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

22 January 2025

Jessica Crockett
Medical Classifications Committee
Product Regulation Branch
Medsafe
NZ Medicines and Medical Devices Safety Authority
PO Box 5013
WELLINGTON 6140

By email: committees@health.govt.nz; Jessica.Crockett@health.govt.nz

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.

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.

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.
-
- **7.7 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 ay 2024 Scheduling Final Decisions Public Notice

College consideration

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

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

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

8.1c Erlanatamab

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

8.1d Etranacogene dezaparvovec

Eyranacogene dezaparavovec-drlb indicated to treat adults with haemophilia B under certain conditions.
From 1 June 2024 estranacogene dezaparvovec was classified as a Schedule 4 (prescription medicine) in Australia.

8.1e Etrasimod

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

8.1f Fezolinetant

Fezolinetant is indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.
From 1 June 2024 fezolinetant was classified as a Schedule 4 (prescription medicine) in Australia.

8.1g Lebrikizumab

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

8.1f Lecanemab

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

8.1h Maribavir

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

8.1i Nelarabine

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

8.1j Tebentafusp

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

8.1k Zilucoplan

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

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

8.2a Naratriptan

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

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

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

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

This scheduling change was implemented on the 1 June 2024.

College consideration

The College notes that:

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

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

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

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

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

Nāku noa, nā

Dr Luke Bradford
BM(Hons), BSc (Hons), FRNZCGP
Medical Director | Mātanga Hauora