Submission
by

THE NEW ZEALAND INITIATIVE

to the Health Committee

on the

Medicines Amendment Bill

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1. INTRODUCTION AND SUMMARY

1.1 This submission on the Medicines Amendment Bill is made by The New Zealand Initiative (the **Initiative**), a Wellington-based think tank supported primarily by major New Zealand businesses. In combination, our members employ more than 150,000 people.

1.2 The Initiative undertakes research that contributes to developing sound public policies in New Zealand. We advocate for the creation of a competitive, open and dynamic economy and a free, prosperous, fair and cohesive society.

1.3 The Initiative's members span the breadth of the New Zealand economy. Improvement in access to medicines is a matter of broad concern. The views expressed in this submission are those of the author rather than the New Zealand Initiative's members.

1.4 We are very strong supporters of the intent of this legislation. That intent was best expressed in the coalition agreements that formed the government: "Require Medsafe to approve new pharmaceuticals within 30 days of them being approved by at least two overseas regulatory agencies recognised by New Zealand."

1.5 Unfortunately, the Bill will not achieve the intent expressed in the coalition agreements that formed the government. Rather than automatically approve medicines already approved by trustworthy overseas regulators, it sets a fast-track approval pathway for a limited subset of medicines approved by those overseas regulators. It also provides Medsafe with ample opportunity to stop the clock on those approvals.

1.6 We believe there are two options for strengthening the legislation to achieve its desired objective.

1.6.1 The Bill could be amended to automatically approve medicines that have been approved by at least two trusted overseas regulators, under the conditions of the overseas approval relied upon. A medicine provided emergency use authorisation by two overseas regulators would here receive emergency use authorisation. Under this option, Medsafe could retain the option to block an automatic approval if it had specific cause for concern. Use of that veto would be regularly evaluated to test whether it should be retained, restricted, or removed.

1.6.2 The Bill could alternatively be complemented by an additional section 29 pathway for NZ-unapproved medicines that have been approved, either fully or provisionally, by at least two trusted overseas regulators. That pathway would maintain current rules on supply-chain documentation to ensure medicines are not counterfeit, that they were from batches that were approved as safe for sale in the authorised market, and that any cold-store requirements were met during importation. Otherwise, those medicines would be treated as comparable to Medsafe-approved medicines. Requirements that medicines be imported for a particular named patient would be removed, as would 29(2) requirements documenting the medicines' use. Currently, only a restricted set of medical practitioners are allowed to supply medicines under s29. That restriction would be eased for overseas-approved medicines.

1.7 Either option should achieve the intent of the legislation, strengthening access to medicines that have been proven safe by trusted regulators. Nothing in either option would prevent Medsafe from collaborating with foreign approval agencies to share the burden of assessing medicines.

2. PROBLEM DEFINITION

2.1 New medicines often arrive late to the New Zealand market. The ultimate reason is that we are a small market with little willingness to pay for expensive new medicines. Pharmaceutical companies have regulatory approvals teams that will prioritise approvals in more lucrative markets over approval in New Zealand. They may delay applying for Medsafe authorisation until approval has been secured elsewhere. If the company thinks there is high likelihood of Pharmac funding, it may bring forward Medsafe application; Pharmac's excellent processes may provide a form of imprimatur.

2.2 The problem then is not *just* that Medsafe can take months or longer to approve a medicine that has already been approved by trusted overseas regulators. The problem is also that companies hold off on seeking Medsafe approval until their regulatory approval teams have capacity for dealing with Medsafe. We are not generally high in anyone's priority ordering.

2.3 Medsafe is far from the only barrier to access. Pharmac funding is necessarily limited. Even under a rule automatically authorising every medicine approved by at least two trustworthy overseas authorities, Pharmac would have to make choices about what should be funded.

2.3 Absence of Medsafe approval can be a barrier to Pharmac assessment. In August 2023, Pharmac published a proposal to decline funding applications for 27 medicines. In 24 of the 27 cases, Pharmac's stated reason for declining to progress funding applications was simply, "We understand there is currently no Medsafe approved product available in New Zealand. We are not aware of any supplier willing to pursue Medsafe registration."[1] While authorisation is not strictly a precondition for Pharmac approval, absence of authorisation can remove medicines from consideration.

2.4 Section 29 of the Medicines Act provides access to unapproved medicines that a medical practitioner requires for the treatment of a particular patient under that practitioner's care. Access under Section 29 remains highly restrictive.

2.5 *A CASE STUDY IN REGULATORY FAILURE*

2.5.1 Consider the monkeypox outbreak linked to the Winter Pride Festival in Queenstown in September 2024 as case study in regulatory system failure and the deficiencies of Section 29.

2.5.2 Jynneos was approved by the European Medicines Agency (EMA) and by Canada in 2013 for smallpox. Canada authorised it for monkeypox in 2020; the EMA recommended it, under the trade name Imvamune, for monkeypox in 2022. The US Food and Drug Administration (FDA) approved it in 2019 and provided Emergency Use Authorisation for monkeypox in 2022. New Zealand's first case was in 2022.

2.5.3 Under a "rule of two" providing automatic approval on authorisation by at least two trusted regulators, Jynneos/Imvamune would have been authorised in New Zealand in 2022.

[1] https://www.pharmac.govt.nz/news-and-resources/consultations-and-decisions/2023-08-02-proposal-to-decline-inactive-funding-applications

2.5.4 The manufacturer did not apply for Medsafe approval until 2023. Despite a global Monkeypox outbreak, and despite regulatory approval overseas, Medsafe took about eighteen months to approve the vaccine.

2.5.5 It is possible to access unapproved medicines under Section 29. However, the patient needs to know that the medicine is an option. A GP may be less familiar with medicines that are not approved. It is illegal to advertise unapproved medicines.

2.5.6 Men who have sex with men are at particular risk of monkeypox. It is difficult to run a public health campaign raising awareness of vaccination as an option when the vaccine is unapproved. Promoting unapproved medicines is illegal, regardless of the public interest in disseminating information in an outbreak.

2.5.7 Medical practitioners administering unapproved medicines are required to inform patients that the patient's name and details will be recorded and provided to Medsafe. Not everyone seeking monkeypox vaccination in advance of the Pride Festival may have been comfortable with their details being recorded for that purpose.

2.5.8 After the Covid vaccines were approved, vaccination was broadly available. Pharmacies could provide it. Mobile outreach vans could reach harder-to-reach communities. All of that is illegal for unapproved medicines. They can only be available by prescription; pharmacists and other health professionals cannot prescribe or administer them.

2.5.9 Medsafe approved Jynneos on 11 September 2024. On 12 September 2024, Health New Zealand reported five monkeypox cases linked to the Winter Pride Festival.

2.5.10 A functional public health system would have had vaccination available and encouraged in advance of the Pride Festival – whether funded or unfunded. Every part of our system failed. Application for New Zealand authorisation was slow. Approval was slow once application was made, despite the pressing circumstances. The system for accessing unapproved medicines was not fit for purpose.

2.5.11 This is no way to run a railroad. Medsafe simply was not going to find a problem that had not already been discovered by much larger and better-resourced regulatory approval agencies overseas. The only thing that Medsafe authorisation contributed was needless cases of monkeypox. No one was protected. Some were harmed.

2.6 *More than just monkeypox*

2.7 Difficulty in accessing unapproved medicines does not just affect those at risk during a global monkeypox outbreak. It is also a regular problem for paramedics.

2.8 Dylan Mordaunt reported in the New Zealand Medical Journal that paramedics are not allowed to administer unapproved medicines independently under section 29. He writes, "[p]aramedics, often the first and only responders, are hindered by legal constraints that prevent them from providing essential care promptly." Dr Mordaunt also pointed to the administrative reporting burden associated with s29.

2.9 Dr Mordaunt noted that "[t]hese constraints hinder paramedics' ability to provide timely interventions, forcing them to choose between delaying treatment or risking legal repercussions." He contrasted s29 with more flexible frameworks in Australia and the UK. There are serious real-world implications of the existing legislation being overly restrictive. Section 29 currently either prevents appropriate use of medicines by

paramedics, or results in the possibility that their actions could be considered unlawful. There should be cross-party interest in this legislation supporting safety, and it currently being unworkable for ambulance services suggests that the balance isn't there.

2.10 To summarise, then. There are many impediments to access to newer medicines. This Bill aims at one particular impediment: failure to appropriately recognise foreign approvals and consequent difficulties in accessing medicines already proven safe and effective by trusted overseas regulators. The problem is not just that approval processes are slow. The problem is also that pharmaceutical companies can delay submitting medicines for New Zealand approval. And while s29 processes may make sense for medicines that have not been approved by other trustworthy regulatory authorities, they are far too onerous for medicines already proven safe.

2.11 This problem will not solve itself. Rather, it is likely to worsen.

2.12 The global pace of medical innovation is likely to accelerate as improved artificial intelligence technologies help researchers make discoveries more quickly. The number of overseas-approved medicines that Medsafe would have to consider, unless we can rely more heavily on those approvals, will increase.

2.13 Price controls threatened by President Trump risk further delays in pharmaceutical companies' seeking New Zealand approval.

2.14 On 12 May, President Trump announced he would sign an executive order implementing a form of reference pricing: he would set price controls on pharmaceuticals sold in the United States. In his words and grammatical choices, "I will be instituting a MOST FAVORED NATION'S POLICY whereby the United States will pay the same price as the Nation that pays the lowest price anywhere in the World."[2]

2.15 Luca Maini and Fabio Pammolli found that this form of reference pricing in Europe resulted in increased entry delays in low-income European countries by up to one year per drug. If a company must charge a price no higher than that which it charges in other countries, it will delay bringing a drug to market in a country where prices will be lower.[3]

2.16 Pharmaceutical companies already delay bringing medicines to the New Zealand market. If bringing a medicine to the New Zealand market would require reducing the price of its medicine in the United States, that delay will worsen considerably.

2.17 We hope that the President's threatened policy is not implemented or that Pharmac finds a way to mitigate the worst of it. Fewer drugs would be developed under the threatened price controls. But companies producing those drugs will have stronger incentive to 'window' the international release of their medicines. The medicine could be released first in high-income countries with strong willingness-to-pay, then later released to the next tier of countries when the gains from accessing a broader market dominate the losses from lower prices in the United States. Some drugs may never be worth releasing in places like New Zealand.

2.18 The problem to be solved is substantial. The Bill will fail to solve the problem.

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[2] https://x.com/america/status/1921693853062492302

[3] Maini, Luca, and Fabio Pammolli. 2023. "Reference Pricing as a Deterrent to Entry: Evidence from the European Pharmaceutical Market." American Economic Journal: Microeconomics 15 (2): 345–83.

3. DIFFICULTIES WITH THE BILL AS DRAFTED

3.1 The Bill proposes a fast-track verification process for drugs already fully-approved by at least two trusted overseas regulators. Pharmaceutical companies could apply for verification through that pathway.

3.2 Before accepting an application, Medsafe may first need to verify that a medicine is eligible for the pathway. It will require unredacted assessment reports from both approving countries' agencies; pharmaceutical companies are not always supplied with those unredacted reports.

3.3 Medsafe can stop the clock on its assessment by asking the applicant for more information. Time spent waiting for a reply does not count toward the approval period. Medsafe may feel tempted to do this if it wants to undertake a more rigorous evaluation than would be warranted for a medicine already approved by overseas agencies.

3.4 Pharmaceutical companies expecting a simpler pathway might bring forward New Zealand applications. But the verification pathway otherwise does not address one substantial part of the problem: that companies delay applying for Medsafe approval because New Zealand's market is an afterthought.

3.5 Let us consider the Covid period and whether this verification pathway would have substantially improved outcomes.

3.5.1 Pharmaceutical companies were slow to put Covid vaccines, particularly for paediatric formulations, into the Medsafe approval process. Nothing in the Bill is likely to speed up applications.

3.5.2 Vaccines were typically provided with Emergency Use Authorisation abroad rather than full approval – as is befitting during an emergency like a pandemic. But only fully-approved drugs are eligible for the verification pathway. The Bill will fail when it is most critical that it succeed.

3.5.3 Medsafe was slow to approve Covid vaccines despite a pressing pandemic and despite overseas approvals. Even if Covid vaccines were eligible for the verification pathway without full approval, a drug company's inability to access unredacted files from the FDA could block access to the pathway. Stopping the approval clock by asking for more information also remains an option.

3.5.4 I first proposed the Rule of Two in November 2021, when Medsafe seemed to see little need for urgency in evaluating paediatric formulations of the Covid vaccine that had already been approved by the United States and Europe.[4] The verification pathway proposed in this Bill would not have helped.

3.6 Unless the Bill causes pharmaceutical companies to put medicines through the pathway for verification, the problems with access to unapproved medicines through Section 29 remain – including the untenable situation facing paramedics.

3.7 Other drugs that could improve lives remain here unapproved and consequently inaccessible.

[4] https://www.stuff.co.nz/business/opinion-analysis/127121998/burden-of-proof-is-on-medsafe-to-justify-its-existence

3.8 The FDA and EMA authorised Abrysvo in pregnancy, to protect infants against RSV, in 2023. In May of 2025, Radio New Zealand headlined the story: "RSV vaccine used in 40 other countries could save babies' lives – doctors"[5]. The National Public Health Service reported that Abrysvo is "not currently approved for use in New Zealand". A search of the Medsafe database shows no evidence that application for approval has yet been made.

3.9 It does not have to be like this. But the Bill will not solve the problem.

4. ALTERNATIVES

4.1 We propose two alternatives.

4.2 In 2023, the Initiative released a report calling for a 'Rule of Two' that would automatically approve medicines that had been approved by at least two trustworthy overseas authorities.

4.3 If a drug had been approved by Canada and by Australia, medicines manufactured to the specifications set out by those agencies and approved for sale in those markets could be imported for use in the New Zealand market. They would already be approved.

4.4 In the version we proposed, Medsafe would retain an 'emergency handbrake'. If it had good reason to expect that a drug were riskier than overseas regulators expected, or had particular risks for the New Zealand market, it could block automatic approval. If later evaluation showed that that emergency brake was used carefully, it would be retained. If instead it showed that the brake was regularly pulled for medicines that posed no risk, the brake could be removed.

4.5 Drug approval agencies need to balance two important risks. Approving an unsafe medicine brings health risks. But delaying a safe medicine hurts those who could have benefitted from it. In general, approval agencies err on the side of caution. Approving an unsafe drug leads to headlines. But delaying a safe drug leads to what economist Alex Tabarrok describes as an 'invisible graveyard'.

4.6 If a medicine has already been approved by two agencies, each of which faces incentives to err on the side of delay, it is unlikely that Medsafe would find problems that those much larger agencies missed.

4.7 An initial investigation found little reason to prefer standard Medsafe authorization over the automatic application of a Rule of Two.[6] If the Rule of Two would have approved a medicine that was later withdrawn from the market, and Medsafe had refused to approve that medicine, then Medsafe would have done a better job than the Rule of Two in preventing riskier drugs from making it to market.

4.7.1 We found one low-dose formulation of lidocaine that would have been approved by the Rule of Two but that was refused by Medsafe. That version remained in use overseas without issue at time of our report. Otherwise, we did not see medicines since 2006 that would have been approved by a Rule of Two but had been rejected by Medsafe. Data prior to 2006 was more difficult to obtain.

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[5] https://www.rnz.co.nz/news/top/560018/rsv-vaccine-used-in-40-other-countries-could-save-babies-lives-doctors

[6] Crampton, Eric. 2023. *Safe to Follow: Faster access to medicines for Kiwis*. The New Zealand Initiative. https://www.nzinitiative.org.nz/reports-and-media/reports/safe-to-follow-faster-access-to-medicines-for-kiwis/document/829

4.7.2 By contrast, a Rule of Two would have approved Herceptin nine to ten years earlier than it was approved by Medsafe. Panolimus would have been approved twelve years earlier. Methadone and Plenvu would each have been approved a year earlier. Approval would not guarantee Pharmac funding but could have hastened consideration while opening the medicines to coverage by private insurance.

4.7.3 We also found that Medsafe tends to remove drugs from the market with timing similar to other regulators. If an overseas regulator relied on by the Rule of Two withdrew approval, that would trigger reassessment here. Application of the Rule of Two would work comparably to existing practice in withdrawing medicines from the market.

4.8 Subsequent extensions to the work identified a few interesting cases.

4.8.1 Rimonabant was approved by the EMA in June 2006 and subsequently approved by Swissmedic in April 2007. That approval would have triggered automatic approval under a Rule of Two; it had not been put forward for Medsafe approval. The FDA deemed Rimonabant non-approvable in June 2007. Under a Rule of Two that triggered reassessment if a trusted agency rejected a medicine, Rimonabant would have been automatically approved for approximately four months before being brought forward for reassessment. The EMA suspended Rimonabant in October 2008.

4.8.2 Ximelagatran was approved in multiple European markets in 2004 but was deemed 'not approvable' by the FDA that same year. Depending on precise timing, it either would have been ineligible for consideration under the Rule of Two or would have quickly been in a reassessment pathway.

4.8.3 Automatic approval of medicines already approved by at least two trustworthy authorities should be coupled with a close watch on whether other trusted authorities subsequently come to a different determination. Medsafe could then decide whether to reassess the medicine.

4.9 We recommend automatic approval over the Bill's proposed verification pathway. It would hasten access to safe medicines.

4.10 Alternatively, the Select Committee could maintain the proposed verification pathway, albeit extended to include provisionally-approved medicines, while adding an improved s29 pathway for medicines already approved, whether fully or provisionally, by trusted overseas regulators.

4.11 The standard s29 pathway could be maintained for medicines that had not been approved by at least two recognised overseas authorities.

4.12 An s29 pathway for medicines approved by at least two recognised overseas authorities would maintain documentation requirements necessary to ensure that imported medicines were eligible to be marketed in the recognised overseas market – rather than either being counterfeit or batches that had been rejected overseas. If temperature-controlled storage is necessary, documentation establishing that the medicines had been transported and stored under appropriate conditions would also be required. Medicines imported under s29 already carry these requirements; these would be retained.

4.13 The s29 pathway for medicines approved by at least two recognised overseas authorities would remove the other restrictions that, while appropriate for more experimental medicines, are inappropriate in this case. A broader range of medical professionals, for example including emergency medical technicians or nurses, could be authorized to apply or dispense the medicines as appropriate.

4.14 Availability of the improved s29 pathway would bridge the gap between overseas approval and application to the verification pathway. It could also hasten application to the verification pathway.

5. CONCLUSION

5.1 A strengthened version of this Bill could meaningfully improve access to medicines not yet approved for use in New Zealand. Medsafe approval is far from the only barrier to access, but the matters addressed by this Bill merit addressing.

5.2 The Bill as drafted may speed up approval of a limited range of drugs, conditional on those drugs being submitted to Medsafe for verification. But it can take years after a medicine is approved abroad before it is submitted for Medsafe approval.

5.3 We can see two pathways for strengthening the Bill. There may be others. A strengthened version of the Bill is worth producing. We look forward to supporting it.

ENDS