The Royal Australian & New Zealand College of Psychiatrists
Tu Te Akaaka Roa
New Zealand National Office

Your Health in Mind
Hauora hinengaro Manatuhia

Health Committee

Medicines Amendment Bill

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Advocacy and collaboration to improve access and equity

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Royal Australian and New Zealand College of Psychiatrists submission

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About the Royal Australian and New Zealand College of Psychiatrists

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) is a membership organisation that represents more than 8700 members, including more than 6000 qualified psychiatrists and 2500 trainees. Psychiatrists are clinical leaders in the provision of mental health care that prepares doctors to be medical specialists in the field of psychiatry, supports and enhances clinical practice, advocates for people affected by mental illness and advises governments on mental health care.

The RANZCP and is guided on policy matters by a range of expert committees made up of psychiatrists and community members with a breadth of academic, clinical, and service delivery expertise in mental health.

Introduction

Tu Te Akaaka Roa, the New Zealand National Committee of the RANZCP, welcomes the opportunity to provide feedback to Select Committee on the Medicines Amendment Bill (the Bill). The recommendations contained within this submission have been made in consultation with expert committees made up of Aotearoa New Zealand based psychiatrists with a breadth of academic, clinical and health service delivery expertise.

Key Messages

To ensure essential safeguards are maintained and potential risks and benefits are balanced appropriately, we recommend:

- Conducting further industry consultation and consultation with iwi to explore alternative pathways for streamlining current processes that maintain local oversight and verification.
- rejecting the proposed amendment of Section 29 and exploring alternative options for improving access to high-quality health care in Aotearoa New Zealand, based on industry consultation.
- specifying the clinical expertise and membership requirements for being appointed to the committee under Sections 9(3) of the current Act.

Amendments to Section 22 – Introduction of Verification Pathway

Tu Te Akaaka Roa believes the risks associated with the proposed verification pathway, in its current form, outweigh potential benefits. While we agree that there is merit in exploring alternative pathways and streamlining existing approval processes, we believe local oversight must be retained to ensure available evidence is verified appropriately.

There are many examples of medications which gained approval from international authorities and were later found to cause considerable harm. The acceptance of a medicine by other jurisdictions should therefore not, by default, presume its effectiveness. Additionally, many international regulators have their own version of a verification pathway in place and emerging information may not be adequately considered throughout these processes.

The unique make up and needs of the population in Aotearoa New Zealand must be adequately considered as part of the approval process for new medicines. For example, some medicines have a higher risk profile for certain groups of the population and specific assessment of available evidence in context of the population in Aotearoa New Zealand forms an important part of the Medsafe approval process. International regulators are unlikely to consider the impacts on tāngata Māori; as a result, Māori are likely to be disproportionately impacted by the proposed changes. We note that specific impacts on

Māori have not been appropriately assessed and iwi were not consulted during the policy development, breaching the Crown's obligations under Te Tiriti o Waitangi.

Additionally, a lack of appropriate safeguards exposes New Zealanders to unnecessary risks of medication harm and makes our country vulnerable to influence from international pharmaceutical companies and public pressure, resulting from lobbying and direct-to-consumer advertising.

Recommendation

> We recommend conducting further industry consultation and consultation with iwi Māori to identify requirement for implementing a streamlined approval pathway in a safe and effective manner, ensuring local verification of evidence is maintained.

Amendments to Section 29 – Prescribing rights

Tu Te Akaaka Roa believes the risks associated with the proposed amendments to Section 29 outweigh any potential benefits.

While we acknowledge the challenges arising from medical workforce shortages in Aotearoa New Zealand, patient safety must not be compromised, and health practitioner regulations must be appropriately matched to the education and training they receive. Tu Te Akaaka Roa highly values the contribution of nurse practitioners to the care of tāngata whai ora across the motu. However, current training and professional standards required for registering as a nurse practitioner are not sufficient to ensure the safe prescription of unapproved medicines.

As described in the RANZCP's Professional Practice Guideline 4: 'Off-label' Prescribing, prescribing medicines for an unapproved has important clinical and ethical considerations that need to be fully considered before changes are made to legislative requirements.

When considering prescription of unapproved medicines (including off-label prescribing), health practitioners must consider the full range of treatment options available for the condition they are treating and be informed by the evidence-base and implications of using medicines off-label, including potential risks outside of their speciality or for specific to vulnerable populations. This requires extensive knowledge in medical sciences, pharmacology and clinical research. Current training requirements for nurse practitioners are not sufficient to enable necessary risk assessments for safe prescribing of unapproved medication.

The intent of the Bill is to expedite the introduction of new medicines into Aotearoa New Zealand by reducing safeguards, meaning that more medicines will become available for unapproved uses, increasing the risk exponentially, particularly for vulnerable populations. Vulnerable groups such as tāngata whai ora experiencing mental health challenges, pregnant people, and children, are particularly at risk as they are often excluded from clinical trials, meaning that mainstream medicines remain understudied in these groups and 'off-label' prescribing is common.

Instead of the proposed amendments, we suggest exploring alternative options to improve for improving access while ensure safety standards are maintained. For example, nurse practitioners may receive approval to prescribe specific medicines for an unapproved use, in-line with their training and experience, and the risk profile associated with a particular medicine. This could be achieved through setting a list of unapproved medications that are low-risk for prescribing, for example, via the gazette notice.

Alternative routes for gaining approval of medicines for additional uses may also be explored. Currently, many evidence-based medications remain off-label owing to sponsors not being financially motivated to apply or have their medications re-purposed. A review of how additional approval can be gained would reduce the need for prescribing unapproved medicines and create clarity and assurance for health practitioners and tāngata whai ora.

Recommendations

To ensure the safety and wellbeing of New Zealanders, we recommend Select Committee rejects the proposed amendment of Section 29. We recommend exploring alternative options for improving access to high-quality health care in Aotearoa New Zealand, based on industry consultation, e.g., reviewed approval pathways for additional indications, or approving nurse practitioner prescribing for selected medicines.

Membership of Committee – Amendments to Section 9

The proposed amendments under Clause 13 eliminate the need to have specific expertise held by members of the advisory committee. The criteria for appointment on bodies such as this one, needs to consist of the relevant clinical expertise to maintain safe standards for the classification of medicines.

Recommendation

Tu Te Akaaka Roa recommends specifying the clinical expertise and membership requirements for being appointed to the committee under Sections 9(3) of the current Act.