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MEDICINES AMENDMENT BILL

Submissions on behalf of
The Law Association of New Zealand
by the
Mental Health and Disability Law Committee

INTRODUCTION

The Law Association of New Zealand (TLANZ) is an independent membership organisation for the New Zealand legal profession with more than 7,000 members. TLANZ maintains expert law committees that support legal review and policy advocacy on important issues. This submission is made by the Mental Health and Disability Law Committee (the Committee) on behalf of TLANZ, in response to the Health Committee's consultation on the Medicines Amendment Bill.

SUBMISSION

The Committee supports the Bill's aim to improve access to medication for New Zealanders and the amendments it puts forward to achieve this, particularly as medication access issues disproportionately affect those with mental health conditions and disabilities. However, we believe that the Bill only scratches the surface of addressing the issue. It needs to go much further if it wants to genuinely improve access to medication in New Zealand, especially for those with mental health conditions and/or disabilities, who rely on medication the most.

We have several areas of concern with the proposed Bill. These are:

- The Director-General's assessment of New Zealand-specific health risks;
- Public funding of fast-tracked and unapproved medicines;
- The ability to approve and/or remove Recognised Regulatory Authorities;
- Access issues for the expanded prescribing rights of non-medical prescribers; and
- Other core access to medicines issues that are unaddressed.

1. Director-General Assessment of New Zealand-Specific Health Risks

1.1. In the Bill, the Minister of Health may only consent to the sale, distribution, and advertising of a new medicine if it "does not require independent assessment by the Director-General to contextualise the benefit-risk profile of the medicine due to local disease epidemiology, public health considerations, or New Zealand specific health risks".[1] Additionally, the Minister can request further information, amend the application, or do both, if they consider that the "information provided indicates the medicine may not be suitable for use in New Zealand."[2]

[1] Medicines Amendment Bill 2025 (134-1), cl 7.
[2] Clause 7.

1.2. We strongly support the inclusion of this provision. It is vital that New Zealand-specific health issues are not overlooked in order to speed up the medicine-approval process. This is particularly so as there are a range of health issues specific to New Zealand not experienced by the other countries listed as Recognised Regulatory Authorities, such as those unique to our Māori and Pacific populations.

1.3. Māori and Pacific peoples have disproportionately worse rates of disease and health outcomes compared to non-Māori and Pacific populations in New Zealand, particularly when it comes to birth outcomes, rheumatic fever, premature mortality,[3] cardiovascular disorders, and diabetes.[4] They are more likely to have a mental health condition,[5] be disabled, and experience harms arising from healthcare.[6] They also experience both under-prescribing of appropriate medications and higher prescribing of inappropriate medications.[7] Pacific peoples face similar experiences, including higher levels of chronic and mental health conditions.[8]

1.4. As such, the importance of such a provision cannot be overstated and should in fact be strengthened in this Bill. The Bill, and/or the accompanying Rules, should include a robust set of criteria to ensure that this is comprehensively assessed by the Minister in issuing their consent for a new medicine. This should include outlining examples of "public health considerations" and "New Zealand specific health risks",[9] to ensure that Māori and Pacific populations and, relatedly, those with mental health conditions and disabilities, are given the utmost consideration that they warrant in this proposed new approval process.

1.5. This should also apply to cl 7 of the Bill that outlines the Minister's rule-making power in a new s 22D into the principal Act.[10] Here, the Minister may make rules setting out various requirements for the consent by verification process.[11] Before doing so, the Minister "must consult organisations or bodies that they consider representative of persons likely to be substantially affected by the rules".[12] This must include organisations and bodies representative of Māori, Pacific, and mental health and disability populations to ensure

[3] Sharon Leitch, Alesha Smith, Sue Crengle and Tim Stokes "The views of New Zealand general practitioners and patients on a proposed risk assessment and communication tool: a qualitative study using Normalisation Process Theory" (2021) 2 Implementation Science Communications 1 at 2.
[4] Sue Carswell, Elaine Donovan and Fiona Pimm *Equitable access to medicines via primary healthcare — a review of the literature* (PHARMAC, September 2018) at 19.
[5] At 19.
[6] Above n 3 at 2.
[7] At 2.
[8] Above n 4 at 28.
[9] Medicines Amendment Bill, above n 1, cl 7.
[10] Clause 7.
[11] Clause 7.
[12] Clause 7.

that they and their unique concerns are duly accounted for in the decision-making process and not left up to the Minister's initiative.

2. Public Funding of Fast-Tracked and Unapproved Medicines

2.1. The Bill aims to greatly shorten the amount of time it takes for a medicine to be approved for use in New Zealand. Again, this is an effort that we are in favour of and should benefit those with mental health conditions and disabilities in particular. However, the Bill does not provide any information as to whether these medicines will be funded at a similar speed.

2.2. The proposed new verification pathway will apply to Medsafe, the regulatory body tasked with approving medicines for use in New Zealand.[13] Pharmac is the government agency that makes the funding decisions for medicines.[14] The impact that this new pathway will have on Pharmac is not discussed in this part of the Bill.

2.3. This change is purported to "increase access to medicines for Kiwis… more quickly."[15] The Bill must specify what it means by access. On its face, this new pathway seems like it will only provide faster access. It does not appear to provide affordable access.

2.4. This would disadvantage people with mental health conditions and/or disabilities who would benefit greatly from timely access to new medicines. People with mental health conditions and/or disabilities are much more likely to be of a lower socio-economic status and therefore struggle to afford an unfunded medicine.[16] In fact, even small co-payments for funded medicines can act as a significant barrier for those of lower socio-economic status in accessing medicine.[17]

2.5. It follows that the Bill should provide clarification on whether new medicines approved through the new fast-tracked verification pathway would experience a similarly paced Pharmac funding assessment. This is essential in ensuring that the Bill's aim of improving access to medicine is achieved for all New Zealanders in an affordable, fair and equitable way.

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[13] Pharmac "How Pharmac works" (16 May 2023) <www.pharmac.govt.nz>.
[14] Above n 13.
[15] Hon David Seymour "Medicines Amendment Bill passes first reading" (10 April 2025) New Zealand Government <www.beehive.govt.nz>.
[16] Stats NZ "Disability statistics: 2023" (31 March 2025) <www.stats.govt.nz>.
[17] Mona Jeffreys, Megan Pledger, Fiona McKenzie, Lis Ellison-Loschmann, Maite Irurzun Lopez and Jacqueline Cumming "Consequences of cost barriers to prescriptions: cohort study in Aotearoa New Zealand" (2024) 13 New Zealand Medical Journal 48 at 48.

2.6. Similar reassurances should be provided for unapproved medicines. The Bill expands the prescribing rights of nurse practitioners to prescribe unapproved medicines. We support this expanded right of these highly trained and expert nurse practitioners. However, once more, the Bill must ensure that those with mental health conditions and/or disabilities do not miss out on this increase in access to broader kinds of medicines due to barriers of cost.

3. Recognised Regulatory Authorities

3.1. The Bill aims to meet its 30-day verification pathway target by relying on medicine assessments by two Medsafe-equivalent approved bodies.[18] This is an understandable change. The Medsafe approval process can be lengthy, only to reach the same conclusion that another well-regarded country has reached using identical information.[19]

3.2. However, the Bill must introduce appropriate safeguards and monitoring measures to ensure that the list of Recognised Regulatory Authorities continues to embody the same healthcare values as New Zealand.

3.3. Currently, the Bill itself does not provide any additional context as to how these Authorities are chosen, and if or when they should be reviewed. However, in the Regulatory Impact Statement for the Verification Pathway, it is noted that the list of Authorities "should be regularly reviewed with more countries added as appropriate", and that "Medsafe will develop an assessment process for how new countries are added."[20]

3.4. We agree with this. However, we propose some adjustments. First, changing the "should" in "should be regularly reviewed" to "must" would greatly strengthen the checks and balances to maintain the credibility and integrity of this pathway.

3.5. Secondly, there should be the ability to remove Authorities from the list, not just to add Authorities to the list. We do accept that requiring the approval of two Authorities is an appropriate safeguard. However, enshrining the ability to remove an Authority into the Bill would greatly enhance this existing safeguard.

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[18] Medicine Amendment Bill, above n 1, cl 7.
[19] (8 April 2025) 783 NZPD (Medicines Amendment Bill – First Reading, David Seymour).
[20] Ministry of Health *Regulatory Impact Statement: Proposed verification pathway for medicines approvals* (30 July 2024).

3.6. As mentioned, this may be necessary if an Authority's medical and/or pharmaceutical policies no longer align with those of New Zealand. An example of this can be found in one of the current approved Authorities, which is the United States' Centre for Drug Evaluation and Research. The CEO of the American Association of People with Disabilities, Maria Town, has called the current Trump administration "a crisis for the disability community" and that "the threat is extremely serious".[21] Under the current Trump administration, the words "accessibility" and "disability" have been deemed acceptable grounds to flag or reject grant applications at the National Science Foundation.[22] The Republican-controlled Congress has proposed cutting funding for Medicaid, which provides healthcare to low-income citizens, by a third over the next decade.[23] Approximately 15 million disabled Americans rely on Medicaid to afford their healthcare.[24] Job cuts in the United States' Food and Drug Agency have led to former Agency officials expressing concerns that it could "jeopardi[s]e billions of dollars in fees" that pharmaceutical companies pay the FDA to "ensure the approval process for drugs is adequately staffed."[25]

3.7. Additionally, the United States Health Secretary, Robert F Kennedy Jr, has called autism an "epidemic", unveiling a "'massive testing and research effort'" that will reveal the cause of the said "epidemic", allowing the government to "eliminate those exposures".[26] He has hired David Geier, who has previously been found to have prescribed puberty blockers to autistic children without being a licenced doctor, to oversee research attempting to link autism to being vaccinated.[27] This is despite the overwhelming evidence that autism is a largely genetic, neurodevelopmental condition, with absolutely no connection to the MMR or any other vaccine.[28] Moreover, Trump has labelled the fact that "the number of children being diagnosed with [ADHD]" and the resulting increased prescription of medication a "dire threat to the American people and our way of life" in a White House press release.[29] Trump called for a Make Our Children Healthy Again Assessment, which will, among other things, "assess the prevalence of and threat posed by the prescription of selective

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[21] Sam Gustin "Donald Trump's Next Diversity Target: People with Disabilities" (18 February 2025) The Nation <www.thenation.com>.
[22] Sara Nović "The US right is coming for disabled people. Here's why that threatens everyone" (27 March 2025) The Guardian <www.theguardian.com>.
[23] Melody Schreiber "Autistic people and experts voice alarm at RFK's 'terrible' approach to condition" (24 April 2025) The Guardian <www.theguardian.com>.
[24] Above n 23.
[25] Christina Jewett and Rebecca Robbins "Kennedy Accuses F.D.A. of Drug Industry Influence That Barred Alternative Remedies" (11 April 2025) New York Times <www.nytimes.com>.
[26] Above n 23.
[27] Above n 23.
[28] Altogether Autism Takiwātanga "No links between vaccinations and autism, researchers prove" (3 September 2019) <www.altogetherautism.org.nz>.
[29] The White House "Establishing the President's Make America Healthy Again Commission" (13 February 2025) <www.whitehouse.gov>.

serotonin reuptake inhibitors, antipsychotics, mood stabilizers, [and] stimulants", all of which are key medicines used in treating mental health conditions.[30]

3.8. It is fortunate that this concerning trend has yet to concretely impact the United States' Centre for Drug Evaluation and Research. Yet, the signs are worrisome, and the Bill must make its expectations for selecting, and removing, Recognised Regulatory Authorities. This will ensure that changes in overseas countries' healthcare policies will not impact how people with mental health conditions and/or disabilities are treated in Aotearoa.

4. Expanded Prescribing Rights of Authorised Prescribers and Access Issues

4.1. We support the expanded prescribing rights of authorised prescribers to prescribe a funded alternative medicine in instances of medicine stock shortages. As intended, this will help to ease the pressure on GPs and help patients avoid costly and time-consuming follow-up appointments with doctors resulting from a stock shortage out of their control.

4.2. Once again, this should particularly benefit those with mental health conditions and/or disabilities. An example of this can be found in stimulant medication, which is used to treat ADHD. Methylphenidate, which is available under brand names such as Ritalin and Concerta, is one of the most commonly used stimulant medications but is in short supply all around the world.[31] This includes Aotearoa, where stock shortages are anticipated to last throughout 2025.[32] The changes in this Bill would mean if someone with ADHD went to a pharmacist to pick up their medication, only to find it was out of stock, the trained pharmacist could prescribe an alternative, funded, Pharmac-approved medication, and the patient would not need to wait for another GP appointment and another prescription. This is particularly beneficial for people with ADHD, who can struggle with executive functioning necessary for tasks such as these, especially when they do not have access to stimulant medication.

4.3. However, the Bill must go further to ensure that patients still receive the same quality of care that they would from their GP. It is widely reported that GPs are facing enormous and overwhelming pressure in Aotearoa and do not receive adequate government funding.[33] However, pharmacists are also struggling with staff shortages and significant increases in

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[30] Above n 29.
[31] Pharmac "Methylphenidate: Supply issue" (14 May 2025) <www.pharmac.govt.nz>.
[32] Above n 31.
[33] Mariné Lourens "GPs disappointed with 'insufficient' increase in Government funding" (18 July 2024) The Press <www.thepress.co.nz>.

workload.[34] These changes could increase their workload even further at a time when they are already facing difficulties in providing quality care to their patients.[35]

4.4. Even without the Bill's proposed amendments, community pharmacists have reported an 80 per cent increase in requests from patients unable to see their GP.[36] 66 per cent of community pharmacists have reported that their work has negatively impacted their mental health and well-being.[37] If this Bill is going to expand pharmacists' prescribing rights, the government must match this added responsibility with the increased funding that pharmacists and GPs are calling out for, or risk facing "'a significant threat'" to the entire health system.[38]

4.5. People with mental health conditions and/or disabilities would be particularly vulnerable to any reduction in the quality of care they receive. Many have already faced adverse or traumatic experiences in healthcare settings.[39] Particularly, mental health medicines can come with a range of mental and physical adverse side effects that require further careful medical attention and must be addressed with the utmost care.[40] The government, as well as healthcare providers, must take active steps to ensure that this already at-risk population is not further harmed by those very people tasked with helping them. This includes making sure that healthcare providers are in the best possible working conditions to enable only the best advice and prescription alternatives.

4.6. It is positive that other prescribers are having their prescribing rights expanded, including optometrists, registered midwives, dentists, and dietitians.[41] This is excellent for those who can access their services. However, aside from midwives,[42] these prescribers primarily operate in the costly private sector, and if they are available through the public sector, patients face lengthy wait times and eligibility criteria just to access their services in the first place.[43] Therefore, such changes are unlikely to make much difference in the lives of

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[34] Tatiana Gibbs "Pharmacists short staffed and mentally suffering, survey says" (4 September 2024) The Press <www.thepress.co.nz>.
[35] Jonathan Chilton-Towle "Pharmacists struggle to provide quality care as pressures mount, survey reveals" (4 September 2024) PharmacyToday <www.pharmacytoday.co.nz>.
[36] Above n 35.
[37] Above n 35.
[38] Above n 34.
[39] Altogether Autism Takiwātanga "Revealing research: Healthcare barriers faced by Autistic people" (29 April 2024) <www.altogetherautism.org.nz>.
[40] Ron Paterson, Sir Mason Durie, Dr Barbara Disley, Dean Rangihuna, Dr Jemaima Tiatia-Seath and Josiah Tualamali'I *He Ara Oranga: Report of the Government Inquiry into Mental Health and Addiction* (November 2018).
[41] (8 April 2025) 783 NZPD, above n 19, David Seymour.
[42] Maternity Services Consumer Council "FAQ" (2025) <www.maternity.org.nz>.
[43] Work and Income "Dental treatment" (2025) <www.workandincome.govt.nz>.

many of those with mental health conditions and/or disabilities, who can struggle to access their services in the first place due to cost or other accessibility factors.[44]

4.7. These changes also ignore the other factors impacting access to medicine, one being communication issues. A particularly relevant example of this is refugee patients. Refugees who have resettled in Aotearoa have highly complex healthcare needs. Refugees are far more likely to have mental health conditions and/or disabilities, with PTSD being extremely common for refugees who have fled traumatic war or persecution in their home countries.[45] They are also more likely to face language and/or literacy barriers, which is the most common challenge that refugees face in accessing and utilising health services after settling in Aotearoa.[46]

4.8. There are interpreting services available for refugees in some hospital and GP settings, with inconsistent success.[47] However, these services are not available when refugees visit a pharmacy and interact with a pharmacist.[48] Written information, such as instructions for how and when to take a medication written on a medicine packet, is only offered in English. Refugees reported wanting to interact with their pharmacist and ask questions, but simply could not due to the language and communication barrier.[49] As a result, many refugees turn to Google, where extensive lists of side effects and warnings displayed without the much-needed context and benefit-risk assessment of a health professional can scare them off of taking the medicine entirely, in what is called the "nocebo" effect.[50] This leads to misunderstandings and a lack of trust in health professionals, and consequently strong refugee dissatisfaction with the services they receive and poorer health outcomes.[51] Again, this is particularly problematic considering the uniquely complex health needs of refugees who disproportionately have mental health conditions and/or disabilities.

4.9. The Bill must take these issues seriously and give further consideration to the real-life barriers that those with mental health conditions and/or disabilities, and their associated population groups, face in accessing medicine that the Bill currently does not address.

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[44] *Equitable access to medicines*, above n 4, at 23.
[45] At 22.
[46] Jagamaya Shrestha-Ranjit, Deborah Payne, Jane Koziol-McLain, Ineke Crezee and Elizabeth Manias "Availability, Accessibility, Acceptability, and Quality of Interpreting Services to Refugee Women in New Zealand" (2020) 30 Qualitative Health Research 1 at 2.
[47] Pauline Norris, Molly George, Vanda Symon, Shirley Keown, Sandhaya Bhawan, Lauralie Richard and Rosalina Richards "Does access to medicines differ from access to healthcare? Experience of barriers to medicines access by people facing social disadvantage" (2025) 21 Research in Social and Administrative Pharmacy 480 at 482.
[48] At 482.
[49] At 482.
[50] The views of New Zealand general practitioners and patients on a proposed risk assessment and communication tool, above n 3, at 7.
[51] Above n 47 at 482.

5. **Cost and Other Unaddressed Barriers to Accessing Medicines**

5.1. On the whole, the Bill fails to address the core issues that have the most impact on access to medicine in Aotearoa. Without meaningfully addressing these issues, this Bill can be held up as mere window-dressing.

5.2. The Bill may get medicines into the country faster. That is a good thing. Yet, it means very little if patients in most need of them cannot access a pharmacist in the first instance.

5.3. One of the fundamental issues preventing access to medicines in Aotearoa is cost. As mentioned in Section 1, Māori face disproportionately worse health outcomes, lower socio-economic status, and are more likely to have a mental health condition and/or disability. They are also more than twice as likely to have a cost barrier to collecting a prescription than non-Māori.[52] 26% of Māori in low-income households reported cost as a reason for not being able to pay a prescription charge at least once a year compared to non-Māori.[53]

5.4. The consequences of this are significant. Those who could not afford to collect their prescription had "poorer self-reported physical and mental health, and subsequent declines in health."[54] 60 per cent of people facing a cost barrier to accessing their prescription were hospitalised at least once during the relevant study period.[55]

5.5. The cost savings of addressing issues at their root are also significant. If the hospitalisation rates of those who could not afford a prescription, representing an unmet need, were reduced to the levels of those with no unmet needs (i.e. could afford their prescription), there could be 27,000 fewer hospitalisations over a three-year period.[56] With the cost of staying overnight in a hospital being estimated at $1200, and the average hospital stay being three nights per stay, this study conservatively estimated potential savings of $32.4 million each year — all by providing free prescription access to those who could not otherwise afford their medicines.

5.6. Other issues preventing access to medicines include the inability to travel and travel costs, childcare costs, loss of wages if healthcare providers are only open during working hours,

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[52] Consequences of cost barriers to prescriptions, above n 17, at 48.
[53] At 48.
[54] At 48.
[55] At 50.
[56] At 59.

and living rurally, among others.[57] These issues remain regardless of how long a medicine takes to be approved in Aotearoa, and independently of who can prescribe a medicine. If the Bill is to succeed in its aim, these factors must be addressed by government initiatives, either in this Bill or in supporting government actions.

CONCLUSION

6. Overall, the Committee supports this Bill, but believe that it does not go far enough to tackle the core issues greatly impeding access to medicines for New Zealanders. The Bill does make important and necessary changes to the medicine approval system to ensure timely verification and entrance of medicine into the New Zealand market. However, there must be appropriate and sufficient safeguards to ensure all New Zealanders — particularly our most vulnerable New Zealanders, such as those with mental health conditions and/or disabilities — are protected from needless further harm. Moreover, the Bill must ensure it provides the requisite funding needed to account for these increased prescribing powers, particularly for pharmacists, and address the funding issues that have led to our healthcare system continuing to operate under crisis.

Thank you for the opportunity to make submissions in respect of the Medicines Amendment Bill. We are available to discuss the submission if required. Should clarification be required with regards to any matters raised, please contact Dan Conway, Head of Legal at TLANZ: daniel.conway@thelawassociation.nz

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Ngā mihi

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The views represented in this submission are not necessarily representative of the views of all TLANZ members but are those of individual TLANZ members or TLANZ committees who have responded to the consultation.

[57] At 61.