19 May 2025

Clerk
Committee Secretariat
Health Committee
Parliament Buildings
Wellington
He@parliament.govt.nz

Medicines Amendment Bill

About the Australian and New Zealand College of Anaesthetists (ANZCA)

ANZCA, which includes the Faculty of Pain Medicine and Chapter of Perioperative Medicine, is the leading authority on anaesthesia, pain medicine and perioperative medicine. It is the professional organisation responsible for postgraduate training programs of anaesthetists and specialist pain medicine physicians, and for setting the standards of clinical practice throughout Australia and Aotearoa New Zealand. Our collective membership comprises 9649 fellows and trainees in anaesthesia and pain medicine, of which about 1300 work in Aotearoa New Zealand. ANZCA is committed to upholding Te Tiriti o Waitangi in the provision of competent, culturally safe care, and to promoting best practice and ongoing continuous improvement in a high-quality health system.

Consultation

ANZCA welcomes the opportunity to provide feedback on the Medicines Amendment Bill (bill). This submission is informed by discussion and consultation with ANZCA members and committees, in particular members and chairs of ANZCA's New Zealand National Committee and Faculty of Pain Medicine and analysis and discussion with Australian colleagues. ANZCA is a member of the Council of Medical Colleges (CMC) and supports its submission.

We note the short timeframe for this submission, and the lack of exploration and analysis of alternative options to the proposed legislation introducing a new verifications pathway to approve new medicines. We would feel more sanguine about this pathway if other options had been fully explored and communicated. While legislation to establish rules for the verification pathway has yet to be developed, we are aware of the indicative process developed by the Ministry of Health.

ANZCA would like to make an oral submission.

General comments

The bill proposes changes to three aspects of medicines regulation to improve access to medicines:

- Expanded prescriber settings for the prescription and administration of medicines
- Introduction of a 'streamlined' verifications pathway to register new medicines (additional reliance pathway)
- Changes to the Medicines Classification Committee

ANZCA strongly supports the purpose of the bill. We are aware that New Zealanders do not have access to the same range of medicines available in comparable countries, and that delayed access, particularly to new medicines, has been attributed, in part, to the slowness of the New

Zealand's Medicines and Medical Devices Safety Authority (Medsafe) approvals processes[1] and to prescribing regulation that may not reflect modern models of care and health practitioner regulation. Access to medicines has also been significantly impacted by the COVID-19 pandemic which necessitated rationing and increased substitution of many commonly used medicines; even now, global supply chains continue to be disrupted. Consequently, many health practitioners, including nurse practitioners and others who are authorised prescribers within their scope of practice, have been unable to work as efficiently as they could. The reasons for changes to the composition of the Medicines Classifications Committee are not clear, and the proposed changes, to the MCC, which ANZCA does not support, are alarming.

As highly trained specialists in anaesthesia and pain medicine, ANZCA members have considerable experience and expertise with using and prescribing advanced medicines to provide safe and effective health care in hospital and community settings. Safe anaesthesia (for which New Zealand has an outstanding reputation) requires extensive knowledge of medicines, because of the potential risk of harm. While ANZCA does not oppose the bill, we are concerned that without appropriate checks and balances, the proposed changes might not deliver the improved access to medicines as intended and may introduce some risk, including to Medsafe's reputation as a credible and effective regulator. Accordingly, we recommend that you consider our comments and note our recommendations should the bill proceed.

PART 1 Consent to distribute medicines by verification

Although Medsafe's latest annual performance statistics indicate that it has accelerated its approval processes[2], its timeframe is longer in some categories than in comparable countries, though not much longer. It is a moot point whether the difference warrants such a drastic change, particularly when it will almost certainly lead to a loss of the considerable technical and regulatory expertise that Medsafe has built up. There are other factors such as decisions by manufacturers, funders and providers of private and public health care, and our small market size which impact on timely access to medicines, so the extent to which the proposed new verifications pathway will make a difference is far from clear. It is disappointing that non-legislative alternatives have not been fully explored, particularly since the Ministry of Health's constrained analysis indicates that there are greater risks, as well as potentially better gains with this pathway.

However, in principle, ANZCA cautiously supports expediting access to medicines by reducing the timeframe for approvals, utilising other countries' decisions on pharmaceuticals, and aligning processes and reporting standards with international best practice. A lot will depend on the 'rules' which must be transparent and detailed to ensure that medicines verified by the proposed process will be safe and effective in Aotearoa New Zealand - however 'comparable', no two countries are the same and what is safe in one country may not be safe in another. Addressing anticipated challenges such as when a medicine is accepted in one jurisdiction but not in others (as happens quite regularly) and the process for selecting the reference regulator from the list of recognised regulatory authorities listed in new subsection 22A (clause 7) will need to be carefully articulated and quality assured. ANZCA would expect that a decision would not be accepted from a recognised regulatory authority where it has used a similar expedited verifications pathway, for instance. Robust protocols will also be needed to insulate decision-making from undue political, industry or media influence. ANZCA is also concerned that the mandatory 30 working day

[1] IQVIA Report. A decade of Modern Medicines An international comparison 2011-2020. New Zealand. Medicines New Zealand. Nov 2021. Available from: https://www.medicinesnz.co.nz/fileadmin/user_upload/IQVIA_Report_-_A_Decade_of_Modern_Medicines_An_International_Comparison_2011-2020__FINAL_.pdf

[2] New Zealand Medicines and Medical Devices Safety Authority. Medsafe Performance Statistics: Reporting period 1 July 2023 to 30 June 2024. Wellington. Medsafe.Nov, 2024.Available from Performance-Jul2023-Jun2024.pdf

timeframe for approvals could put Medsafe's other programmes of work at risk. We trust that this aspect is factored in when establishing the verifications pathway and is included in the reviews the Ministry has indicated it will undertake.

Clause 6 Section 21 amended (Applications for Minister's consent)

Clause 6 updates all the particulars required for applications to register a new medicine. However, there is no specific requirement for **safety** or **efficacy**, two critical factors which are included in section 21(2) which requires:

(i) *reports of any tests made to establish the **safety** of the medicine for the purposes for which and in the manner in which it is intended to be used*

*(j) report of any tests made to control the strength quality purity or **safety** of the medicine of the method of tested.*

(k) *any reports relating to the **efficacy** of the medicine*

We strongly recommend that all applications be required to report on the safety and efficacy of the medicine.

PART 2 Other amendments

Clause 11 Section 29 amended (Exemption for medicine required by medical practitioner)

Subclauses 1- 3 add nurse practitioners to the exemption medical practitioners have, enabling them to prescribe unapproved medicines for reasons other than a supply shortage. The term 'unapproved' is problematic because it encompasses a very large number of medicines and treatments with very different risk profiles, the vast majority of which are routine substitute medicines widely used by doctors and nurse practitioners in primary and aged care, where timely access to medicines is critical in reducing pain and further illness, and addressing entrenched health equity issues. Section 29 also includes a small number of high-risk medicines, where specialist sign off is required. Health practitioners only prescribe within their regulated scope of practice in the area they practise in.

Substitute medications are used when a supply runs out. They are generally 'unapproved' because the pharmaceutical company, not wanting to go through the expensive, lengthy registration process for that specific medicine, registers it under section 29. It is a way of ensuring supply without lengthy registration. A doctor can prescribe a section 29 medicine, but the information on the drug and patient needs to be supplied to the Ministry of Health for monitoring purposes. Patient consent is required for using a section 29 drug and specifically consent to provide personal details to the Ministry. Nearly all section 29 drugs are medications that are used frequently, and it is the supplier / formulation that has changed. Nurse practitioners are currently not allowed to prescribe section 29 medicines, which includes routine primary care medications such as B12 injections, Morphine elixir, Sofradex ear drops - resulting in delays to patients getting the medication they need, and health practitioners' time wasted filling in and signing forms unnecessarily to cover colleagues working within their scope of practice.

While the proposed changes to section 29 would remove this very significant barrier to timely, efficient access to medicines, particularly in primary care and aged care, we suggest a safer alternative would be to differentiate between substitute and routine medications which may be unapproved but are commonly used, and high-risk untested new medicines such as new cancer treatments, which require the advanced pharmacology training that medical specialists have. This in no way undermines our support for nurse practitioners whom we recognise as skilled health practitioners and could be a sensible precaution to protect public safety where new medicines pose a risk.

We support repealing the reporting requirements for the exemption, section 29 (2) and (3), noting the revised reporting requirements in new subsections 29A and 29B.

Clause 12 New Sections 29A and 29B inserted

The proposed new section 29A provides for the supply of funded alternative medicines and for authorised prescribers to prescribe and administer them when there is a shortage of an approved medicine; it clarifies that this exemption applies only when the unapproved alternative is funded by Pharmac**.** ANZCA supports this clause which aligns prescribing practise with the robust regulatory framework established by the Health Practitioners' Competence Assurance Act, 2003 (HPCA). We are satisfied with the integrity of the Responsible Authorities (RAs) under the HPCA which determine the standards of education, training, and qualifications determining what health practitioners can do within their scope of practice. We note, however, that the HPCA is currently under review, and take this opportunity to affirm the importance of maintaining an independent regulatory system, with strong clinical governance, to assure safe, competent practise in all health settings.

ANZCA supports new section 29B revising the reporting requirements for the sale or supply of new medicines exempted under section 29 or 29A.

Clause 13 Consequential and other amendments as set out in Schedule

Section 9 Medicines Classifications Committee (MCC).

Section 9 new subsections 3, 3A and 4 propose:

- increasing the number of members from six to seven
- removing the requirements for two representatives from the New Zealand Medical Association (now defunct), the Pharmaceutical Society of New Zealand and the Ministry of Health
- limiting the term to six years.

While we can see the advantage in having a larger pool from which to appoint MCC members, ANZCA does not support new subsection 3A: *The Minister must not appoint a person to the Committee unless they are satisfied that the person is suitably qualified to be a member*. It is hardly a consequential amendment as it proposes a very significant change to the composition of the MCC which ANZCA strongly opposes.

The MCC is charged with classifying prescription medicines, restricted medicines or pharmacy-only medicines. This requires independent clinical expertise because of the potential risk to public safety where access is controlled by the classification. The single criterion for appointment - that the Minister is satisfied that the person is "suitably qualified" - is too open for a position requiring specific expertise. The risk of harm in misclassifying medicines is potentially exacerbated by Aotearoa New Zealand being the only country, apart from the United States of America, that allows direct advertising of prescription medicines. It is vital that most members of the MCC are independent medical and pharmaceutical experts in clinical practice. We strongly recommend that new subsection 3A is amended accordingly, specifying *at least* two medical and two pharmaceutical experts in clinical practice on the MCC. This is particularly important given that only two of the six members of the Medical Review Committee are required to have experience of clinical practice.

Changes to sections 23 – 24 and section 30

ANZCA supports changing the respective timeframes from days to 'working days' which is in line with international practice.

ANZCA
FPM

Recommendations

We again thank you for the opportunity to comment on the bill. We recommend that you:

- **Note** that we wish to make an oral submission.
- **Note** that ANZCA **supports**, in principle and with some reservation, the proposed new verification pathway.
- **Agree** that consistent and careful review will be needed to ensure that the 30 working day timeframe does not impact negatively on Medsafe's work programme.
- **Amend** new section 21(2) to require all applications to include evidence of both the safety and efficacy of the medicine.
- **Note** that ANZCA does **not support** clause 11 subsections 1-3 amending Section 29 (Exemption for medicine required by medical practitioners) inserting "or nurse practitioner".
- **Agree** that that the category of 'unapproved' medicines is too broad to be useful in the current context of medicines regulation and that separate procedures for:

    a) high-risk, new medicines and
    b) routine and substitute medicines

  would help facilitate timely access to medicines and efficient utilisation of the regulated health workforce.

- **Note** that ANZCA **supports** clause 12 allowing authorised prescribers to prescribe and administer approved alternative medicines that are funded by Pharmac
- **Delete or amend** the parts of clause 13 that apply to Section 9 new subsection 3A pertaining to the composition of the Medicines Classification Committee, to ensure a minimum of two members with medical and two members with pharmaceutical expertise and experience in clinical practice.

Nāku noa, nā

Graham Roper
Chair
New Zealand National Committee

Rachel Demsey
Deputy Chair
New Zealand National Committee

ANZCA
FPM

For further information please contact:
Stephanie Clare, ANZCA Executive Director – New Zealand
sclare@anzca.org.nz +64 27 711 7024