A Medicines Strategy to reflect the changing world of medicines

Introduction

Hundreds of New Zealanders go without the medicines they need to live healthy, productive lives. For many New Zealanders, funding for pharmaceuticals is a matter of life or death, or the difference between a life of pain and suffering or living freely. Affordable access to medicines is one of the hallmarks of any advanced economy.

Yet the medicines market is notoriously difficult to navigate, and there are huge dollars at stake.

The global pharmaceutical market is a $1.48 trillion industry, and the prices drug companies charge can be prohibitive for many patients if they were to pay the full price drug companies are charging. The Government's funding role, implemented through Pharmac, negotiates lower prices with drug companies and subsidises certain medicines on behalf of the taxpayer.

However, the Pharmac model is not well suited for a changing world of medicines. New medicines, particularly cancer treatments, are becoming more diverse and personalised, and are available to patients well before developing a strong evidence-base of efficacy.

Compared to other OECD countries, New Zealand is consistently the worst —or one of the worst — performers when it comes to accessing new medicines.

Between 2012-2021, New Zealand was at the bottom of the OECD pack in launching new medicines. Of 460 new medicines, 16 per cent were launched in New Zealand, compared with 34 per cent for Australia and an OECD average of 41 per cent. New Zealand also ranks bottom of the OECD when it comes to the proportion of new medicines reimbursed by public insurance plans. In New Zealand, only seven per cent of new medicines were publicly reimbursed, compared with 29 per cent as the OECD average. Finally, New Zealand takes longer than other countries to publicly reimburse new medicines. The time taken between global first launch and public reimbursement for new medicines was 71 months, compared with four months for the United States, 47 months for Australia and an OECD average of 45 months[1].

A Medicines Strategy is needed to ensure New Zealanders' access to affordable medicines keeps up with changing times.

ACT will require the Ministry of Health to develop a Medicines Strategy, updated every three years. The Medicines Strategy will entail research into domestic and international developments in health needs and the availability of treatments. It will also entail specific obligations for Pharmac and Medsafe, and the Strategy will evaluate outcomes based on those obligations.

A Medicines Strategy will ensure that the regulatory system and funding system for pharmaceuticals is sustainable and not unreasonably holding back access. The Strategy will enable New Zealanders to develop realistic expectations and make more informed calls about the accessibility of medicines through the Pharmac subsidy system versus other private options.

Instead of relying on the luck of the draw or politically motivated funding announcements, ACT says New Zealand needs a dedicated strategy to ensuring access to medicines.

ACT will:

- Require the Ministry of Health to publish a Medicines Strategy every three years.
- Require Medsafe to approve within one week any drug or medical device that has been approved by two foreign regulatory bodies with comparable or more robust systems compared with New Zealand.

What's at stake?

New Zealand's poor performance in enabling access to new medicines has caused a lot of criticism to be loaded on Pharmac, as the decider of what drugs get subsidised.

The very nature of new medicines —which are often expensive when first released to market —means they may struggle to meet Pharmac's threshold for funding due to the small populations they are likely to apply to, and the thin evidence-base available upon their release. The individualised nature of these medicines calls into question whether Pharmac is the right funding model, given it is stewarding a fixed pool of money to purchase on behalf of all New Zealanders.

1. https://www.nzinitiative.org.nz/reports-and-media/reports/policy-point-pharmac-should-not-be-criticised-simply-for-being-selective-and-slow-about-the-medicines-it-funds/document/807

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There are reasons to be wary of calling for Pharmac to be quicker in funding new medicines too. As economist Dr Bryce Wilkinson argues:

> *"A new medicine may be too costly and/or too ineffective. Pharmaceutical companies globally have an incentive to release new medicines that are close substitutes for older medicines that are soon to lose patent protection that will make them much cheaper. Pharmac knows this. What Pharmac used to be about, and should still be about, is to use its fixed budget to subsidise cost-effective pharmaceuticals…*
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> *…Bargaining for a good price is particularly important for medicines. This is because pharmaceutical companies have to price discriminate across countries for complex reasons. Bargaining takes time. It would be useful if the media made a habit of asking the lobbyists for new funding what Pharmac should stop funding, given its fixed budget."*[2]

A 2019 German study found that of 216 new drugs that came on the market between 2011-2017, only 54 were of "major" or "considerable" benefit, 37 were of "minor", "less", or non-quantifiable" benefit. And there was "no proof of added benefit" for 125 of the drugs[3].

A 2020 study of new drugs approved by the US Food and Drug Administration (FDA) and European Medicines Agency (EMA) found that less than a third of new drugs approved over the past decade were rated as having high therapeutic value[4].

There is also the question of who pays, and who benefits from funded medicines. According to Pharmac, 3.81 million people receive funded medicines each year, but only 10 per cent of those people account for 84 per cent of the spending. The proportion of funds used by the top 10 per cent of people is increasing over time: six years ago, 10 per cent of people accounted for 79 per cent of spending[5].

Finally, sheer affordability remains an issue. Emeritus Professor Peter Davis argues that New Zealand would have to treble the current pharmaceutical budget just to match the prices Australia pays[6]. Expanding Pharmac's budget will require cutting spending in other areas.

The Pharmac model was meant to take the politics out of pharmaceuticals. Yet in the absence of a Medicines Strategy, political parties have made promises to treat certain diseases or fund certain pharmaceuticals outside of the Pharmac model, without the need for any proper analysis or rigour.

A Medicines Strategy is needed so that New Zealanders get a fair deal. That means:

- Ensuring New Zealanders get timely and affordable access to medicines
- Ensuring that the government is spending taxpayers' money more effectively than if the taxpayer could spend their own money
- Prioritising within a fixed budget
- Managing the regulatory environment so to remove unnecessary barriers to access.
- Ensuring that the voice of patients is considered in Pharmac's decisions.

What will the strategy include?

Developments in medicines and medicines markets

An analysis of developments in medicines and medicines markets, and description of the government's role (and the role of specific institutions) in adapting to these changes.

New Zealand is at the bottom of OECD rankings on a number of measures of access for new drugs. As discussed earlier in this paper, there are reasons to be cautious of calling for more and faster access if the evidence base is not yet available. Yet there are still fundamental questions that policymakers to date have failed to grapple with, which the Medicines Strategy will require them to focus on.

The Strategy's analysis should include thoroughly setting out New Zealanders' unmet need for treatment. The Ministry of Health should develop an understanding of what the new medicines are offering, the state of the evidence base, and how other countries are managing costs in this area. The economics of pharmaceutical markets matters too. The Ministry of Health should develop an understanding of how prices change over time, and the main causes of those changes.

This analysis should help inform the view of what the government's role should be in adapting to these changes: is it a wait-and-see approach? Are there feasible options for funding? The Strategy may include recommendations on whether the Pharmac model could be adapted.

2. https://www.nzinitiative.org.nz/reports-and-media/reports/policy-point-pharmac-should-not-be-criticised-simply-for-being-selective-and-slow-about-the-medicines-it-funds/document/807
3. https://www.raps.org/News-and-Articles/News-Articles/2019/7/German-Study-Finds-Most-New-Drugs-Fail-to-Improve
4. https://www.bmj.com/content/371/bmj.m3434
5. https://pharmac.govt.nz/about/what-we-do/how-pharmac-works/mythbusting-pharmac/
6. https://www.nzherald.co.nz/nz/peter-davis-pharmac-and-the-dark-shadow-of-adversarial-politics/5CBUCWGF4ZHSDAL7E5BIAEWQYA/

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Funding might also occur outside the Pharmac model, but there would need to be a justification of why doing so would be justified from the perspective of the taxpayer, and from an evidence-based approach.

Such analysis, and a clear articulation of how the government intends to respond, might also be used by private health insurers to understand how they can adapt their packages and offerings to address the inevitable gaps that occur when the government must work within a fixed budget. Though they are unlikely to have the commercial clout of Pharmac, private insurance companies might also be able to negotiate lower prices for consumers if they agree to insure some drugs and not others.

Performance benchmarking of Pharmac

Pharmac will be subject to regular performance reporting and international benchmarking.

It is difficult to get a true sense of whether Pharmac's performance is up to scratch unless there is systematic benchmarking. At the moment, it is difficult to conclude how effective Pharmac is compared to other countries unless it is benchmarked against a range of measures. As Dr Bryce Wilkinson argues, "Pharmac is often criticised for not funding enough new medicines and for being too slow to determine which ones it will fund. However, being slow and focused is not proof of being too slow or too focused"[7].

Performance benchmarking would not only be informative from the perspective of policymakers, but would also help contribute to a more evidence-based public debate on whether Pharmac is meeting taxpayers' expectations. Indicators that the Ministry of Health would publish include:

- Long term productivity gains from pharmaceutical funding decisions (for example, measuring long term benefits from pharmaceutical funding decisions can inform decision making that frees up hospital beds faster, or enables people to live independently, reduces carer burden and return to work or study sooner.)
- Productivity losses incurred from illnesses, in the time taken between a pharmaceutical being put on the Options for Investment list, and it being subsidised
- The range of illnesses and diseases treated by subsidised pharmaceuticals, compared with , the range of illnesses or diseases where no subsidised treatment is available.
- Price performance against that of top medicine procurers in other countries.

World-class regulatory approval speeds

A regular analysis of what regulatory regimes have comparable or more robust systems compared with New Zealand, to ensure Medsafe is not wasting time performing the same work that these bodies have already completed. Medsafe would be required to approve within one week any drug or medical device that has been approved by two foreign regulatory bodies with comparable or more robust systems compared with New Zealand.

One of the impediments to getting access to new drugs faster in New Zealand is Medsafe, which gives regulatory approval for medicines and medical devices.

The average time for Medsafe to consent an application for a high risk medicine is 630 days. For intermediate risk, it is 661 days and for lower risk it is 830 days[8]. The average time taken just for processing some lower risk categories is 176-210 days.

This is an unacceptable length of time, given there other regulatory bodies replicating that exact same work overseas.

ACT says if a drug or medical device has been approved by any two reputable foreign regulatory bodies (such as Australia, United States, United Kingdom), it should be automatically approved in NZ as well within one week unless Medsafe can show extraordinary reason why it shouldn't be.

This simple change would significantly improve access to medicines that have already been subject to rigorous testing and analysis through other regulatory regimes.

The Strategy would include a working list of international regulatory regimes that have comparable or more robust systems compared with New Zealand. It will also include an analysis of areas where international analysis might not be directly relevant to the New Zealand population: for example, if there are significant differences in population make-up that would distort medical efficacy.

7. https://www.nzinitiative.org.nz/reports-and-media/reports/policy-point-pharmac-should-not-be-criticised-simply-for-being-selective-and-slow-about-the-medicines-it-funds/document/807
8. https://www.medsafe.govt.nz/regulatory/Performance1Jul2022-30Jun2023.pdf

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Access to over the counter medicine

Require post-implementation evaluations of pharmacist-only and prescription-only classifications for medicines used to cure common ailments. The evaluation would take into account the latest evidence, review whether the policy has achieved the envisioned outcomes, and ensure the benefits outweigh the costs of limiting New Zealanders' access.

In 2011, the Government banned over-the-counter sales of medicines containing pseudoephedrine. In 2020, codeine was reclassified as a prescription-only medicine. Now in 2023, it is almost impossible buy cough medicine for a dry cough over the counter[9].

While individually there seem to be good reasons to restrict access to these products, the cumulative effect of banning so many different products is that it is now extremely difficult to access cold and flu medications.

The decision to restrict pharmaceuticals is most often done from a risk-based perspective: could restricting certain medications reduce the risk of harm, either from a medical perspective or social perspective? While the consideration of possible risk is important, it is not the full picture. Restricting access by designating a pharmaceutical prescription-only and pharmacist-only has costs that would not be picked up on in a pure health-based analysis.

Reducing access increases costs for the consumer. Having to gain a prescription requires the cost of a doctor appointment, which in turn increases the strain on GP clinics. Pharmacy-only medications also make it more difficult for people to purchase medications on behalf of others. For example, a family member picking up some medication for an elderly person who cannot readily leave the home. It is also out of step with new technologies, which enable online purchases and home delivery of medications.

The Ministry of Health will be required to offer recommendations on how the same outcomes can be achieved more efficiently and at a lower cost to consumers.

If the medicine has restricted access because it poses risks to the user (which appears to be the case with dry cough medicine) the Ministry of Health should explore options for how to best reflect that risk. At the moment, policymakers are relying on the increased inconvenience deterring people. However, there are more effective ways of ensuring patients are aware of risks. For example, rather than requiring patients to have a consultation with a pharmacist, patients purchasing goods online might instead have to agree to an online declaration that they understand the risks associated with the medicine.

9. *https://www.stuff.co.nz/business/131378093/medsafe-seeking-advice-on-cough-medicine-after-it-was-banned-in-australia-and-france*