
  SHINGRIX is an expensive private market vaccine, costing between $500-$600 to the consumer. While SHINGRIX has been extensively studied in individuals aged 50 and older, and in immunocompromised groups from 18+ over, there is limited data available to support its use in healthy adults under 50. Table 25.1 of the Immunisation Handbook provides the most effective clinical tool that should be used by pharmacists to identify those individuals 18+ who are high risk and recommended to receive this vaccine. Unnecessary vaccination may lead to inappropriate vaccination at the expense to the individual.

- **Timing considerations can impact its safe and effective use**
  There are a number of specific timing considerations with regard to the administration of this vaccine that have not been mentioned in GSK's submission, but which have relevance for both its safe and effective use and may necessitate specialist input prior to vaccine administration in community settings like pharmacies.
  - Those with pre-existing ocular zoster should have disease quiescence for at least 12 months prior to receipt of SHINGRIX. Caution is required in these individuals because there have been rare reports of flares of pre-existing inflammatory eye disease including ocular herpes zoster following SHINGRIX administration.
  - Those who are severely immunocompromised may respond sub-optimally to the vaccine and timing of vaccination should be informed by discussions with relevant specialists to factor in current and future treatment plans.
  - Duration of protection from SHINGRIX beyond 10 years is unknown and the need for booster doses of SHINGRIX has not yet been established. Risk of herpes zoster increases with age. Younger people who are immunocompromised may benefit from discussing this with their specialist first to assess the relative benefits of waiting versus receiving immediately.

Including authorised vaccinators (AV) in this reclassification is unnecessary and could create legal uncertainty regarding the AV scope of practice

Including authorised vaccinators in this reclassification is unnecessary and could create legal ambiguity around the AV scope of practice. Currently, AVs can already administer SHINGRIX without a prescription to high-risk individuals aged 18+ who meet the high-risk funding criteria. The effect of the proposed reclassification would enable them to also administer SHINGRIX without a prescription to individuals aged 18+ who are not funded but are recommended to receive the vaccine.

There is currently no other vaccine on the National Immunisation Schedule (NIS) for which AVs are permitted to administer unfunded doses without reliance on a prescription or standing order. Creating an exception for SHINGRIX risks introducing legal confusion around the AV scope and is likely to be unnecessary given that AVs tend to be nurses with access to standing orders for this reason and clinicians who are able to provide prescriptions as required.

Conclusion

Reclassification of vaccines can be an effective strategy for improving access to vaccines in New Zealand particularly where there are compelling equity of access and broader community health justifications. Any decision must be carefully balanced against the need to also preserve the quality and safety of vaccination services. We are not convinced that there is a case for reclassifying the proposed travel vaccines. We believe reclassification could compromise the quality and safety of travel health services. We are supportive of the proposed reclassification of SHINGRIX, a vaccine that Pharmacists have experience in and access to appropriate clinical support to screen for and administer.

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2. Boggilda AK, Castelli F, Gautret P, Torresi J, von Sonnenburg F et al. Vaccine preventable diseases in returned international travelers: Results from the GeoSentinel Surveillance Network. Vaccine 2010 Vol 28, Issue 46, 7389-7395
3. Steffen R, Chen LH and Leggat PA. Travel vaccines—priorities determined by incidence and impact. JTM 2023 1-14.
4. Gautret P, Botelho-Nevers E, Brouqui P and Parola P. The spread of vaccine-preventable diseases by international travellers: a public-health concern. Clinical Microbiology and Infection, 2012 Vol 18 Suppl 5.

Yours sincerely

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New Zealand Society of Travel Medicine Incorporated
13 January 2025

To Medicines Classification Committee (MCC)
By email: committees@health.govt.nz

Kia ora koutou,

The New Zealand Society of Travel Medicine Incorporated (NZSTM) would like to thank the MCC for the opportunity to comment on the Agenda for the 73rd meeting of the MCC to be held shortly.

The Society was first formed in 1995 and has a current membership of 1560, which is comprised of doctors, nurses and a small number of pharmacists. Our kaupapa is to support the provision of excellence in travel medicine in Aotearoa/New Zealand and to provide educational support to health care professionals involved with the provision of travel medicine in Aotearoa/New Zealand.

Submission

The NZSTM wishes to comment on Agenda item 6.3 Travel vaccines. This submission from Green Cross Health Limited proposes the reclassification of 8 vaccines indicated for international travel from prescription only to allow:

- Authorised vaccinators or pharmacist vaccinators to administer 7 of these without a prescription (i.e. hepatitis A, hepatitis B, Japanese encephalitis, poliomyelitis and typhoid vaccines and combination vaccines hepatitis A & B and hepatitis A & typhoid), provided they:
  - have successfully completed the Vaccinator Foundation Course; and
  - hold the relevant travel medicine qualifications from an approved facility; and
  - comply with the immunisation standards of the Ministry of Health.

And

- Authorised pharmacist vaccinators to administer yellow fe"'.er (VF) vaccine without a prescription, provided they:
  - have successfully completed the Vaccinator Foundation Course; and
  - are authorised as a VF vaccinator in accordance with regulation 44A of the Medicines Regulations 1984.[1]

[1] *Any medical practitioner or other person who is authorised by the Director-General 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.* (www.legislation.govt.nz)

General Comments

The Society is disappointed to see a further submission to reclassify travel vaccines so shortly after a similar Ministry of Health submission was rejected by the 69th meeting of the MCC in October 2022. Especially as, again, this submission has been made without consultation with health professionals currently providing travel health services in Aotearoa/New Zealand and prior to an adequate framework of competencies, policies and resources being in place before any such reclassification be considered.

Travel medicine is a dynamic and specialised field and delivery of pretravel services requires adequate time, expertise and resources to deliver the appropriate standard of care. The Society's view is that regardless of whether a doctor, nurse practitioner, nurse, or pharmacist delivers travel vaccines, administration should be:

- Within the context of a comprehensive pretravel consultation.
- By a healthcare professional suitably trained and up to date in travel medicine.
- By a healthcare professional trained and authorised in vaccine administration.

Training

Essential training to deliver pretravel health services should cover pretravel risk assessment, vaccine preventable diseases, prevention of vector-borne diseases, risk management, information on and the prescribing of travel vaccines and medications, activity-specific advice, management of pre-existing conditions during travel, access and use of travel health resources, and how to communicate tailored recommendations to travellers to help them make informed choices.

The submission proposes that authorised vaccinators and pharmacist vaccinators be able to administer the suggested travel vaccines without a prescription if they "have successfully completed the Vaccinator Foundation Course (VFC) and hold the relevant travel medicine qualifications from an approved facility." However, the VFC through the Immunisation Advisory Centre (IMAC) was developed for vaccinators, including pharmacist vaccinators, administering vaccines from the national immunisation schedule (NIS) and other authorised programmes (such as COVID-19 vaccines), provides neither specific training nor information on travel medicine or travel vaccines, and the trainers are not qualified in travel medicine. While it is encouraging that the submission does recognise therefore the need for travel medicine qualifications, it does not make clear the minimum standards these qualifications should be, nor the need to regulate for standards, and in fact gives conflicting information as to what it considers appropriate.

The submission refers to 4 options, namely the:

- 'Introduction to Travel Health' IMAC course
- Postgraduate Certificate in Travel Medicine (PGCertTravMed)
- Postgraduate Diploma in Travel Medicine (PGDipTravMed)
- Masters of Travel Medicine (MTravMed)

The latter 3 involve distance learning through the University of Otago. The PGCertTravMed consists of 2 compulsory papers (introductory and applied concepts of travel medicine) over 1 semester of full-time study or equivalent in part-time study and the PGDipTravMed 2 further papers (including a compulsory paper on tropical infectious disease) over 1 year of full-time study or equivalent in part-time study. (Most would consider the MTravMed an unlikely training option for this submission.)

The submission proposes (under no.23, 2nd page) that "at least one of the above qualifications be completed by the pharmacist vaccinator to ensure that the appropriate knowledge is acquired before administering travel vaccines." But suggests (same page) "For a vaccinating pharmacist wanting to deliver basic travel health consultation for non-complex travellers ... they can complete the Introduction to Travel Health training course available through IMAC." However, defining 'non-complex travellers' is not necessarily straight forward. For example, a traveller going on a short trip to Bali may be considered 'non-complex', but this does not mean that the pretravel consult should not include rabies advice (as the risk of an animal bite is substantial in Bali), or the need to refer the traveller if they are pregnant, immunocompromised or a child (as these individuals are recognised as high-risk travellers). Importantly, this 8-hour course is not intended as a comprehensive, standalone training course, and IMAC itself notes that the course does not replace the need for those who will prescribe travel medicine to complete post-graduate education (IMAC, 2024). So, this short course should not be considered adequate training for a pharmacist vaccinator to administer travel vaccines without a prescription to any traveller.

The submission further states (same page) "For pharmacists that would like to further their education, and understand the complexities of travel medicine, there are currently three options available through the University of Otago" and in several other instances refers to encouraging such additional training in pharmacists. But then goes on to state (under no.24, 2nd page) "It will be mandatory requirement for pharmacist vaccinators to complete a postgraduate study in travel medicine before administering travel vaccines in this submission." The Society believes that training in travel medicine should be required by all travel health providers, not just encouraged. Furthermore, travel health providers need not only initial training, but also need to undertake appropriate continuing educational activities to keep up to date - as travel medicine is a rapidly evolving specialty with changing disease epidemiology, emerging diseases and ongoing research.

Comparison of Vaccine Classification/Pharmacist Vaccinators in Other Countries

Green Cross Health report on pharmacist vaccinators and the classification status of vaccines in Australia, UK, US and Canada (under no.9) to illustrate the expansion of pharmacist scope of practice in these countries and justify reclassifying travel vaccines in NZ to harmonise with these overseas jurisdictions.

In Australia, the scope of pharmacist vaccinators is legislated by the 8 individual states and varies in terms of vaccines and age restrictions. The submission states (under no.9, 5th page) that "Hepatitis A, Hepatitis B, Poliomyelitis and Typhoid vaccines are part of the National Immunisation Programme (NIP) and can be administered by pharmacists across Australia without a prescription". However, this is not correct (and the table included refers to the Australian Capital Territory only). In the Australian NIP, hepatitis A vaccine is only scheduled for Aboriginal and Torres Strait Islander children in 4 states and typhoid vaccine is not included for any group (Dept Health & Aged Care, 2024). A pharmacist vaccinator can administer unfunded hepatitis A vaccine in 6 states and typhoid vaccine in 4 states, but a prescription from a medical or nurse practitioner may be required in accordance with jurisdictional standards (NCIRS, 2024). NSW also requires a pharmacist vaccinator refer high-risk travellers to a GP or travel medicine practitioner and lists the medical conditions and types of travellers that require referral (NSW Government, 2024). This list is comprehensive and means only a small subset of travellers is in fact considered suitable to be seen solely by a pharmacist. The submission further states (next page) that "pharmacist vaccinators in New South Wales, Queensland, South Australia and Victoria can also administer Japanese encephalitis vaccine without a prescription". However, again this is misleading as this is in response to recent local outbreaks of the disease, not for overseas travel.

In the UK, all vaccines are classified as prescription only medicines (POM). Pharmacists cannot supply or administer them unless they are independent prescribers, working under national immunisation protocols, or working under a Patient Specific Direction (PSD) or a Patient Group Direction (PGD) (Evans, 2018). The Royal College of Physicians and Surgeons of Glasgow (RCPSG) note PGDs have greatly expanded the range of immunisation programmes in the UK (including those for travel vaccines) but these written standing orders take a significant amount of time and resource to develop and implement and users need to be proficient working with them (Chiodini et al, 2020). The submission does acknowledge (under no.9, 4th page) that similar to the UK standing orders could provide a pathway here to deliver the vaccines in their submission to improve access for travellers. However, they then imply that reclassifying travel vaccines would be justified here as the training for UK pharmacist vaccinators to deliver travel vaccines is similar to the Otago postgraduate certificate in travel medicine. However, this is misleading as UK pharmacists administering travel vaccines that have been prescribed or under standing orders is not equivalent to pharmacists administering travel vaccines without a prescription.

In North America, as with Australia, the scope of pharmacist vaccinators is regulated by individual states or provinces. In the 50 US states, most pharmacists require a prescription or a collaborative practice agreement (CPA) with a physician to administer both routine and travel vaccines and can only administer routine vaccines independently in 15 states and travel vaccines (with travel health training) in 8 states (Hurley et al, 2019; NASPA, 2024). In Canada, pharmacists can administer vaccines in 11 of the 13 provinces. However, for Schedule 1 drugs (which includes travel vaccines) pharmacists cannot administer in 7 provinces, require a CPA to administer in 5 provinces, and can only administer independently (with additional training) in Alberta (Canadian Pharmacists Association, 2023).

Therefore it is misleading to suggest reclassifying travel vaccines will harmonise scope of pharmacist vaccinating in NZ to that overseas. Harmonisation is in fact not possible due to the variation within and among the countries reviewed. In NZ, pharmacist vaccinators can currently supply/administer 9 vaccines without a prescription - namely influenza, COVID-19, meningococcal B, meningococcal ACWY, HPV, varicella zoster, Tdap, and MMR vaccine (with various age restrictions) (IMAC, 2024), in addition to the oral cholera vaccine (Dukoral) following its previous reclassification (MCC, 2019). The Society acknowledges that pharmacists are key providers of healthcare in NZ, have significantly extended the vaccinator pool and are readily accessible to the public. It is therefore commendable if pharmacy groups wish to extend pharmacist scope of practice and improve equity and access to vaccines in NZ. However, the Society believes they can best do this by encouraging pharmacist

vaccinators to become authorised to vaccinate all age groups (via the extended skills training offered by IMAC since March 2024) and focusing their efforts on getting the other NIS vaccines reclassified in 2022 (i.e. haemophilus influenzae, hepatitis B, pneumococcal, poliomyelitis and rotavirus vaccines) included in pharmacist vaccinator training. Furthermore, for those pharmacists interested in travel medicine, overseas experience points towards using standing orders- not the reclassification of travel vaccines.

Travel Medicine Resources

Much of the information in this submission is from the vaccines' datasheets and general immunisation guidelines in the Immunisation Handbook. However, travel health providers need to utilise and know where to access much more than this information.

In NZ there are currently no national travel medicine guidelines. The focus of the Immunisation Handbook and IMAC is on NIS vaccines and plans to include guidelines for travel vaccines are in their infancy, with only brief information on travel indications for hepatitis A, hepatitis B, polio and meningitis vaccines in the handbook. There is no national phone/email support for travel health providers here, who rely on support from colleagues in specialised travel clinics or primary care or, if members, can post clinical queries to the International Society of Travel Medicine (ISTM) mailing list.

In contrast, the UK, US & Canada all have national travel medicine guidelines-via the Green Book and National Travel Health Network and Centre (NaTHNaC) in the UK, the Yellow Book and Centers for Disease Control and Prevention (CDC) in the US, and Public Health Agency of Canada (PHAC) and Committee to Advise on Tropical Medicine and Travel (CATMAT) in Canada. For travel health providers in the UK and US there is also national phone/email support. In Australia, the Australian Immunisation Handbook does cover all of the travel vaccines, and the Australasian College of Tropical Medicine (ACTM) is starting to develop travel medicine guidelines for travel health providers.

Standards of Practice

Travel health services are unregulated in most countries and provided in a range of settings including specialist travel clinics, primary care, pharmacies and other settings. However, in many countries inconsistencies have been noted in the standards of training, competency and auditing by the various regulatory bodies ofthe different healthcare professionals involved. Increasingly it has therefore been recognised there is a need for a framework to define minimum standards of practice in this area.

The RCPSG published such a framework In 2020, which details standards of practice and training in travel medicine and can be used to identify a travel health provider's current level of practice and further requirements to support their continuing professional development (Chiodini et al, 2020). Recently Travel Health Nurses of Australia and New Zealand (THNANZ) also developed a competency framework, adapted from Royal College of Nursing competencies, to guide the training and upskilling of nurses who wish to work in travel medicine (THNANZ, 2021). This has been endorsed by the ACTM and NZSTM.

No such competency framework is mentioned in this submission regarding pharmacist vaccinators. In fact, the submission only states (under no.24) that pharmacists will comply with immunisation standards of the Ministry of Health and be well-informed by the various pharmaceutical organisations (including Green Cross Health). This is concerning as these organisations have no experience in travel medicine and would appear, judging from this submission, to have little understanding of what makes up a comprehensive pretravel health service. However, the Society believes a guidance/framework defining minimum standards for any provider of travel health services needs to be in place before consideration of any regulatory change to travel vaccines.

Justification for Reclassifying Travel Vaccines

The submission quotes figures (under no.11) from Healthpoint to justify the need for further access to travel vaccines, especially in the South Island. However, Healthpoint is not an accurate source for this type of information - illustrated by a search for 'travel vaccinations' resulting in a similar number of listings by both GPs/A&M clinics (526) *and* pharmacies (494) (Healthpoint, 2024) - nor does this information consider population density. While it is recognised that improving the vaccinator pool

here is necessary to improve equity and accessibility to **NIS** vaccines, the Society is not aware of any reliable data that indicate this applies to travel vaccines.

The submitters state (under no.11, 2nd page) "Vaccines in this submission have been included by considering the travel habits of Kiwis and their likelihood of being exposed to specific diseases in various countries." However, their choice bears little relationship to the data they present (including chart 1). The latter and accompanying information show that in the 12 months to February 2024, of 2.8 million trips overseas, 40% (1.1 million visits) were to Australia and the other countries making up the top 5 were Fiji, the US, China and the UK, with Asia dominating the remainder of the top 20 destinations (Infometrics, 2024). Travellers would not be exposed to yellow fever in any of these countries. The risk of Japanese encephalitis in China and the rest of Asia varies with type of trip and season and many would decide against vaccination (due to cost) - whereas the potential for rabies exposures in these countries is significant (but the submission makes no mention of rabies vaccine). Similarly the risk of typhoid is considered negligible to very low in the top 20 countries listed, apart from India and Samoa - with recent data in travellers reporting an incidence rate of <1/million for North-East Asia (including China), the Americas and Europe and <1/100,000 for Southeast Asia (Forster & Leder, 2021). Furthermore, most of the typhoid reported in travellers to South Asia and Oceania is in the known high-risk group of VFR travellers (i.e. those visiting friends and relatives), not tourists. Finally, hepatitis A vaccine has long been considered a primary travel vaccine. However, the risk of this disease in travellers has also decreased over time, primarily through improvement in hygiene and sanitation and access to clean water in endemic countries. Hence, even for hepatitis A vaccine, a risk assessment is indicated in travellers rather than wholesale administration.

To support their submission, Green Cross Health refer to the communal benefits of immunisation (under no.22) quoting global immunisation efforts have saved 154 million lives and state "The increased access to travel vaccines is expected to do the same, where having more people immunised will directly reduce the spread of infection from person to person." However, while this figure is indeed impressive, it is from a study (Shattock et al, 2024) quantifying the global health impact over 50 years of national immunisation programmes - not travel vaccines. Vaccines in travellers are primarily for individual benefit (hence why an individual benefit vs harm assessment needs to be made) not for communal benefit, and hence are unfunded and not NIS vaccines. The submission goes on further to refer to herd immunity and states (under no.23) "The reclassification of vaccines proposed in this submission will fundamentally improve access to travellers, allowing for a boost in immunity against preventable diseases not just for individuals but for their communities upon return." However, herd immunity has no bearing on Japanese encephalitis and yellow fever vaccination in travellers - these viruses are transmitted by mosquitoes, which are not present in NZ, so there is no communal benefit as no risk here. Also our geographical isolation, temperate climate and standard of living mean some vaccine-preventable diseases do not pose the same risk to public health here as they may in other countries. The submitters broad generalisations and obvious lack of even basic understanding of travel medicine therefore go far from justifying the proposal. Instead they illustrate the potential for harm if providers with this type of knowledge were permitted to administer travel vaccines without a prescription.

Standing Orders

The submission makes little mention of standing orders. This process was developed to improve patients' timely access to medicines and has been legislated for some time here under the Medicines (Standing Order) Regulations 2002. Nurse vaccinators are therefore already able to administer travel vaccines under standing orders, and are increasingly doing so, following the guidance set out by the Ministry of Health (2016). This details the responsibilities of both prescriber and health professional authorised to administer the medicine, competency of the person administering, necessary contents of a standing order and countersigning/audit and review requirements.

The Society therefore suggests that if access to travel vaccines is seen as an issue in a particular region, access could be improved if submitters such as Green Cross Health concentrate on encouraging pharmacists to work with local travel medicine prescribers to develop standing orders, rather than try and circumvent this proven and regulated process by attempts to reclassify travel vaccines.

Consultation & Collaboration with Travel Health Providers

The submission makes several generalisations about working with GP colleagues and other health professionals to provide travel health services to achieve collaborative care for patients. It further states (under no.24, 2nd page) that "Professional bodies have been consulted and notified of this submission". However, this is untrue - there was no consultation/notification by the submitters to any of the professional bodies/groups involved in travel medicine/health here, including the NZSTM, RNZCGP, Otago postgraduate travel medicine studies and Worldwise, nor IMAC (the current trainers of pharmacist vaccinators). This total lack of engagement with travel health providers only leaves those working in the field to conclude that pharmacists view travel vaccines primarily as a financial opportunity and the submission is essentially business driven. The Society also notes the obvious conflict of interest with one of the pharmacists on the MCC working for Green Cross Health as a business development manager.

Proposed Vaccines

The Society wishes to divide the vaccines listed in the Green Cross Health submission into 3 categories for discussion purposes:

1. Hepatitis A, hepatis Band poliomyelitis vaccines
2. Typhoid and Japanese encephalitis vaccines
3. Yellow fever vaccine

1. Hepatitis A, Hepatitis B and Poliomyelitis Vaccines

These 3 vaccines were reclassified at the 69th meeting of the MCC to include administration without a prescription -with hepatitis Band poliomyelitis vaccines considered 'non-travel' vaccines (as primarily used in the NIS) and hepatitis A vaccine noted to have indications for travel and non-travel purposes in NZ and the vaccine reclassified for the latter use (MCC, 2022). Health New Zealand (2024) is starting to develop immunisation standards to include travel indications (with traveller recommendations for hepatitis A, hepatitis Band polio vaccines in the handbook chapters 8, 9 and 18, respectively), but these vaccines are not included in those currently covered by !MAC training for pharmacist vaccinators. Also differentiating vaccines into non-travel and travel vaccines is not that useful in travellers. Rather a comprehensive pretravel consultation should determine which 'routine, recommended and required vaccines' the traveller needs (based on an assessment of their vaccination history and trip itinerary and risks) rather than consider an arbitrary subset of 'travel' vaccines.

The submission (under no.6, 2nd page) also proposes, if these vaccines were reclassified, to limit administration by pharmacist vaccinators for hepatitis B vaccine to children 10 years and for the other vaccines in the submission to children 3 years (except Jespect 18 years). However, if these vaccines are indicated for a child traveller below these age cutoffs, limiting access due to the vaccinator's scope rather than the vaccine's licensing (or in the case of Jespect, off-label use) is not consistent with best practice.

The submission also seeks reclassification of 2 combination vaccines, hepatitis A & typhoid vaccine (Vivaxim) and hepatitis A & hepatitis B vaccine (Twinrix). However, Vivaxim is no longer available (Sanofi notified discontinuation in February 2024). The Society also believes that Twinrix is of limited use in Kiwi travellers. As if both hepatitis A and Bare indicated it is more cost effective for an adult traveller to receive a single monovalent hepatitis A vaccine and a rapid 3-dose hepatitis B course (than rapid Twinrix). Similarly, Twinrix jnr is rarely indicated in children who are immune to hepatitis B if had their childhood immunisations (and, if not, can get hepatitis B via a funded catch-up programme).

2. Typhoid and Japanese encephalitis vaccines

Off-label indications and/or varying route of administration are more commonly used with vaccines for travel than routine vaccines. The Green Cross Health submission does not address off-label use, use of Section 29 vaccines or vaccines with different routes of administration, but this particularly applies to the Japanese encephalitis and typhoid vaccines listed in their submission. Off-label use of vaccines improves availability to the traveller, with use by practitioners here based on overseas evidence and guidelines.

Jespect is licensed in NZ for those aged 18 years on a DO & 28 schedule but can be given off-label to children aged 2 months and for adults by accelerated schedule (DO & 7) if travel is imminent. Imojev is the other Japanese encephalitis vaccine available in NZ under Section 29 (of the Medicines Act 1981), which requires 1 dose and can be given to children aged 9 months. Therefore, limiting a traveller's options to one vaccine and not including off-label use is not giving them choice of the available vaccines for this disease risk.

Similarly, this submission lists Typhim Vi alone for reclassification as the typhoid vaccine. However, oral typhoid vaccine (Vivotif) is also available in NZ. Vivotif is recommended over Typhim Vi if a traveller has had several of the latter in the past (due to the reduced efficacy recognised with multiple doses of the polysaccharide vaccine) and has the advantage of providing longer cover (with an off-label 4-dose schedule). So, again, limiting a traveller's options to one vaccine for protection against the disease due to the vaccinator's scope is not consistent with best practice.

3. Yellow fever vaccine

It is acknowledged that there are gaps in accessing YF vaccine in some parts of NZ and this prompted nurses being considered to administer YF without a prescription (in accordance with the Medicines Regulations 1984). However, this policy change only came about after the hard work of experienced travel nurses and required extensive consultation, assessment through a pilot programme, and careful determination of the necessary level of travel health experience required. Subsequently, more nurses are undertaking and completing this process and becoming authorised YF vaccinators.

The Society is therefore surprised at the inclusion of YF vaccine in this submission. The submitters state (under no.22, 2nd page) "The risks with Yellow Fever vaccine are a little more complex than the other vaccines listed in this submission" and imply several times this is solely because it is a live vaccine and has a number of contraindications. However, those practising travel medicine are well aware that knowledge about YF needs to include much more than this and these statements demonstrate the submitters lack of understanding of the complexity involved in prescribing YF vaccine.

Importantly also the proposal for pharmacists to administer YF vaccine without a prescription does not comply with the International Health Regulations (IHR) regarding YF vaccination and certification (WHO, 2016) and the New Zealand YF Policy under the IHR, which regulates YF vaccinators and YF vaccination centres here (Health New Zealand, 2017). This policy dictates who can be authorised as a YF vaccinator, their required training and experience, and conditions of YF vaccinating centres. Stipulations include:

- Initial YF authorisation requires the YF vaccinator be a NZ registered:
  - medical practitioner with general scope of practice, or
  - nurse practitioner with general scope of practice and an authorised prescriber, or
  - nurse with vaccinator authorisation for all age groups, with 5 years postgraduate experience (including 3 years in travel health), and who is currently working in travel health.
- Authorisation requires evidence of an approved postgraduate qualification in travel medicine.
- All YF vaccinators are only able to be fully authorised if they are operating from an authorised YF vaccinating centre, and vice versa.
- YF vaccination centre authorisation is restricted to individual registered medical centres that hold current Cold Chain Accreditation (CCA) and is not transferable to another medical centre.
- Only YF vaccination centres with one or more YF vaccinators may order YF vaccine from a supplier.

Therefore, pharmacists are not included in those eligible to be authorised YF vaccinators in NZ and, as can be seen from the stipulations above, pharmacists are not able to fulfill the same nurse criteria to administer YF vaccine without a prescription. Namely, they do not have the required experience in travel health to become authorised YF vaccinators and are not operating from authorised YF vaccinating centres. Furthermore, the latter means a pharmacist could not provide the International Certificate of Vaccination or Prophylaxis (ICVP), which travellers require after receiving the YF vaccine to enter into certain countries under the IHR.

Similar national requirements for YF vaccinators and YF vaccinating centres exist in Australia and the UK, and vaccinators in general practice and pharmacy are not authorised to administer YF vaccine in either country.

Other Considerations

In recent years there have been global shortages of travel vaccines, including hepatitis A, typhoid, rabies and yellow fever vaccines. Thus, if travel vaccines were reclassified from prescription only this is likely to lead to spread of supply, which is already often limited, across a wide range of providers and not necessarily improve access to those who most need them.

Green Cross Health has not considered rabies vaccines in their list of travel vaccines. However, the risk of an animal bite is substantial while travelling in rabies-endemic countries -with recent experts estimating a risk of0.5% per month of travel (Steffen et al, 2023). Rabies vaccines are commonly given in specialised travel clinics and some primary care practices by intradermal (ID) administration, which requires specific training. This significantly reduces cost to the traveller, especially families, and improves availability as multiple doses can be given from an equivalent IM dose. Furthermore, vaccine recommendations for rabies are complex and require a good understanding of the options (and depending on the current vaccine/s available in NZ, may have different licensing regarding number of doses and whether ID administration is off-label or not). It is also essential the traveller is advised about animal avoidance and post-exposure prophylaxis, including its importance, use of rabies immunoglobulin and the different schedules (depending on whether had pre-exposure prophylaxis). Thus, pharmacist vaccinators being able to administer a subset of travel vaccines without a prescription fragments pretravel care and, in the case of rabies, the requisite pretravel rabies advice may not be given, or the traveller would need to be referred elsewhere for vaccination. The latter would also be the case if meningitis vaccination was indicated for travel, including to the meningitis belt in sub-Saharan Africa or for the Haj.

Many travellers also require prescription medicines (e.g., antimalarial, antibiotic, acetazolamide, as indicated for their trip), which are outside the scope of pharmacist vaccinators. This would necessitate seeing another provider and is therefore not actually improving access to travellers. Such doubling up of consult costs to get both vaccines and other indicated medications also risks travel medicine being viewed by the travelling public in a less than positive light.

Other potential issues include pharmacists having difficulty maintaining competency as giving the various travel vaccines on an infrequent basis and needing to keep up with vaccine recommendations, which are subject sometimes to sudden change due to changing disease epidemiology. Further, pharmacists may not recognise when to refer high-risk travellers (e.g. travellers who are pregnant, children, elderly, immunocompromised, travelling long-term or to visit friends and relatives) to more experienced providers to cover their additional health needs. Finally, the Society has received some anecdotal reports from members about the vaccinating standards of some pharmacists. Such instances have resulted in some health practitioners feeling less confident that the pharmacy sector is adhering to the required immunisation standards expected of all vaccinators and voicing concerns that this situation will only worsen if pharmacists are allowed to administer travel vaccines without appropriate training, competency and audit processes in place.

Summary

The Society acknowledges and supports measures in Aotearoa/New Zealand to increase the vaccinator pool to improve coverage and inequities in access to scheduled vaccines (and control local outbreaks). However, there is no data to suggest that access to travel vaccines here is an equity issue; these are not funded, travel for most is by choice, and a traveller's decision to get vaccines (even if indicated and available) is often influenced by their budget.

Overall the Society is disturbed by this 35-page submission, which offers little justification for travel vaccines being reclassified and contains much cherry picking, misinformation and conflicting or false information - some of which is noted in our comments. This illustrates the lack of understanding of travel medicine by the submitters, who appear to take the simplistic view that all vaccines are the same and can be approached in the same manner. However, the context in which travel vaccines are given is very different from routine vaccines. Travellers are <u>not</u> a homogenous predefined group; vaccines for travel are <u>not</u> the same as NIS vaccines and require an individual benefit-risk assessment

prior to administration, which requires time, expertise and updated knowledge (not just information from datasheets); and a pretravel health service is not just a vaccination service.

The submission often refers to pharmacists providing a vaccination service (and offering some companion sales), and only occasionally alludes to giving pretravel advice. However, in a comprehensive pretravel consultation the travel health provider needs to determine the traveller's itinerary, activities, risk profile and risk tolerance, and apply current knowledge of the diseases and risks the traveller can expect to encounter to give appropriate advice on how they can manage these risks (including advice for the many risks not covered by vaccines). Vaccinations therefore make up only part of a pretravel consult, and this may often be a small part. Failure to understand this is likely to result in inadequate pretravel advice being given, in addition to possible failure to appropriately vaccinate, or to inappropriately vaccinate. Therefore, a 'jab and charge' service is not sufficient to meet the health needs of travellers and simply fuels the public and poorly informed practitioners' understanding that travel medicine and travel health is only about vaccination. This proposal would also put significant pressure on nurses and pharmacists to administer travel vaccines without support and oversight in practices/pharmacies that see these vaccines solely as another source of income, especially if appropriate travel medicine training and ongoing competency are not mandated.

As the world recovers from the COVID-19 pandemic, return of travel has seen the need for pretravel care return and rise. So Aotearoa/New Zealand is in an ideal position to learn from the experience of providers overseas and recognise the importance of setting standards around provision of pretravel health services, regardless of which professional group delivers the care. For that reason, this submission to reclassify travel vaccines represents a huge step backwards and we believe has significant potential for harm to both travellers and vaccinators.

Therefore the Society is strongly opposed to the reclassification proposed. It welcomes pharmacists extending their scope of practice into travel health. However, it urges pharmacist groups focus their efforts towards this goal by engaging and collaborating with local travel health providers to determine how this can best be achieved, rather than undermining existing expertise and practice of travel medicine through repeat attempts to merely reclassify vaccines.

Naku noa, na

Lisa Scotland
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Submission in Support of the Proposal for the Classification of Travel Vaccines

I am writing in support of the proposed classification for the following travel vaccines, as outlined in the attached submission:

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

The proposal suggests the classification of these vaccines as follows:

- **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 or a Medical Oficer 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.*
- **All other vaccines:** *except when administered by vaccinators or registered pharmacists, who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health), hold the relevant travel medicine qualifications from an approved facility and who comply with the immunisation standards of the Ministry of Health (but excluding vaccinators who have completed the Provisional Vaccinator Foundation Course.*

I understand that the Committee, in a previous judgment (MINUTES FOR THE 69th MEETING OF THE MEDICINES CLASSIFICATION COMMITTEE HELD IN WELLINGTON ON 25 OCTOBER 2022 AT 9:32 AM), noted that the existing requirements for training and authorisation to use these vaccines would apply regardless of classification. Additionally, the Committee did not find a compelling argument for rescheduling travel vaccines to improve equity and accessibility. However, I respectfully disagree with this assessment and would like to present the following arguments to address the Committee's concerns.

The Committee correctly highlighted that training and authorisation requirements for the use of vaccines would still apply, regardless of how vaccines are classified. This ensures that safety and quality standards remain high. However, I believe that rescheduling travel vaccines will still significantly improve access to these important vaccines, especially in terms of equity and accessibility.

While training and authorisation remain essential, there are still significant barriers to accessing travel vaccines in New Zealand, particularly for individuals living in rural and underserved areas. By enabling qualified pharmacists to administer vaccines, we can overcome these barriers. Pharmacies are widely distributed across New Zealand, including in areas where GP services may be limited. This widespread access allows more New Zealanders to receive travel vaccinations without having to travel long distances or wait for a GP appointment.

In many rural or remote areas, pharmacies are often the most accessible healthcare facility. Enabling trained pharmacists to administer vaccines means that people in these areas can receive the necessary travel vaccinations closer to home, which improves geographic equity in access to health services.

Current access to travel vaccinations in New Zealand is primarily through GPs, who may charge additional consultation fees on top of the cost of vaccines. For many individuals, this additional cost can be a significant barrier. Allowing pharmacists to administer these vaccines would provide a more afordable option. Pharmacies can ofer lower-cost services and may provide more flexible payment options, which can help make travel vaccines more financially accessible to a broader population.

Additionally, pharmacies typically ofer extended hours, including evenings and weekends, which makes it easier for people with busy schedules to receive vaccinations outside of normal GP ofice hours. This addresses time-related barriers to access, particularly for working individuals who may find it dificult to make appointments during regular ofice hours.

In response to the Committee's view that there isn't a compelling argument for rescheduling to improve equity and accessibility, I believe the case for rescheduling becomes much clearer when we consider the broader access issues. These include:

- Pharmacies are present in both urban and rural communities. This allows for improved access to travel vaccinations for those who may not otherwise have easy access to GP services, which is especially important in geographically isolated areas. In these areas, rescheduling would ensure that people do not face barriers to travel vaccinations due to the location of healthcare facilities.
- The cost of vaccines and the associated consultation fees with GPs can discourage some individuals from seeking timely immunisation. By enabling pharmacists to administer vaccines, we can lower costs for individuals, especially those without easy access to afordable healthcare. This is particularly relevant in the context of equity, as it ensures that all New Zealanders, regardless of their financial situation, can receive the necessary vaccinations before traveling abroad.
- Many individuals are not aware of the required vaccines or the timeframes for receiving them, especially as travel plans change. With pharmacies operating beyond traditional GP hours, they provide an important point of access for travellers who need vaccinations at short notice. This flexibility directly addresses accessibility issues that many New Zealanders currently face when trying to access travel vaccinations.

An important consideration in supporting the rescheduling of travel vaccines is the upskilling of pharmacist vaccinators in New Zealand. Pharmacists are already undertaking significant professional development as part of the pathway to becoming whole-of-life vaccinators with many pharmacists upskilling to become authorised vaccinators (independent from 3 years and over) on the pathway to becoming whole-of-life vaccinators. This evolving role for pharmacists in New Zealand is a logical extension of their existing responsibilities and expertise.

By incorporating travel vaccines into the scope of their practice, this proposal would align with the increasing role of pharmacists in managing public health through vaccination. Allowing pharmacists who are trained and authorised as authorised and/or whole-of-life vaccinators to administer travel vaccines would not only enhance access but would also ensure that the people administering these vaccines are highly skilled and knowledgeable. This makes the inclusion of travel vaccines into their scope of practice a natural progression, particularly as part of the broader goal of improving public health outcomes in New Zealand.

This proposal also aligns with international best practices. In countries like Australia and the United Kingdom, pharmacists are already authorised to administer travel vaccines, including the Yellow Fever vaccine, under appropriate training programs.

- In Australia, pharmacists can administer vaccines, including travel vaccines, once they have completed a nationally accredited training program. This model has helped improve accessibility to vaccines, especially in underserved areas, and has contributed to better overall public health outcomes.
- Similarly, in the United Kingdom, pharmacists who have completed the necessary training can administer travel vaccines, including those for Yellow Fever, under strict guidelines set by the National Health Service (NHS). This system has successfully expanded access to vaccines, particularly for last-minute travellers or those who face barriers to seeing a GP.

I also acknowledge with this submission, support of the proposal from Green Cross Health, which has highlighted that rescheduling travel vaccines would address critical access issues. Their submission notes the importance of improving access in rural areas, reducing costs, and ensuring more convenient access to travel vaccinations.

In summary.

While I respect the Committee's concerns regarding the existing training requirements and the classification of travel vaccines, I strongly believe that rescheduling certain vaccines, particularly for travel, is a necessary step toward improving equity and accessibility. The current framework, which requires vaccines to be administered only by GPs, restricts access for many New Zealanders, especially in rural or remote areas, and imposes unnecessary financial and logistical barriers.

By expanding the role of trained pharmacists in the administration of these vaccines, we can significantly improve access to vital immunisations, ensuring that all New Zealanders, regardless of their location or financial circumstances, have the opportunity to receive the protection they need. This approach is consistent with international practices in Australia and the United Kingdom and would help reduce health inequities, particularly in underserved communities.

Furthermore, given the increasing role of pharmacists as whole-of-life vaccinators in New Zealand, the addition of travel vaccines to their scope is a logical and necessary extension of their current responsibilities. This would help ensure that more New Zealanders have timely access to travel vaccines and are better protected while abroad.

I urge the Committee to reconsider the potential positive impact of this proposal in improving access to travel vaccines across New Zealand and to approve the rescheduling of these vaccines to empower trained pharmacists to administer them, ensuring a broader, more equitable reach for travel vaccinations.

Nāku iti noa, nā

Scott Percy

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17 January 2025

Dear members of the Medicines Classification Commitee,

Letter to support the proposal to reclassify several vaccines for pre-travel administration by authorised and pharmacist vaccinators.

GSK New Zealand is writing in support of the travel vaccines reclassification proposal submitted by Green Cross Health for review at the 73rd MCC meeting in February 2025.

With international travel returning to pre-pandemic levels there is greater demand by New Zealanders to receive advice they need to travel safely. Pharmacists are well placed to provide accessible travel health services in addition to existing travel health providers. Pharmacist vaccinators already provide a range of immunisations to their communities, and this proposal would provide a pathway to expand their scope of practice.

The proposal for reclassification includes three GSK vaccines against hepatitis A and B. Hepatitis remains a significant health concern in many countries frequented by New Zealanders, and we continue to observe cases of both hepatitis A and B in New Zealand, some of which are imported due to international travel. *Havrix, Engerix B*, and *Twinrix* vaccines are indicated for use in individuals traveling to high-risk areas. They have well-documented safety and efficacy profiles, supported by several decades of post-marketing experience.

Pharmacy offers accessible and professional point of care

Pharmacy has an increasingly important role in delivering professional services, including immunisation to New Zealanders. There are now over 900 vaccinating pharmacies across the motu delivering both National Immunisation Schedule and privately funded vaccines.[1] The suite of immunisations available in pharmacy has expanded significantly beyond COVID-19 and flu vaccines, supported by the increasing expertise and knowledge of pharmacist vaccinators in immunisation.[2]

Individuals that receive pre-travel immunisations have improved health outcomes and reduced need for healthcare utilisation while travelling.[3] While a proportion of diligent travellers routinely seek the advice, many don't and are unaware of the risks of disease at their destination. Pharmacies are well-positioned to provide travel health services due to their extended opening hours and the convenience of no appointment requirements, at least for a quick conversation to assess travel needs. Additionally, pharmacists can opportunistically identify travellers purchasing travel products who may not have considered the need for immunisation. Pharmacies also play an important role in public health promotion by raising public awareness about diseases, risks and treatments and can potentially reach a wide audience across New Zealand.

An increase in pre-travel consultations may boost the uptake of travel immunisations and improve the coverage of routine vaccines such as MMR (measles, mumps, and rubella). This is crucial because contracting measles while abroad could result in a significant and devastating outbreak in New Zealand if the disease is imported. Inspecting vaccination history would also enable assessment of up-to-date scheduled immunisation and completion of primary vaccination series, particularly important for diseases such as tetanus and hepatitis B in older adults who wouldn't have had the same access to

scheduled vaccines as we do today. The benefit of pre-travel consultations extend beyond infectious disease awareness and prevention. Registration with Safe Travel, deep vein thrombosis prevention, environmental risks such as altitude and or temperature and safety considerations are all likely to be covered for at risk individuals.[4]

Lastly, we support the opportunity for pharmacists who wish to offer travel consultations to extend their scope of practice to service the clinical needs of their communities.

Travel remains a risk factor for Kiwi's contracting hepatitis A or B

There has been a reduction in rates of hepatitis A since the 1970's, atributable to the use of hepA vaccination in travellers and a reduction in hepatitis A prevalence overseas.[6] In 2018 and 2019, 68 and 58 hepatitis A cases were reported to ESR respectively which constitute cases contracted while travelling and those contracted in New Zealand.

Acute hepatitis B notification rates have decreased in New Zealand since vaccination was incorporated into the paediatric national immunisation schedule in 1988.[7] The hepatitis B notification rate in 2019 was 0.6 per 100,000 population (28 cases).[7] The most common reported risk factors were overseas travel, migration and sexual contact with a confirmed case or carrier.[7] Many older adults have not routinely received hepatitis B vaccination therefore there is an opportunity for the risk of infection is appropriately assessed before travel.

Havrix, Engerix B and Twinrix vaccines have a large body of evidence to support safety and effectiveness

GSK has supplied over 1.7 billion hepatitis A, hepatitis B and hepatitis A and B vaccine doses since 1988 in more than 120 countries.[8] GSK currently supplies *Havrix* and *Havrix Junior*, Engerix-B and Engerix B *Paediatric* for funded high risk groups in New Zealand and all four vaccines are available for private purchase.[6,7] *Twinrix* and *Twinrix Junior* are currently available in New Zealand for private purchase.

As clinical support for healthcare professionals immunising against hepatitis A and B, clinical guidance is provided in sections 8 and 9 within the Health New Zealand Immunisation Handbook and additional resources are available through the Immunisation Advisory Centre.[6,7]

Hepatitis A Vaccine (suspension for injection)

Havrix 1440 (1440 ELISA/dose suspension for intramuscular injection)

Havrix Junior 720 (720 ELISA/dose suspension for intramuscular injection)

Havrix is indicated for the active immunisation against hepatis A infection in subjects at risk of exposure to hepatitis A virus. A single dose is recommended for primary immunisation and boosters can be offered to prolong protection.[9] With reference to travellers, *Havrix* is recommended for persons travelling to area's where the prevalence of hepatitis A is high.[9]

In addition to clinical studies, post marketing surveillance data support the acceptable safety profile and vaccine effectiveness of *Havrix*.[5] The timing of the booster dose is not critical to effectiveness, which has advantages for the protection of travellers to regions of high endemicity.[5] Data from several pivotal trials for *Havrix Junior* and *Havrix* show them to be highly immunogenic within 14–30 days of the first dose.[9]

Hepatitis B Vaccine (suspension for injection)

- *Energix-B* (20mcg/dose suspension for intramuscular injection)

- *Energix-B Paediatric* (10mcg/dose suspension for intramuscular injection)

Engerix-B is indicated for the active immunisation against hepatitis B virus infection. Use for immunisation relevant to this proposal relates to short-term tourists or business travellers to areas of high hepatitis B virus endemicity (may consider vaccination); however the risk of hepatitis B is generally minimal provided exposure through sexual contact, injecting drug use, tatooing or ear piercing is avoided. Long term visitors to areas of high hepatitis B virus endemicity, who anticipate close personal contact with local residents should be vaccinated.[10]

Primary vaccination consists of three intramuscular doses of vaccine according to either of three different schedules based on the risk of infection at the destination and the time before departure. Booster doses can be administered. Both clinical and post marketing data is included in the New Zealand *Engerix-B* data sheet.[10]

Hepatitis A and Hepatitis B vaccine (suspension for injection)

- *Twinrix Adult* (720 ELISA/20mcg dose suspension for intramuscular injection)

- *Twinrix Junior* (360 ELISA/10mcg dose suspension for intramuscular injection)

Twinrix Adult and *Twinrix Junior* are indicated for active immunisation against hepatis A and hepatitis B virus infection in individuals (from 1 year and over) at risk of, or who wish to be protected against, both infections. It is indicated for travellers to areas of high hepatis A virus and hepatitis B virus endemicity and persons originating from areas of high hepatitis A virus and hepatitis B virus endemicity. Different vaccination schedules are provided in the Data Sheet based on age, vaccine and standard or rapid dose schedule.[11]

In summary, GSK is supportive of the proposal to reclassify vaccines used pre-travel and for authorised vaccinators and pharmacist vaccinators to expand their scope to pre-travel advice. GSK welcomes requests from the Medicines Classification Commitee for further data if required, relating to *Havrix, Engerix B* and *Twinrix* vaccines. Please contact GSK at the email address supplied on the cover leter.

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6. Health New Zealand Immunisation Handbook 2024 v7.0; Section 8 Hepatitis A

7. Health New Zealand Immunisation Handbook 2024 v7.0; Section 9 Hepatitis B

8. GlaxoSmithKline Data on File (from GSK Hepatitis Plan Document 2025).

9. GlaxoSmithKline Havrix New Zealand Data Sheet NZ V8 2023. Medsafe.govt.nz

10. GlaxoSmithKline Engerix New Zealand Data Sheet NZ V10 2023. Medsafe.govt.nz

11. GlaxoSmithKline Twinrix New Zealand Data Sheet NZ V8 2023. Medsafe.govt.nz

SUBMISSION on 6.3 National Immunisation Schedule
(For discussion as per the Agenda for the 73rd meeting of the Medicines Classification Committee to be held 26 February 2025)

Thank you for the opportunity to provide a submission on 6.3 National Immunisation Schedule - proposed change to prescription vaccine classification **Travel vaccines (Green Cross Health Limited),** statements from the Ministry of Health.

ABOUT WORLDWISE GEOMED TRAVELLERS HEALTH CENTRES OF NEW ZEALAND

WORLDWISE is the only Travel Health Medical Assessment and Advisory Service Group in New Zealand. We have been active in our work for 30years. We are a group of 7 either 'stand-alone' or 'General Practice related' primary health centres. The focus of our work is pre-travel health advice giving resultant vaccinations and appropriate medical prescriptions, intra-travel service advice, post-travel assessment of lesions contracted from travelling abroad and finally; research into ongoing health, safety and security advice for New Zealand travellers.

I am **Professor Marc Shaw, Medical Director WORLDWISE GEOMED New Zealand**. I have 30 years' experience in Travel and its associated Tropical medicine. I have post-graduate qualifications in both Public Health and Travel Medicine.

Each of the clinicians at our clinics are either trained to a post-graduate level in Travel and/or Tropical Medicine, or receive on-site continuous training in travellers' medical, health and vaccinations issues.

Our group would conservatively see, assessment, review, manage and then vaccinate (if appropriate) approximately upwards pf 10,000 intending travellers throughout the country every year. Indeed, this number is greater than any other medical service unit in the country, due to the franchise nature and consistency of medical advice of the **WORLDWISE GROUP.**

FEEDBACK ON THE PROPOSED CHANGES

My colleagues and I do not support the projected changes by the Ministry of Health, under the current proposal Travel vaccines (Green Cross Health Limited). In our opinion, this proposal is not appropriate and further consideration needs to be investigated by the Submitters as to what other resources are available. They note in their submission *'Currently there is a barrier to advice and administration of travel vaccines in the community, especially in certain regions where the workforce pressures are severe. These barriers can leave individuals unvaccinated and unprotected during overseas travel with the potential for them to fall extremely ill, and/or bring with them foreign diseases into New Zealand'.*

The key to those aspects noted by the sub mission is 'information, knowledge and availability of appropriate knowledge'. Such *knowledge is currently available* – our own clinics have been offering virtual consultation and advice on such matter for 5 years now. This composite of evidence-based material is currently being delivered on a regular basis by WORLDWISE GEOMED [and indeed may be available from other approved clinics also] clinics to intending travellers throughout the country. The benefits of having such a service that is currently available are significant: i) the Travel Health Consultant is approved by the Ministry of Health ii) the information given is consistent ii) the information is regularly update and iii) there is no limitation of time commitment to such a virtual consultation.

Whilst it is to be applauded that the pharmacists suggested within the submission are to be appropriately qualified, there will not be large numbers that will be so. Thus the questions arises 'what happens if there is no qualified pharmacist available?' A generalist pharmacist [most likely in the locations the submission is targeting] is simply not available, given their current work capacity, to give unlimited time resources to a travel medicine consultation that currently we undertake as being 30 – 60 minutes**. It is to this group that I direct my focus for in remote locations they practically *are* going to give advice and administer vaccines if they can, possibly in default to the absence of the Specialist Pharmacist. Lack of expertise, knowledge and appropriate traveller-information will result.**

Whilst there is no questioning of a pharmacist's capabilities or professionalism [we currently have two pharmacists working with WORLDWISE GEOMED and who are exceeding capable with their academic knowledge in managing travellers], the main issue here is INFORMATION and NOT 'vaccinations'. Having a traveller approach any

service for the latter is not current global thinking in travel medicine and health. The important thing is to give INFORMATION to allow personal decisions.

WORLDWISE GEOMED is a service that gives this information. Not all travellers require vaccinations but they ALL do need information on how to keep health which MAY require vaccinations [currently around 20-30% of consultations are likely to be vaccine-free], information on mosquito avoidance, safety and security issues, information on medical kits and the use of appropriate medical therapies, expedition medical advice, and passage through various countries [given that travel health practitioners are indeed travellers and thus can give experiential advice as well]. Such information is the resources of the qualified travel health consultant and should not be in the hands on the generalist pharmacist as is seen in most Green Cross locations – especially those that are likely to be sought in remote locations. **Given the amount of knowledge required for the specialisation of the Travel Health Practitioner [Doctor, Nurse, Pharmacist] and the fact that the majority of pharmacists simply do not have this knowledge, then the primary reason for their submission could be inferred as financial.**

As we understand it, from current provided information from the Ministry of Health, the proposition is to widen the classification for a number of vaccines to allow vaccinators who have successfully completed the Vaccinator Foundation Course (or equivalent course) approved by the Ministry of Health and who comply with the immunisation standards of the Ministry of Health to both distribute and administer vaccines. **Whilst we welcome such specialisation within Pharmacy, we also are pragmatic to infer that this would not be the majority of pharmacists. In addition, it needs be remembered that because a vaccine is hard to get does not mean that it has to be more accessible. Often it is not and this is invariable due to i) global vaccine availability ii) cold chain storage iii) transportation difficulties and iv) lack of supply.**

Vaccines to be included in the submission include those Travel Medicine Practitioners' use to prevent **Hepatitis A, Hepatitis B, Typhoid, Japanese encephalitis, Poliomyelitis, and Yellow Fever. It would appear that those submitting this application are unaware of the fact that there is no combination of Hepatitis A and Typhoid available. The inference would be that those submitting are not keeping abreast of information in the 'travellers health field', thus emphasizing limited knowledge of the specialty of travel medicine.**

That there has been a recognised inadequacy and inequity in access and administration of scheduled childhood vaccinations and thus a need to increase the vaccinator pool to increase access to these vaccines is a given. New Zealand has experienced this phenomenon during the ongoing COVID pandemic. At a time when i) there were huge numbers of persons to vaccinate in the prevention of COVID and ii) declining immunisation rates, this was an important Public Health initiative that had widespread governmental and public support. **These parameters no longer exist in our Post-COVID status.**

Travellers presenting to a vaccinator to have their travel health vaccinations, often come with a list of what they think they should have, what they want or what someone told them they need for their intending travel. Invariably, from our experience, these folk have little knowledge of the true risk of their travel in relation to other diseases that may be communicable or non-communicable. Such travellers respond usually to an understanding of why vaccines may or may not be advised. This is where the specialist advice of the Travel Health Professional [THP] is required.

However, the administration of travel vaccinations or immunisations during the time of the Covid pandemic was almost universally undertaken throughout New Zealand by WORLDWISE Travellers Health Centres (**WORLDWISE GEOMED**) as the only surviving group of travel health professionals in the country. There was indeed no evidence of inadequacy and inequity in access to travel vaccinations and their obligatory support of information on related travel health preventative measures to support a need for travel-health vaccinations to be incorporated in the proposal, viz:

6.3 Travel vaccines (Green Cross Health Limited). The proposal is to classify as: 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 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.

All other vaccines: except when administered by ***vaccinators or*** registered pharmacists, who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health), hold the relevant travel medicine qualifications from an approved facility and who comply with the immunisation standards of the Ministry of Health (but excluding vaccinators who have completed the Provisional Vaccinator Foundation Course.

Vaccinations for travel are different from scheduled childhood vaccinations.

- They are not funded by the Ministry of Health (although Hepatitis A could be during an outbreak)
- They are not part of the immuisation schedule (exception Hepatitis B and Polio),
- The context in which they are given is completely different.
- They historically have side-effects that require vigilance, and maintenance in their management, by travel health professionals AND the Ministry of Health
- The requirement for skill and knowledge around this context is vastly different than other scheduled vaccines, given that concurrent knowledge and advice on other travel health treated issues are also required as an addendum to vaccination.

THE CONTEXT OF A TRAVEL VACCINATION:

The act of vaccinating a traveller is the endpoint of a consultation process that requires an understanding the traveller's past medical history, prior travel experience, prior vaccinations (including routine vaccinations), duration and mode of intended travel, destinations to be visited and intended activities. As mentioned, this process in consultation time takes a minimum of 20 minutes and often anything over an hour, as questions and answers are parried. Often there are repeat consultations about vaccines and about their effects post-vaccination. Academic papers on the role of the THP indicate both the extent of the role of the THP and the value of advice of the THP.

That the specialist THP requires a significant understanding of the epidemiology of diseases (vaccine preventable and non-vaccine preventable), outbreak information, and usually an understanding of the some of the geography and current history for the intended destination is not disputed. It is to be noted that vaccine preventable diseases make up only a very small part of a traveller's risk, the traveller needs to be educated about the other risks, such as food and water precautions, vector-borne disease (Dengue, Zika, Malaria), travellers' safety and security including activity-based risks (e.g. mountaineering, altitude travel, cycling, water-based activities etc), global health and air quality, and the need for medical insurance. A skilled evaluation of the traveller's risks, their risk tolerance, and the need for any vaccination (if required) together with the prioritisation of costs of vaccination needs to be made in conjunction with the traveller. A traveller **presenting to a pharmacy for vaccination** [as the submission alludes to] would miss out on the above information for **not all travellers that attend our clinics with a list of what they feel that they need are advised to have vaccinations**, if this is not indicated with evidence-based data for their need.

In addition, those not vaccinated will have been educated about risks and risk reduction measures for their intended travel. **To simply arrive at a centre that solely performs vaccinations without any of the pre-vaccination consultation, as outlined, would be a purely naive and unjustified approach to preserving the health of our fellow countryfolk travelling abroad**. Thus, the actual role of vaccinations in the overall risk reduction is small. Most THPs would also consider the impact of travel on host countries and communities and, with a need for eco-consideration they would give additional advice on responsible travel. Certainly, that is the brief of the **WORLDWISE GEOMED** Group. Indeed, THAT is the point of having a group, such as ours, practising this specialisation in medicine – to preserve local and international standards of travel healthcare. General vaccine availability at pharmacies without addition travel health advice is not appropriate. Whilst the specialist pharmacists have appropriate knowledge is not debated, however to say that generalist pharmacists [for they are the ones more likely to be available in remote regions] have the time to spend in appropriate travel health/medicine pre-travel consultation is fallacious.

TRAVEL HEALTH EDUCATION AND RAISING STANDARDS:

In the specialisation of those who choose to do Travel and Geographical Medicine, there have been huge steps from both international and local organisations to improve and maintain the standards of delivery in Travel Medicine. These have been acknowledged by the NZ Ministry of Health (MOH).

In Australia and New Zealand there has been a concerted effort to raise standards through the :

- **Academic Qualifications**
  - James Cook University in Townsville, Australia. The regions oldest Travel Health institution for 30 years. Prof Shaw has a Doctorate in Public Health and Trop Med from this University
  - University of Otago with Certificates, Diplomas and Masters qualifications in Travel Medicine
  - London School of Hygiene and Tropical Medicine. Dr Bester has qualified recently from this institution.
- **Professional Qualifications**
  - Australasian College of Tropical Medicine (ACTM)
  - New Zealand Society of Travel Medicine (NZSTM)
- **Ongoing professional education**
  - WORLDWISE travel medicine courses and seminars – to which pharmacists are invited, though they rarely attend

    - Lectures and evidence-based travel medical courses run by the Australasian College of Tropical Medicine, International Society of Travel Medicine and the Asia Pacific Travel Health Society.
- Writing appropriate articles in New Zealand Doctor, some of which are reprinted in Pharmacy Today
- The development of Nurse Competencies in Travel Medicine by the NZSTM, and in both Australia and New Zealand by ACTM. These measures have been taken up buy the NZ MOH.

Such focused activity has enabled NZ academics (doctors and nurses and appropriate pharmacists) hold prominent positions in international organisations that promote Travel Medicine as a speciality, all with the common cause of improving standards of care, e.g. the International Society of Travel Medicine. Whilst the education that this confluence of organisations produces is aimed at THPs, ultimately it is primed to increase public awareness that travel health is not just about 'vaccinations and malaria'.

It will be obvious from our discussion that we are trying to convey the fact that **considerable efforts are going into improving the knowledge, experience and standards in travel medicine**, noting that the tool of vaccination at the end of a travel health consultation is a very small part of the pre-travel health advice experience. Simply having this service available at a pharmacy where there is no qualified Travel Health Professional demeans and devalues the Speciality of Travel Medicine and prevents significant focus upon its consequences for those who travel. That is to say, if it is given the status of ''sunscreen' in a pharmacy there is limited incentive to find out the specifics of the product and its use, for there will be an inference of its ability, which is oft not understood.

This proposal to open vaccination for above stated vaccines is inappropriate given the aforementioned discission. All the previous work done to raise standards, including the Ministry's work to set standards of accreditation for administration of Yellow Fever vaccination (which importantly requires training in Travel Medicine and Health, Yellow Fever specific training, and evidence of ongoing CME in standards of yellow fever and travel health academia). **This proposal also feeds into the erroneous narrative that Travel Health is only about the vaccination.**

NUANCES OF TRAVEL VACCINATIONS THAT REQUIRE SPECIFIC KNOWLEDGE

Travel vaccinations demand more knowledge than many other vaccines – due to their need for storage, an understanding of their adverse reactions, the fact that some are live vaccines with the urgent need to often be given together, and because many are often given over a short interval in time. This requires understanding the evidence, safety and need for informed consent and shared decision making. This is a very different scenario from routine childhood vaccinations. For example:

- **Japanese encephalitis vaccines are two in number in New Zealand, one of which is 'on label. JEV vaccination is only licensed in NZ as a 2-dose intramuscular vaccination on days 0, and 28. Yet it is most often given off label with informed consent by, with different schedules nand the possibility of intradermal route.** This is based on changing evidence of the immunopotency of the vaccine. This education is even more important for those who have chosen *not* to have the vaccination and this information can only be imparted if a consultation has taken place.
- There are **specific vaccine peculiarities for all vaccines that the Travel Health Practitioner is aware of –** e.g. Typhoid intramuscular vaccination is only 70-75% effective, does not cover paratyphoid, and become less effective with the greater number of doses given, requiring switching to an oral vaccine.
- **Yellow Fever vaccination and NZ's Yellow Fever Policy is regulated by the International Health Regulations set out by the World Health Organisation. As mentioned, the Ministry of Health requires certification for Yellow Fever Vaccinators and Vaccinating Centres and has set a bar much higher than most developed nations for Travel Health education and ongoing education, and record keeping.** This is because of the potential serious consequences of the vaccine being given inappropriately and to comply with WHO regulation. A Yellow Fever Vaccination Certificate has to be issued, in a very specific format according to World Health Organization WHO criteria, otherwise it becomes invalid and the traveller can be denied entry to the specific country.
- Travel vaccines are not always available due to supply issues. **The fact that a vaccine is unavailable should not prevent the traveller from education about the disease, risk reduction and disease recognition and magement**. Currently **WORLDWISE GEOMED** could give such a consultation without expecting to vaccinate. With the submission, the inference is that travellers attend for vaccination. Thus they are unlikely to be given appropriate preventative advice on the disease.
- **Different brands of travel vaccines for the same disease have different licensing and administration recommendations** including vaccination interval or younger age of vaccination. This applies to Japanese encephalitis, Hepatitis B, and Typhoid. The use of these vaccinations requires often extra-ordinary explanation and consent.

- **Rapid schedules of vaccinations are frequently given to last minute travellers.** This is unapproved but evidence based, and requires informed consent. **Examples are yellow fever, Japanese encephalitis and combined B vaccines.**

THERE ARE A NUMBER OF CONCERNS ABOUT HOW THIS PROPOSAL WAS PUT FORWARD THAT NEED EXPLANATION:

1. *The way in which we have found out about the possibility – poor process*
    a. Process could be improved by engagement and consultation with NZ based leaders and organisations in Travel Medicine such as Prof Marc Shaw (Prof James Cook University), Dr Jenny Visser (senior lecturer at University of Otago), and the New Zealand Society of Travel Medicine.
2. *The Recognition that travel medicine is much more than just vaccinations – knowledge deficit*
    a. Travel medicine is a speciality however many health professionals and vaccinators are unaware of this and of what the 'don't know that they do not know'. There are many General Practitioners, and Nurses or Nurse Practitioners who prescribe travel vaccinations without a thorough travel consultation. This is why education is important and why there have been strenuous efforts to increase knowledge. Interest in conferences, education and feedback on Travel Medicine related articles suggest real progress is being made.
3. *The potential to totally undermine the speciality of travellers' health advising, ministering and managing in this country. It would potentially be the end of our specialisation here in New Zealand. A specialisation that we have locally developed slowly but surely over 30 years. We now have significant trust amongst our colleagues and we have developed significant global alliances – knowledge deficit*
    a. In reviewing travel vaccinations, the Ministry is well positioned to highlight the need for travellers' vaccinations to be given in the context of excellence in travel medicine understanding and experience. Alternatively, the Ministry can undermine efforts to raise the standard, and such a proposed initiative as this for pharmacists would do this, thus in the process undermine the speciality of Travel Medicine in New Zealand. It is sincerely hoped the former approach would be taken.
    b. Rather than trying to include, or exclude certain vaccinator groups in the administration of travel vaccines and create dissent amongst providers, the Ministry are urged to consider, develop and require core competencies and standards for all groups influenced in this proposal.

We remain optimistic that a full understanding of the issues relating to both Travel health Professional (THP) and vaccinator will adequately convey the need for a differentiation of the role of vaccinator from that of THP and why there is an ongoing need to ensure travellers health vaccinations are underlined as part of an essential specialisation for New Zealanders going abroad now and well into the future.

The Ministry of Health has a responsibility to ensure appropriate standards. In order to do this, appropriate understanding and acknowledgement of the work of those in the specialisation needs to be fully understood. Further consultation is required to this end. **A good logical solution to this raised issue, would be to work with Travel Health Professionals who conduct the travel health consultation either live or by virtual consultation; they would then refer to the appropriate provider [including skilled pharmacists] to administer the vaccine.**

'**It is the job of a Travel Health Professional to guide the knowledge that contributes to good judgement acquired by our traveller with respect to their travel.'.** That is why I, in representing our Group, am doing this job that I love.

Yours sincerely

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