



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

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Tēnā koe Jessica

MedSafe Medical Classifications Committee (MCC) 74th Meeting

The Royal New Zealand College of General Practitioners (the College) is the largest medical college in Aotearoa New Zealand with a membership of 6,018 specialist General Practitioners (GPs). Our General Practice Education Programme (GPEP) and Rural Hospital Medicine Training Programme (RHMTTP) trains the specialist General Practitioner and Rural Hospital Doctor workforce. The Medical Council of New Zealand accredits the College to deliver a Vocationally Registered workforce through its Continuing Professional Development Programme, making up 40 percent of the specialist medical workforce. The College is committed to prioritising the reduction of health inequities experienced by Māori, honouring Te Tiriti o Waitangi, and the rights of Māori. To do this we prioritise initiatives that support our members to develop cultural safety capability throughout our Training, Member Professional Development and Quality¹ programmes.

Our members provide first point of contact medical care to patients and their whānau to manage 90 percent of all patient healthcare concerns in the community. Each year approximately 24 million² patient contacts are recorded by 1,085 general practice teams working across Aotearoa.

The College's comments on the MCC 74th meeting agenda items:

5 Submissions for reclassification

5.1 Resubmission - Tenofovir disoproxil and emtricitabine – proposed classification change to widen access to HIV prophylaxis medication (PrEP) in New Zealand

Tenofovir was an agenda item in the 73rd meeting – item 5.1. The meeting requested further information and resubmission by the Burdett Foundation.

Proposed addition:

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 is satisfied that the added submission of the Burnett Foundation in the 74th Meeting Agenda has considered and addressed concerns raised in our submission to the 73rd Agenda of the MCC meeting.

¹ As at June 2025, 972 out of 1085 general practices met the RNZCGP Foundation Standard.

² Ministry of Health, 2024 data.

We support reduction of barriers to prescribing HIV PrEP. Its reclassification 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.

Any barriers to accessing HIV PrEP will have a negative impact on prevention the prevention and elimination of HIV in Aotearoa New Zealand, and counterproductive to improving outcomes for people most affected. The reclassification enables access via pharmacists increasing the opportunity to support collaboration and continuity of care to improve uptake of medication for people who not currently using the health system or enrolled with a health services.

Protection from preventable disease provides immediate health benefits for people and economic benefits for the country:

- Saving time and money by preventing HIV and treating those with the condition.
- Increased collaboration will benefit those who are most disadvantaged in the health system, or do not access primary care.
- Pharmacist involvement will increase opportunities to provide access to equitable HIV prevention and treatment, and better access to advice and administration of specific travel vaccines.
- Additional advice outlined in [the guideline](#), regarding the indication and dosage will be useful for pharmacists and those in the network who educate the public about prevention and protection.

Community touchpoints provide an opportunity to increase continuity of care for unenrolled populations who are the hardest to reach. We strongly support pharmacist and pathology training to ensure they are part of a strong and supportive referral network, which is already engaged in prevention and testing.

5.6. Paracetamol – proposal to allow provision by vaccinators (Te Whatu Ora, Health NZ)

The RNZCGP supports the proposal by Te Whatu Ora³, that:

‘except when administered by vaccinators, registered pharmacists, or registered intern pharmacists who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by the Ministry of Health) and who comply with the immunisation standards of the Immunisation Handbook, to a child under the age of two with the administration of Bexsero vaccine to prevent and treat fever’.

- The proposed amendment will enable reclassification of Paracetamol so it can be administered by vaccinators to children receiving the Meningococcal B vaccine (this application has been made by Te Whatu Ora).
- The College is supportive, provided the usual caveats around awareness of paracetamol overdose in young infants is included, as this amendment would impact an estimated 1,708 vaccinators who immunise children under two years old and would be delivered outside of general practice settings.
- Vaccinators must be supported so they can reduce dosing errors and meet the needs of the communities they serve without unnecessary legal or logistical barriers. We note that Pharmac does not fund oral syringes, so this is an existing barrier to accessing suitable and safe devices for administering paracetamol. We recommend that the funded provision of suitable oral syringes for safety (of both the vaccinator and the child) is imperative, especially outside of general practice settings.
- Vaccinators must operate within the parameters of a safe system and be culturally appropriate. We strongly recommend Māori led solutions and guidance such as the *Paracetamol Study*⁴, to increase understanding and support of vaccinators and whanau to support safe, equitable and efficient immunisation delivery in NZ.

³ Caroline McElnay. Clinical Lead Submission with Proposed medicine classification amendment for consideration. Medical Classifications Agenda – 9 June 2025. National Public Health Service, Te Whatu Ora.

⁴ Jansen R, Cribb-Su’a A, Phillipson-Puna T, Heher M, Hayward S, Fung B. The Paracetamol Study. Final Report for the New Zealand Health Research Council. February 2024. Available at: <https://www.nhc.maori.nz/wp-content/uploads/2024/11/Report-The-Paracetamol-Study-26-Mar-2024.pdf>

Matters arising

8.3 Sedating antihistamines

The College supports the MCC previous recommendation to retain the restricted classification for sedating antihistamines for children over 6 years of age.

Promethazine is listed in Schedule 1 of the Gazetted Classifications of Medicines on April 17 2025, and Schedule 2 indicates that it is for oral use in medicines for adults or *children over 2 years of age* other than in medicines used for sedation or the treatment of insomnia; for oral use for the treatment of insomnia in adults and children.

For MCC consideration

The College does not consider Promethazine to be suitable for use in children under 6 years.

We are not aware of any evidence of efficacy for use of promethazine as a sedative in children, and it does not appear in clinical or professional body guidelines in New Zealand or internationally. We consider sedating antihistamines should not be used for the treatment of cough, cold and flu symptoms in children under 6 years, years of age as they can cause serious harm, or death, and there is little if any evidence that they are effective in treating cough, cold and flu symptoms.⁵

- The Medicines Adverse Reactions Committee (MARC) removed the indication for sedating antihistamines used for children to be removed from over-the-counter medicines (OTC).
- In 2024, Ministry of Health advice was to, '*not give any child under 6 years of age promethazine tablets or promethazine elixir*'.⁶
- MedSafe circulated an Alert, '*Promethazine (oral) products are now contraindicated (do not use) in children under 6 years of age*'.⁷
- New Zealand Data Sheet: Phenergan - Promethazine Hydrochloride, states, '*This product should not be used in children under 6 years of age* (see Section 4.4 Special warnings and precautions for use)'.
- Advice from the Australian Committee on Medicines (ACM)⁸ on first-generation oral sedations, including those available over-the-counter (OTC).

Thank you for the opportunity to comment on the MCC 74th meeting agenda.

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

Nāku noa, nā



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⁵ The Medicines Adverse Reactions Committee (MARC). Item 3.2.3 - Use of oral sedating antihistamines for sedation at its [182nd meeting](#) (11 June 2020).

⁶ The Ministry of Health. Medsafe issues alert against giving promethazine to children under 6 years of age. 14 May 2024. Available at: <https://www.health.govt.nz/news/medsafe-issues-alert-against-giving-promethazine-to-children-under-6-years-of-age>

⁷ Medsafe. Safety Information – Alert communication. Promethazine (oral): Do not use in children under 6 years of age due to the risk of psychiatric and central nervous system side effects. Available at: https://medsafe.govt.nz/safety/alerts/promethazine_dont_use_in_children_under_6.asp

⁸ The Department of Health, Disability and Ageing. Medicines Safety Update, Therapeutic Goods Administration. Australia. 13 July 2022.