Regulatory Impact Statement: Increasing the maximum prescription duration

Coversheet

Purpose of Document	
Decision sought:	Agreement to amend the Medicines Regulations 1984 to increase the prescription duration limit (period of supply), to allow prescribers to issue longer prescriptions.
Advising agencies:	Ministry of Health | Manatū Hauora
Proposing Ministers:	Hon Simeon Brown, Minister of Health
Date finalised:	21 November 2024

Problem Definition

The current prescription duration limit, of 3 months, is unnecessarily restrictive for patients with stable, well-managed conditions. This limits access to medicines by requiring practitioners to issue new prescriptions every 3 months, even when no additional clinical review of the patient is necessary. Issuing new prescriptions comes at a cost for patients and creates additional administrative work for practitioners. Prescribers would likely issue longer prescriptions, when appropriate, if the law allowed.

Executive Summary

Regulation 39A(1) of the Medicines Regulations 1984 (the Regulations) sets a limit for the period of supply (from here referred to as the "prescription duration limit") of prescribed medicines, of up to 3 months (oral contraceptives are the only exception as they can be prescribed for up to 6 months). A 3-month prescription is considered reasonable for most patients as the medicine is required for a short-term issue or regular clinical review is needed to adjust type or dosage. However, for patients with long-term, stable conditions this limit creates an unnecessary administrative and financial barrier to access their medicines.

There are a range of regulatory approaches used in other countries to manage prescriptions and dispensing of medicines. New Zealand's current limit of 3 months is relatively short when compared to other countries, particularly Sweden, Norway, USA and the UK where 12-month prescriptions are authorised.

In addition to the status quo, this Regulatory Impact Statement (RIS) considers options to increase the prescription duration limit to 6-months or 12-months. The Regulations do not currently set a specific dispensing limit – this is the maximum amount of medicine that can be dispensed (provided to) a patient at one time. However, in practice this limit is determined by the prescription duration limit, of 3 months. All options in this RIS include retaining the dispensing limit of 3 months, as this is considered an appropriate limit and increasing this limit is not necessary to achieve the policy objectives.

These objectives are to:

a. Improve access to medicines by allowing for a longer maximum prescription period;

b. Maintain appropriate clinical oversight;
c. Alleviate pressures on the health system, including for prescribers, and;
d. Improve cost-effectiveness across the health system.

When considering these options, the Ministry consulted with affected stakeholders to understand the clinical and financial implications of the proposal. Through this consultation the Ministry received **132** submissions from individuals and organisations. Most submissions came from medical practitioners and pharmacists, or organisations representing those professions. The Ministry also worked closely with Pharmac and Health NZ to estimate the likely financial impacts for patients, health providers and the government from this proposal.

Concerns were raised by practitioners that an increase to a 12-month limit could increase risk to patients from inappropriate prescribing, reduce quality of care due to less frequent clinical review and negatively impact general practice revenue. Some submissions did suggest that an increase to 6-months would mitigate these concerns to an extent.

Increasing the prescription duration limit will provide more flexibility for prescribers to determine how long patients can continue on their medicines between clinical reviews. Prescribers are still required to only prescribe what is appropriate and safe for each individual patient. On balance, the Ministry prefers an increase to 12 months due to the greater cost savings for patients and the associated benefits to the health system from improved medicine adherence.

Limitations and Constraints on Analysis

In September 2024, Hon Dr Shane Reti, Minister of Health, requested advice from the Ministry of Health (the Ministry) on expediting a proposal to allow prescribers to issue prescriptions for longer than the current limit of 3 months. This proposal was to be considered by Cabinet as part of a package of primary care initiatives in November 2024.

Given the timeframe, the Ministry conducted a short, targeted consultation with key stakeholders. The Ministry sought feedback from responsible authorities (regulators), professional organisations, medical colleges, clinical networks and general practice networks on a proposal to increase the prescription duration limit to 12 months. Many submitters expressed that there was not sufficient time to provide detailed feedback on the proposal.

The Ministry worked with Pharmac and Health NZ on modelling the financial implications for patients, health providers and the government. There is significant uncertainty associated with this modelling as multiple factors can affect demand for medicines and co-payment revenue, including underlying population growth, ageing, epidemiology, patient and prescriber behaviours, and pharmacy business practices (particularly the practice of paying prescription co-payments on patients' behalf). It is also unknown how the change to a regulatory limit will impact patient and prescriber behaviour.

Responsible Manager(s)

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Ministry of Health

Date signed out: 21 November 2024

Quality Assurance (completed by QA panel)	
Reviewing Agency:	
Panel Assessment & Comment:	The Ministry of Health QA panel has reviewed the Impact Statement titled *"Increasing the maximum prescription duration",* produced by the Ministry of Health and dated November 2024. The panel considers that the Impact Statement **Meets** the quality assurance criteria. The Impact Statement is clear, concise, complete, and convincing. The analysis is balanced in its presentation of the information."

Section 1: Diagnosing the policy problem

What is the context behind the policy problem and how is the status quo expected to develop?

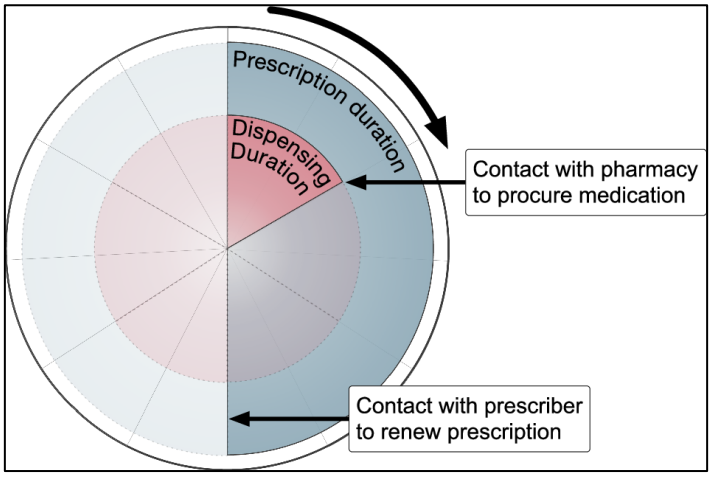
Background

1. The Government Policy Statement on Health 2024-2027 contains the objective to improve patient access to medicines. There is also a focus on timeliness and access to primary and community health care services, which must be achieved by supporting and enabling the health workforce to deliver services.
2. The purpose of the medicines regulatory system in New Zealand is to ensure sustainable access to, and appropriate use of, safe, effective, quality-assured, and affordable medicines and pharmaceutical services that contribute to better health care delivery systems.
3. In support of the Government's objectives and expectations for the health system, an opportunity was identified to make the medicines prescribing and dispensing system more efficient, by allowing prescribers to issue prescriptions for longer than the current limit of 3 months.
4. Increasing the prescription duration limit has been previously explored. In 2011, the government considered increasing the limit to 6-months, however, chose not to progress at the time due to the cost and difficulty in implementing IT changes to accommodate longer prescriptions.

Prescribing and dispensing durations

5. **Prescription duration** is defined as the entire period of treatment, based on the quantity of medicine, for which a health care provider may prescribe a medicine (which may or may not include several repeat dispensings).
6. **Dispensing duration** is defined as the period of treatment for which a pharmacist may dispense the medicine at a single time point. **Figure 1** illustrates the concepts of prescription duration and dispensing duration.

Figure 1: Prescription duration and dispensing duration[1]



[1] af Geijerstam P, et al., 2024

International context

7. Dispensing duration varies between countries, with 30, 60, or 90 days being the most common. **Figure 2** shows the maximum prescription and dispensing durations of medicines for chronic conditions in several jurisdictions.

8. Prescription duration limits vary internationally. New Zealand's current limit of 3 months is relatively short when compared to other countries, particularly Sweden, Norway, USA and the UK where 12-month prescriptions are authorised.

9. These countries manage the risks associated with longer prescriptions in different ways. In Australia, the 12-month maximum prescription duration is limited to medicines for stable, ongoing health conditions.

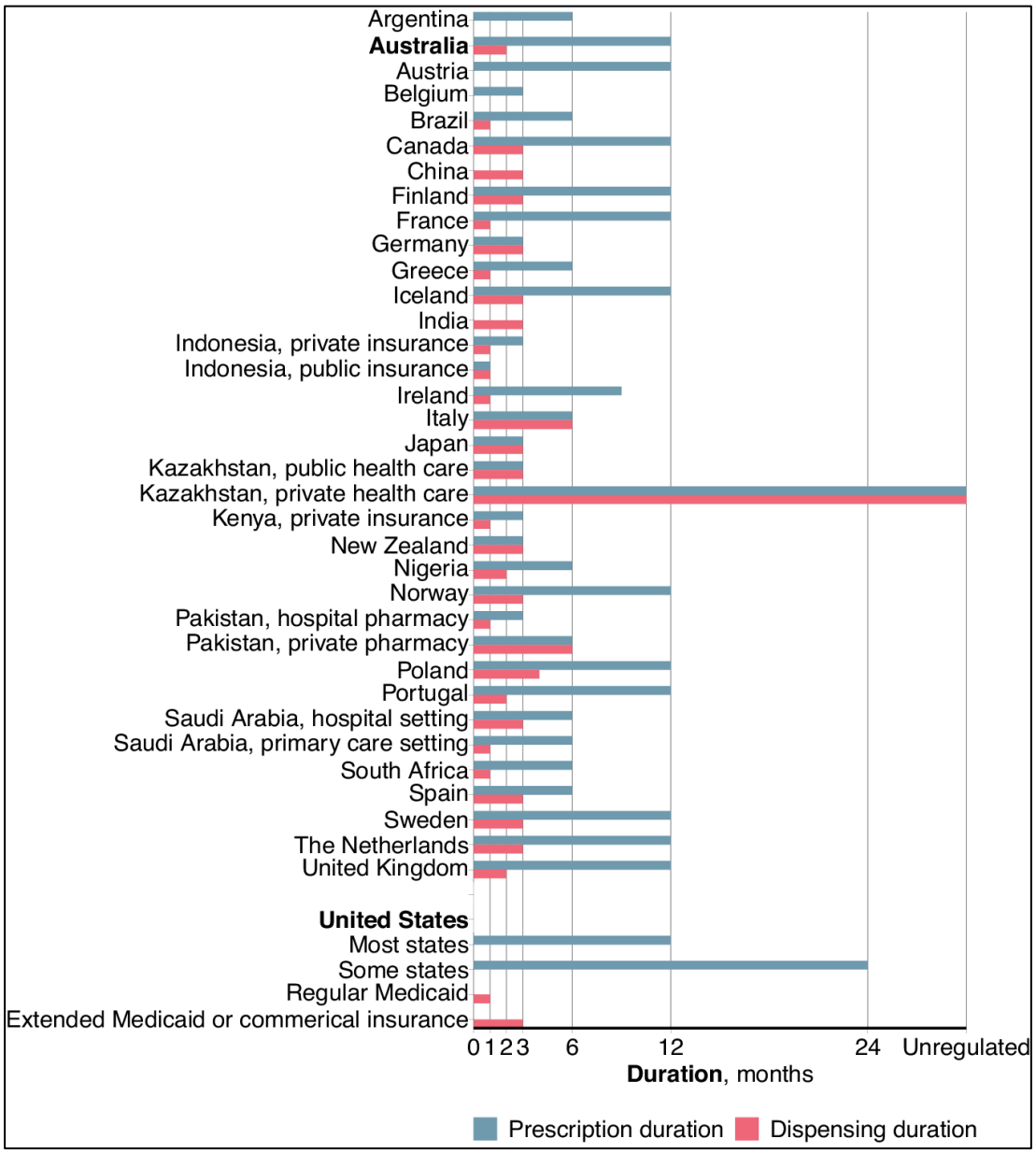
10. In 2023, Australia made changes to the **dispensing limit** to allow patients with stable, long-term conditions to receive 60 days' supply of their medicine at once. Australian regulation allows multiple repeats on prescriptions (up to 5), so the recent changes enabled these patients to receive up to 12 months' supply of their medicine on a single prescription (at 60-day intervals).

11. The changes in Australia were introduced gradually in 3 stages over 12 months, with the final stage on 1 September 2024. The full list of medicines deemed as safe and suitable for 60-day prescriptions was recommended by the independent Pharmaceutical Benefits Advisory Committee (PBAC), and now contains approximately 300 medicines.

12. The changes in Australia are too recent for a formal evaluation of the impacts, but Australian health officials reported to us that no significant issues have arisen, and uptake of the increased limits has been steadily increasing.

13. Due to the different funding and regulatory mechanisms, the implementation of changes in Australia would not be easily replicated here. However, the successful implementation does provide some confidence for increases to prescription duration limits in New Zealand.

Figure 2: Jurisdiction comparison of maximum prescription and dispensing durations



Source: af Geijerstam P, et al., 2024

Duration limitations are by law, guidelines, or subsidy programme requirements, or if not regulated, as advocated or customary. For some countries, regional examples are used when regulations vary depending on region. Actual durations may be shorter or longer depending on practising cultures and traditions, as well as medicines package sizes, adherence, and dosage.

Current context in New Zealand

Prescribing

14. Prescribers are authorised to determine the total quantity of supply of a medicine for an individual, within maximum legal limits.

15. Under regulation 39A(1) of the Medicines Regulations 1984, an authorised prescriber may only prescribe a 3-month supply of any prescription medicine (except for an oral contraceptive, in which case 6 months' supply may be prescribed). This is referred to in the Regulations as the 'period of supply,' this document will refer to this as the 'prescription duration limit.'

16. The prescription duration limit is intended to serve two purposes:

    a) encourage regular clinical review for patients taking medicines long-term; and

    b) reduce medicines wastage from patients receiving potentially unnecessary medicines.

17. For patients taking medicines long-term, a renewal prescription must be written every 3 months (or more frequently if determined by the prescriber or Pharmaceutical Schedule funding rules). The renewal prescription may be issued by the prescriber during a consultation with the patient, or it may be approved once requested by the patient via a phone call or mobile app.

18. While the need for a renewed prescription provides the opportunity for clinical review, the Regulations do not mandate that one take place. It is the prescriber's discretion to determine what information they require before deciding to issue a new prescription.

Dispensing

19. There is no specific limit in the Regulations for how much medicine can be dispensed (provided to the patient) at one time. Instead, this is also restricted by the prescription duration limit of 3 months.

20. The are additional rules relating to how medicines are dispensed set out in various parts of the Pharmaceutical Schedule.

21. Under the Pharmaceutical Schedule, default dispensing is in a single 'lot'. This usually means a 90-day (3-month) supply (180 days or 6 months for an oral contraceptive).

22. Under the Pharmaceutical Schedule, certain medicines must be dispensed in monthly lots, generally due to high cost or limited supply. There are exceptions to limited dispensing requirements, such as if the prescriber or pharmacist endorses the prescription, or if the patient qualifies for an access exemption due to factors such as limited mobility, distance from the pharmacy, relocation, and travel.

Costs to patients

23. Patients often pay for a consultation to obtain a prescription from a prescriber, such as a general practitioner (GP).

24. Patients on regular medicines may request a prescription renewal without a consultation, for which there is generally a lower fee. Prescription renewal fees differ by practice but can be around $15 - $35 per prescription, or $40 for an urgent, same-day prescription (for enrolled patients).

25. Patients are also required to pay a prescription co-payment fee (usually $5) when their prescription is dispensed for the first time. Repeat dispensings, using the same prescription, do not attract a prescription co-payment fee. Patients aged under 14, aged 65 and over, or with a Community Services Card are exempt from the $5 charge. Once a person or their family have collected 20 paid prescriptions in a year, they can get a Prescription Subsidy Card, meaning they will not have to pay any more prescription charges for the rest of the year.

26. Some major chains of pharmacies (Bargain Chemist, Chemist Warehouse, and Woolworths Pharmacy) do not collect the prescription co-payment from the patient. Instead, these businesses pay the cost on the patients' behalf.

Funding access to medicines (Pharmac and Health NZ)

27. Pharmac is the agency responsible for funding medicines in New Zealand. This is managed through the Combined Pharmaceutical Budget (CPB). This is a fixed budget which Pharmac must use to ensure funded medicines are available and accessible for New Zealanders.

28. Health New Zealand (Health NZ) contracts with community pharmacies to provide pharmacy services under the Integrated Community Pharmacy Services Agreement (ICPSA).

29. Under this agreement, there is a fixed fee structure for services. Community pharmacies are compensated under the ICPSA for a range of activities, relevant to this policy are the "Case Mix Service Fees." The fee structure assumes pharmacies receive a new prescription every 3 months, repeat dispensings on the same prescription are paid on a sliding scale. Repeats 4 – 12 on a prescription are paid at a lower rate than repeats 2 – 3.

What is the policy problem or opportunity?

30. Under the current system, patients who take long-term medicines for stable, ongoing health conditions are required to interact with their prescriber (such as a GP) at least four times a year to obtain a new prescription. For many patients this creates an inconvenience, and for some this may be unaffordable, potentially leading to non-adherence to medicines.

31. There is an opportunity to improve patient access to medicines, patient experience, and medicine adherence through lower cost and improved convenience.

32. Patients with chronic illnesses experience an additional burden from managing their treatment.[2] In addition to managing their medicines and monitoring their effects, patients need to organise visits to their doctor/s, any relevant laboratory tests, and to feedback information to other health care providers. This work is costly and time intensive. Their experience is likely to be improved by reducing barriers to accessing prescribed medicines.

33. The administrative burden and cost associated with long-term medicine use can contribute to reduced adherence.[3] Medicine adherence refers to patients continuing their use of a medicine as prescribed by a practitioner. Improving adherence through reducing these barriers can support better health outcomes and lower health care costs, contributing to efficiencies across the health system.

34. There are complex, interdependent reasons for why patients may not take prescribed medicines. Reasons include the processes for obtaining and filling prescriptions and any financial costs to the consumer.[4]

35. Patients with chronic conditions such as hypertension, diabetes, and asthma are particularly vulnerable to poorer health outcomes if they do not continue with their

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[2] May C, Montori V M, Mair F S. We need minimally disruptive medicine. BMJ. 2009. https://www.bmj.com/content/339/bmj.b2803

[3] Tordoff JM, Brenkley C, Krska J, Smith A. Exploring Medicines Burden Among Adults in New Zealand: A Cross-Sectional Survey. Patient Prefer Adherence. 2019. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6930007/

[4] Khan R, Socha-Dietrich K. Investing in medication adherence improves health outcomes and health system efficiency: Adherence to medicines for diabetes, hypertension, and hyperlipidaemia. OECD Health Working Papers, No. 105. 2018. https://doi.org/10.1787/8178962c-en

prescribed medicines. Poor adherence also leads to an increased burden on secondary care services, such as outpatient care, emergency department visits, and hospitalisations, especially among patients with the most prevalent chronic conditions.

36. In New Zealand, higher levels of chronic conditions are experienced by Pacific peoples, Māori, and those of low socioeconomic status.[5] These groups experience a high treatment burden, with associated costs and other barriers (such as less access to health services) which undermine adherence.

37. There are many benefits across the health system that arise from greater medicines adherence[6]:

- Health outcomes: Mortality rates for patients with diabetes and heart disease who do not adhere are almost double compared to patients who do adhere. Patients who do not adhere to medicines prescribed by their health practitioner are also more likely to experience further health complications.
- Pressures on the health system: Non-adherence to prescribed medicines places additional pressures on the health system via increased use of health care services, including hospitalisation.
- Cost-effectiveness: Research demonstrates that greater adherence to prescribed medicines is cost effective for a number of chronic conditions, including hypertension (average cost-benefit ratio of 1:13.5) and diabetes (1:8.6), even after accounting for any increase in spending on medicines.

38. The current system also adds to the high workload for general practice and some other prescribers. There may also be pressures on emergency departments from patients unable to access primary care when a new prescription is due. There is an opportunity to alleviate pressures on the health system, in particular primary care.

What objectives are sought in relation to the policy problem?

39. There are four objectives sought in relation to the policy problem:

    a. **Objective 1:** Improve access to medicines;
    b. **Objective 2:** Maintain appropriate clinical oversight;
    c. **Objective 3:** Alleviate pressures on the health system, including for prescribers, and;
    d. **Objective 4:** Improve cost-effectiveness across the health system.

40. Objectives 1 and 3 favour a longer maximum prescription period, which is expected to reduce barriers for patients and alleviate pressures on prescribers. However, there is a balance to be made with maintaining appropriate clinical oversight (Objective 2). Objective 4 takes a system-wide lens in considering costs and benefits to patients, providers, and the Government.

[5] Sheridan NF, Kenealy TW, Connolly MJ, Mahony F, Barber PA, Boyd MA, et al. Health equity in the New Zealand health care system: A national survey. International Journal for Equity in Health. 2011.

[6] Khan, R. and K. Socha-Dietrich (2018), "Investing in medication adherence improves health outcomes and health system efficiency: Adherence to medicines for diabetes, hypertension, and hyperlipidaemia", *OECD Health Working Papers*, No. 105, OECD Publishing, Paris, https://doi.org/10.1787/8178962c-en.

Section 2: Deciding upon an option to address the policy problem

What criteria will be used to compare options to the status quo?

41. **Access to prescribed medicines**: Patients, particularly those with stable ongoing health conditions, should be able to access regular medicines without undue time and cost burdens. Reducing these burdens is expected to increase patient adherence to prescribed medicines, which will improve health outcomes.
42. **Clinical oversight**: Prescribers should retain the choice of clinically appropriate prescribing, ensuring closer monitoring of patients where clinically required, so as to not compromise patient safety.
43. **Health system pressures**: The option should go some way to relieve pressures on the health system, both in the short-term (e.g. reducing administrative work for prescribers working in primary care) and the long-term (e.g. fewer hospitalisations, reduced demand for secondary care services).
44. **Financial impacts on health providers**: The option should minimise financial impacts on providers, particularly general practices and community pharmacies.
45. **Efficient use of medicines**: The option should minimise medicine wastage.

What scope will options be considered within?

46. The scope of options has been limited by the Government's direction to consider an increase to the prescription duration limit and the tight timeframe. Other options that may achieve the identified objectives (e.g. changes to the $5 prescription co-payment) have not been considered.
47. These options are also being assessed under the assumption that there will be no reduction in the amount charged to patients for initial prescription (currently set at $5 per initial prescription). Under current settings patients pay a $5 prescription co-payment for the first (initial) dispensing on a prescription (unless this is paid by the pharmacy). The Ministry understands that the government intends to apply $5 prescription co-payments for repeat dispensings every 3 months.
48. Health NZ has raised that implementing this change to prescription co-payments will require some significant changes to the payment system, ProClaim, and pharmacy vendor systems.

What options are being considered?

49. The options discussed in this section are:
    - **Option 1** – status quo.
    - **Option 2** – increase the prescription duration limit to 12 months.
    - **Option 3** – increase the prescription duration limit to 6 months.

Increased prescription duration limit in practice

50. Both options being considered are increases to a limit within the Regulations. Prescribers retain the authority to determine an appropriate prescription amount and dispensing schedule, within the legal limit.
51. **Figure 3** and **Figure 4** show the number of prescriptions and dispensings required to obtain a medicine over a 12-month period under each option, with single lot and monthly dispensing under the Pharmaceutical Schedule respectively.
52. These figures are examples of likely dispensing timelines for patients provided the maximum prescription length.

Figure 3: Number of prescriptions and dispensings required to obtain a medicine over a 12-month period (single lot dispensing under the Pharmaceutical Schedule)

	Month												Total
	1	2	3	4	5	6	7	8	9	10	11	12	
Status quo	**P** ID			**P** ID			**P** ID			**P** ID			**4x P** 4x ID
12-month prescription limit (Option 2)	**P** ID			RD			RD			RD			**1x P** 1x ID 3x RD
6-month prescription limit (Option 3)	**P** ID			RD			**P** ID			RD			**2x P** 2x ID 2x RD

ID: Initial Dispensing; P: Prescription; RD: Repeat Dispensing.

Figure 4: Number of prescriptions and dispensings required to obtain a medicine over a 12-month period (monthly dispensing under the Pharmaceutical Schedule)

	Month												Total
	1	2	3	4	5	6	7	8	9	10	11	12	
Status quo	**P** ID	RD	RD	**P** ID	RD	RD	**P** ID	RD	RD	**P** ID	RD	RD	**4x P** 4x ID 8x RD
12-month prescription limit (Option 2)	**P** ID	RD	RD	RD	RD	RD	RD	RD	RD	RD	RD	RD	**1x P** 1x ID 11x RD
6-month prescription limit (Option 3)	**P** ID	RD	RD	RD	RD	RD	**P** ID	RD	RD	RD	RD	RD	**2x P** 2x ID 10x RD

ID: Initial Dispensing; P: Prescription; RD: Repeat Dispensing.

Option 1 – Status quo

53. Under the status quo, the maximum prescription duration is 3 months (6 months for oral contraceptive). Prescriptions can generally be dispensed in a single lot to patients (referred to as “stat medicines”), unless there are specific restrictions under the Pharmaceutical Schedule.

54. For monthly dispensing medicines, patients will often receive a 1-month initial dispensing with 2 repeats.

55. Patients are required to request a new prescription every 3 months. It is up to the prescriber whether any clinical review is necessary before issuing a new prescription.

Option 2 – Increase the maximum prescription period to 12 months (preferred option)

56. Option 2 proposes to increase the maximum prescription period for all medicines (excluding controlled drug medicines), from 3 to 12 months. There would be no change to the current dispensing limit of 3 months.

57. This proposal would require an amendment to the Medicines Regulations 1984, which can be done by Cabinet via an Order in Council.

58. Under this option, prescribers can issue a 12-month prescription if they decide it is clinically appropriate for a patient. For single lot dispensed medicines, patients can receive a 3-month initial dispensing with 3 repeat dispensings (each of 3 months). For monthly dispensing medicines, patients can receive a 1-month initial dispensing with 11 repeat dispensings.

Option 3 – Increase the maximum prescription period to 6 months (scaled down option)

59. Option 3 proposes to increase the maximum prescription period for all medicines (excluding controlled drug medicines), to 6 months. As with Option 2, the current dispensing limit of 3 months would be retained.

60. This proposal would require an amendment to the Medicines Regulations 1984, which can be done by Cabinet via an Order in Council.

61. For the 6-month maximum prescription period, prescribers will be able to issue a 6-month prescription. For single lot dispensed medicines, patients can receive a 3-month initial dispensing with 1 repeat dispensing. For monthly dispensing medicines, patients can receive a 1-month initial dispensing with 5 repeat dispensings.

Impacts from increasing the prescription duration limit

Access to prescribed medicines

62. Both Options 2 and 3 will help patients to access prescribed medicines by making it easier and more affordable to do so.

63. We expect Options 2 and 3 will primarily benefit people with chronic conditions. Provided their prescriber determines that it is clinically appropriate, patients with stable, ongoing health conditions will be able to receive longer prescriptions, thereby reducing the number of interactions they have with their prescriber. Such interactions have costs for patients, namely prescription renewal fees (charged by prescribers when a patient needs to continue their medicines but does not need a full consultation).

64. Both options will result in consumer savings. For Option 2 estimated to be between $45 and $105 per year (for an average patient, with a chronic condition, taking long-term prescribed medicines).[7]

65. Research shows that fees can be a barrier to medicine adherence, particularly for low-income patients.[8] Options 2 and 3 may therefore improve adherence, which will improve health outcomes. Improved adherence results in decreased progression of disease, reduced risk of treatment failure, reduced emergency department attendance and hospitalisation, enhanced quality of life, cost savings, and patient empowerment.

66. Access to prescribed medicines will still be restricted by the 3-month dispensing limit. This limit is deemed necessary to reduce the risk of medicine wastage from unused medicines and manage medicine supply issues. A dispensing limit has an additional benefit of providing an opportunity for oversight from a pharmacist to identify changes in patient need.

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[7] Based on a prescription renewal range of $15 - $35

[8] Khan, R. and K. Socha-Dietrich (2018)

67. However, through consultation on this proposal some pharmacists noted that longer prescriptions may increase their role in managing clinical risk for patients with chronic conditions. Pharmacists expressed that this would be challenging given current resourcing and capacity constraints.

68. Pharmac will continue to restrict certain funded medicines for 1 month dispensing to further manage supply issues.

Clinical oversight

69. Increasing the prescription duration limit will mean that some patients will have less frequent clinical reviews. This could lead to changes in a patient's condition not being identified and medication plans not being updated promptly.

70. The Medical Council's *Good Prescribing Practice Guide* states: "Patients receiving repeat prescriptions should be assessed in person on a regular basis to ensure that the prescription remains appropriate, adverse effects are monitored, and the patient is taking or using their medicines as intended. Patients who need a further examination or assessment should not receive repeat prescriptions without being seen by a doctor. This is particularly important in the case of medicines with potentially serious adverse effects. It is at the doctor's discretion whether a patient is given a repeat prescription. Decisions not to issue a repeat prescription should be explained to the patient and documented accordingly."

71. Under the proposal, the duration of a prescription will still depend on the prescriber's clinical assessment of the individual patient. Health practitioners with prescribing authority are required to ensure that they meet their professional standards and always act in their patient's best interests. Therefore, regardless of the maximum limit that is within regulation, practitioners are required to only prescribe for a duration that is appropriate for the individual patient.

72. For example, under Option 2, a prescriber would still be able to issue a 3-month (or shorter) prescription if they determined that the patient would benefit from a review at this earlier time. However, if they deemed that the patient's condition is stable and a clinical review within this timeframe would be unnecessary, then they would have the option to write a prescription for up to 12 months.

73. It is anticipated that prescribers would only administer longer-term prescriptions to patients with ongoing, stable health conditions, for whom a clinical review every 6, 9, or 12 months would be appropriate. There will not be a set list of conditions and medicines available for longer-term prescribing, however guidance to this effect could be issued by prescribing practitioners' Responsible Authorities.

74. Through consultation with the Ministry, practitioners raised concerns prescribers will face increased pressure from patients to provide longer prescriptions if the maximum duration is increased. There are obvious incentives for patients to request longer prescriptions due to the high cost of obtaining new prescriptions.

75. While it is reasonable to expect some patients to request longer prescriptions, even when it may not be clinically appropriate, this does not represent a significant change from existing pressures that practitioners may be placed under to prescribe medicines.

76. Prescribers are highly trusted practitioners due to the high professional standards and responsibility. In all cases, prescribers should be able to explain the clinical reasoning for the length of prescriptions issued.

77. Practitioners can be supported to make good prescribing decisions through best practice clinical guidelines. Their respective Responsible Authorities (RAs) can set standards and incorporate these into practitioners' scopes of practice. Practitioners who work in teams (e.g. in a diabetes clinic or aged care service) can set protocols for their practice to ensure appropriate clinical decision-making input and review, including reviewing medication plans.

78. Pharmacists have a key clinical role in medicine supply as they provide clinical oversight of patients when accessing their medicine. Retaining a dispensing maximum of 3 months will also ensure that patients still need to frequently collect their medicines and interact with a health practitioner.

Health system pressures

79. As is described above, we expect there to be greater medicine adherence from Options 2 and 3, which in turn is predicted to reduce wider health system pressures.

80. Increased levels of medicine adherence are associated with a reduction in the risk of health complications and less use of emergency care and secondary care services (OECD). This is particularly true among patients with chronic conditions (e.g. diabetes, hypertension, and congestive heart failure). For instance, it has been estimated that medicine non-adherence in the United States costs the health system $105 billion per year from avoidable hospitalisations.[9]

81. Research has demonstrated that improving medicine adherence among patients with chronic conditions is cost effective for the health system, even after accounting for any increase in demand for (and thus expenditure on) medicines. Across a range of chronic health conditions, average cost-benefit ratios have been calculated as between 1:3.8 (hyperlipidaemia) and 1:13.5 (hypertension) (OECD).

82. It is known that general practice workload in New Zealand has been increasing, with high rates of burnout. According to the RNZCGP's 2022 Workforce Survey, GPs are on average working unpaid for 7.2 hours per week.

83. Increasing the maximum duration of prescriptions will reduce the administrative requirements associated with processing repeat prescriptions. However, we heard through consultation that GPs often assess patient repeat prescription requests outside of their normal working hours. As such, Options 2 and 3 may reduce some administrative tasks but may not increase capacity for primary care practices.

84. There is a risk that existing workload pressures may be an incentive for GPs to write longer prescriptions than would be clinically appropriate. However, for the reasons outlined in the previous section on clinical oversight, we do not expect this to have a significant impact on prescriber behaviour.

85. If either of Options 2 or 3 is chosen, we expect there to be minimal impact on community pharmacists' workload as a direct result of longer prescriptions. However, as longer prescribing becomes more commonplace, it is possible that a greater burden will fall on pharmacists to clinically assess patients when they collect repeat dispensings.

86. Although under both options, there is predicted to be an increase in the amount of medicines dispensed, thereby increasing pharmacists' workload, this will be offset by a reduction in the ratio of initial:repeat dispensings (noting that repeat dispensings typically require less work from pharmacists than initial dispensings).

Financial impacts

On primary care (e.g. general practice)

87. Owing to a reduced volume of repeat prescription requests, it is reasonable to expect some reduction in revenue for general practices. During sector consultation, it was highlighted that a reduction in revenue for general practice risked increasing the financial pressure on already stretched businesses.

[9] Khan, R. and K. Socha-Dietrich (2018)

88. For several reasons it is challenging to provide a reliable estimate on the overall expected reduction in revenue for general practice. This is primarily because we do not know how commonly 6- or 12-month prescriptions will be issued by prescribers.

Community pharmacies

89. For community pharmacies, there is expected to be a reduction in revenue associated with fewer initial dispensings and more repeat dispensings, as repeat dispensings are paid at a lower rate.

90. Under the Integrated Community Pharmacy Services Agreement (ICPSA), Health NZ contracts with community pharmacies to provide services. Due to the current fee structure under this contract, Options 2 and 3 will likely reduce revenue for pharmacies related to patients on long-term prescriptions.

91. Health NZ provided some modelling on the impacts for community pharmacies under the Options 2 and 3:

- Option 2 (12 months): Could reduce revenue by $14 million - $42 million (mid-range $28 million)
- Option 3 (6 months): Could reduce revenue by $8 million - $24 million (mid-range $16 million.

92. There is a great deal of uncertainty around these estimates, particularly due to uncertainty of how much and how quickly prescribers will adopt these longer prescriptions. In consultation with the sector, the Pharmacy Guild provided estimates on the potential loss of revenue for community pharmacies. Their analysis concluded a reduction within the range provided by Health NZ.

93. The overall impact for community pharmacies may be minimised by an increased demand for pharmacy services as a result of the lower costs for patients to receive prescriptions. However, if the fee structure remains as it is pharmacy will receive significantly less funding for the work they will be doing (per item dispensed).

Efficient use of medicines

94. As noted above, increasing the maximum prescription duration may lead to an increase in medicine wastage.

95. Medicine wastage is where medicines are dispensed to the patient but never used. Reasons why this may happen include non-adherence, changes in treatment or dose, allergic reaction or intolerance to the medicine, resolution of the condition or death of the patient. In a New Zealand survey completed by 452 people, 56% reported that they collect all items prescribed by their doctor, and just over 25% collect all medicine repeats, even if the medicine is no longer needed or wanted. Only 13% of respondents reported that they returned unwanted medicines to a pharmacy.[10]

96. Unused medicines end up accumulating in people's homes, where they can cause safety issues such as accidental or intentional overdose, inappropriate sharing of medicines or use of expired medicines which may no longer be effective. This is also an inefficient use of the Combined Pharmaceutical Budget.

97. Under Options 2 and 3, a patient may be more likely to collect all repeat dispensings on a 6- or 12-month prescription, as the cost for each dispensing will be $5 (from the prescription co-payment).

98. Again, the extent of this risk will depend on prescriber behaviour. It is expected that longer prescriptions would be written for patients with chronic conditions for medicines

[10] BPAC. Piles of pills: Prescribing appropriate quantities of medicines. 2015. https://bpac.org.nz/BPJ/2015/August/pills.aspx

that the patient has already been taking for some time, and that they are unlikely to stop taking. Many of the reasons for medicine wastage relate to short-term or new prescriptions; for example side effects of a new medicine, or dose adjustment early in treatment.

99. Under Options 2 and 3, the dispensing limit will be retained at 3 months. Pharmac will also continue to be able to designate medicines for monthly dispensing. This should effectively manage the risk of medicine wastage.

Consultation

100. The Ministry of Health with a range of key stakeholders on this proposal, including professional organisations, regulators, community pharmacies and general practices, primary health organisations,

101. Out of 132 respondents, most responses opposed the increase to prescription duration from 3 months to 12 months, only around 22 percent were in favour of the change.

102. However, around 31 percent of the respondents that opposed the change, supported changing prescription duration to 6 months. This group felt that six months would balance the cost saving for the patients while maintaining frequent clinical oversight.

103. Some key themes from the consultation were:

- Risk of reducing quality of care – due to a loss of opportunistic care
- Potential increased harm from medicines continuing without review
- Financial impact on general practice and pharmacy
- Pressure on prescribers to issue long prescriptions

Other options

104. Other options that could achieve these policy objectives, such as changes to prescription or general practice co-payments or additional funding for services have not been fully considered as alternatives at this time due to the limited scope and time constraints.

How do the options compare to the status quo/counterfactual?

	Option 1 – Status quo	Option 2 – 12-month maximum prescription duration	Option 3 – 6-month maximum prescription duration
Access to prescribed medicines	**0** Under the status quo, patients who take long-term medicines for stable, ongoing health conditions are required to interact with their prescriber at least 4 times a year to obtain a new prescription. For many patients this creates an inconvenience, and for some this may be unaffordable. Particularly affected are patients with chronic disease, who face a variety of socioeconomic and environmental barriers to achieving good health outcomes.	**++** Under this option, patients on regular medicines may only need to obtain one new prescription per year, if they have a condition that is appropriate for longer term prescribing. This may increase access to prescribed medicines by reducing the cost and administrative burden for patients. Increased access is expected to lead to increased medicine adherence, with associated health benefits for patients with chronic conditions.	**+** Under this option, patients on regular medicines may only need to obtain two new prescriptions per year, if they have a condition that is appropriate for longer term prescribing. The benefit in terms of access and adherence for patients with chronic conditions is expected to be less than the 12-month prescription duration option.
Clinical oversight	**0** Under the status quo, there is a legal requirement for prescribers to issue a new prescription after 3 months, to continue medicine access. Prescribers may insist on a full consultation or approving a repeat prescription request; the level of oversight is also determined by the prescriber. This frequency of clinical review may not be necessary in all cases,	**-** Under this option, prescribers are required to renew prescriptions less frequently, so clinical oversight may decrease. However, prescribers would only write 12-month prescriptions if they deem a 3-month review unnecessary. Adhering to professional standards, prescribers will continue to review as clinically necessary.	**-** As per the 12-month option, there would be a reduced legal requirement to review compared to the status-quo. Of a lesser scale than the 12-month option (1 more repeat prescription consultation/request required per year), however prescribers will continue to review as clinically necessary.

	Option 1 – Status quo	Option 2 – 12-month maximum prescription duration	Option 3 – 6-month maximum prescription duration
	especially for patient with ongoing, stable health conditions.		
Health system pressures	**0** For GPs, there is a significant workload associated with the legal requirement to issue new prescriptions every three months. As a result of access barriers, low medicine adherence leads to poorer health outcomes. Complications from chronic conditions lead to health system pressures, particularly for emergency care and secondary care services.	**++** Under this option the workload for GPs is expected to decrease due to a lower volume of repeat prescription requests, this is expected to be minimal. Due to a greater demand for medicines, there may be an increase in pharmacists' workload. However, this is expected to be balanced as they will have fewer initial dispensings and more repeat dispensings, which are generally less involved. In the longer term, increased access to prescription medicines for patients with chronic disease is expected to lead to better overall health outcomes. This may reduce pressures on the health system, particularly secondary care services.	**+** Impacts are expected to be similar to the 12-month option, but of a lesser scale.
Financial impacts on health providers	**0** In terms of the model for prescribing services, general practices gain revenue from patient consultation and repeat prescription fees, as well as capitation payments. Community pharmacy practices gain revenue from service fees for initial and repeat dispensings.	**--** Owing to a reduced volume of repeat prescription requests, a drop in GP practice revenue is expected. For pharmacists, there is expected to be a reduction in revenue expected associated with fewer initial dispensings and more repeat dispensings, as these are paid at a lower rate.	**-** Impacts are expected to be similar to the 12-month option, but of a lesser scale.

	Option 1 – Status quo	Option 2 – 12-month maximum prescription duration	Option 3 – 6-month maximum prescription duration
		Increased demand for medicines may offset the overall reduction in revenue for pharmacy.	
Efficient use of medicines	**0** Under the status quo, there is a level of medicine wastage from over-dispensing, where medicines are dispensed to the patient but never used. This is limited by maximum dispensing limits.	**0** With a reduction in barriers to obtain prescriptions, an increase in dispensings and in medicine wastage is expected. It is expected that the proportion of dispensed medicines that are wasted will not increase, particularly as patients are less likely to collect unwanted repeat dispensings. On the other hand, more medicines will be dispensed and used as prescribed.	**0** Impacts are expected to be similar to the 12-month option, but of a lesser scale.
Overall assessment	**0**	**++**	**+**

++: much better than doing nothing; **+**: better than doing nothing; **0**: about the same as doing nothing; **-**: worse than doing nothing; **- -**: much worse than doing nothing. Note: plus/minus ratings are for the purpose of reading the table at a glance, and are not meant to be added up with a conclusion reached based on a numerical calculation

What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

Option 2 (12 months) is the preferred approach

105. Increasing the prescription duration limit will enable patients with long-term, stable conditions to continue receiving their medicines, without requiring frequent renewals from their prescriber.

106. While there are likely to be financial impacts for providers in the short term from a change to the legal prescription duration limit, this does represent a reduction in cost for patients to access the medicines they need. In the long-term providers will likely adjust their business models to account for any change in revenue.

107. Option 3 (increase to 6 months) is a scaled down option that achieves some of the same objectives as Option 2, just to a lesser extent. It was also suggested through sector consultation as an option to mitigate some risk to patients from inappropriate prescribing, encourage more frequent clinical review, and to reduce the financial impact for prescribers.

108. Option 3 is a reasonable approach, particularly to reduce the financial impact for the government, which may be preferred in the current fiscal environment.

109. However, on balance we think that the increase to 12 months is the better option due to the more significant cost savings for patients and the associated benefits to the health system from improved medicine adherence.

What are the marginal costs and benefits of the option?

110. In addition to the cost savings for patients, there are financial implications from this proposal, including for government and private health providers.

111. There is significant uncertainty associated with the estimates (outlined below) as multiple factors can affect demand for medicines and prescription co-payment revenue, including underlying population growth, ageing, epidemiology, patient and prescriber behaviours, and pharmacy business practices (particularly the practice of paying prescription co-payments on patients' behalf).

Affected groups *(identify)*	**Comment** *nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks.*	**Impact** *$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.*	**Evidence Certainty** *High, medium, or low, and explain reasoning in comment column.*
Additional costs of the Government's preferred option compared to Option One			
Patients/Consumers	Possible that health providers increase costs for some services to account for **– High uncertainty** for this impact as the need to increase costs will vary between providers and competition for services will encourage lower prices.	Low	Low

Affected groups *(identify)*	**Comment** *nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks.*	**Impact** *$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.*	**Evidence Certainty** *High, medium, or low, and explain reasoning in comment column.*
Prescribers (e.g. GPs)	Ongoing reduction in revenue due to fewer prescription renewal consultation payments. There is low certainty for this impact as it is unknown how prescribers will use the increased limit. It is also likely that prescribers will increase other costs to account for the reduction in prescription renewals.	Low - Medium	Low
Community pharmacies	Reduction in revenue due to fewer initial dispensings and more repeat dispensings. There is relatively high certainty for this impact as it is based on an existing fee structure under a contract (the ICPSA) with Health NZ.	High $14m - $42m (mid-range $28m) Initial estimate – highly likely to change as the contract with pharmacy (ICPSA) is renegotiated.	Medium - High
Health New Zealand	Increase in the amount of dispensing fees paid to pharmacies (on-going, due to higher demand for medicines).	Health NZ estimates: approx. $20m – $39m per year	Medium
	One-off cost to upgrade IT systems (including ProClaim, Health NZ payment system, general practice management systems (PMS) and pharmacy management systems (PhMS)).	Unknown	High

Affected groups *(identify)*	**Comment** *nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks.*	**Impact** *$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.*	**Evidence Certainty** *High, medium, or low, and explain reasoning in comment column.*
	High certainty of the need to upgrade IT systems to accommodate 12-month prescriptions and to apply prescription co-payments every 3 months. However, costs unknown at the time of writing.		
Pharmac	Impact on the CPB due to higher demand for funded medicines. Pharmac has provided high level estimates of the impact on demand from reducing out-of-pocket costs for patients.	Initial Pharmac estimate: $32m - $61m Revised Ministry of Health estimate: approx. $20m	Medium
Additional benefits of the Government's preferred option compared to Option One			
Patients/Consumers	Ongoing benefits for patients/consumers –, fewer prescription renewal consultation payments (GP fees).	These fees are usually $15 - $35 each. Saving up to $105 a year (3 x fewer renewals)	Medium
Prescribers (e.g. GPs)	Reduced administrative workload from less frequent prescription renewals.	Low	Low
Health New Zealand	Short term reduction in pharmacy expenditure. This is due to the lower costs for repeat dispensings.	$14m - $42m (mid-range $28m) Initial estimate – highly likely to change as the contract with pharmacy (ICPSA) is renegotiated.	Medium
	Increased medicines adherence , in the medium to longer-term, is expected to reduce overall system costs – reducing	Medium	Medium

Affected groups *(identify)*	**Comment** *nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks.*	**Impact** *$m present value where appropriate, for monetised impacts; high, medium or low for non-monetised impacts.*	**Evidence Certainty** *High, medium, or low, and explain reasoning in comment column.*
	health system inefficiencies such as avoidable hospitalisations and disease management costs.		

Section 3: Delivering an option

How will the new arrangements be implemented?

112. Increasing the prescription duration limit requires an amendment to the Medicines Regulations 1984, which can be done through an Order in Council.

113. Successful implementation will require several non-legislative steps, the Ministry of Health will work with Health NZ and Pharmac to address the following:

Clinical and public guidance

114. Increasing the prescription duration is a significant change for both clinicians and patients.

115. Consultation on this proposal highlighted the need for clear guidance on the appropriate use of an increased prescription duration. This includes clinical guidance for prescribers on the types of medicines and conditions that are likely appropriate for 12-month prescriptions and public guidance to manage patient expectations.

116. This was a key aspect of the recent changes in Australia, where the Department of Health and Aged Care launched a website with information for stakeholders.

117. The Ministry of Health will work with other health agencies, professional organisations and the relevant RAs to develop this guidance.

Updates to IT systems

118. There are several types of prescribing and dispensing IT systems used in New Zealand. Health NZ will need to work with the vendors of these systems to ensure they can accommodate prescriptions for 12-month prescriptions.

119. These IT systems are also designed around the existing prescription co-payment rules. Several systems would need to be updated to enable a prescription co-payment to be applied on repeat dispensings (every 3 months).

120. Health NZ will be responsible for these IT updates, although they have noted that they are already undertaking significant changes to existing IT systems, prioritising this change risks delaying that work.

Change to the Pharmaceutical Schedule

121. Minor changes will be required to the Pharmaceutical Schedule, managed by Pharmac, to resolve any unintended conflicts with an increased prescribing limit.

How will the new arrangements be monitored, evaluated, and reviewed?

122. The new arrangements will be monitored by the Ministry of Health, with support from Health NZ, Pharmac, and the Health Quality and Safety Commission.

123. The impacts of this proposal, including benefits and risks, are largely dependent on how prescribers choose to use the increased limit when prescribing for their patients. We heard through consultation that prescribers would initially be cautious to provide 12-month prescriptions.

124. Many international systems have accessible, central medicine monitoring databases to provide surveillance of prescribing behaviour and practice. New Zealand does not have such a system, which makes accurate monitoring and evaluation of the impact of regulatory changes related to medicines difficult.

125. Given this uncertainty, the Ministry, supported by other health agencies, will develop a plan to monitor the impacts of the increased prescribing limit. This plan could focus on identifying:

- the uptake of the increased prescribing limit

- any changes to prescribing trends for particular medicines
- signs of inappropriate use of the increased prescribing limit
- realised financial impacts for private providers (e.g. general practices and community pharmacies)
- reduction in costs for patients
- increase in demand for medicines.