Briefing

Improving safe access to opioids

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Security level:	IN CONFIDENCE	**Health Report number:**	H2023023247
To:	Hon Dr Ayesha Verrall, Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

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Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Improving safe access to opioids

Security level:	IN CONFIDENCE	**Date:**	1 May 2023
To:	Hon Dr Ayesha Verrall, Minister of Health		

Purpose of report

1. This briefing provides an update on a recent review of controls that impact safe access to opioids, a summary of engagement on potential regulation changes to improve safe access, and advice on which of these regulation changes can be progressed.

2. This report discloses all relevant information and implications.

Summary

3. Since January 2023, Manatū Hauora has been conducting a review of existing controls that manage access to opioid medicines. This review began after concerns were raised about a recent regulation change that increased the amount of Class B opioid medicines that can be prescribed at one time.

4. The review identified priority areas for improving safe access to opioids, one of which is to further amend prescribing regulations to address issues in the short to medium term.

5. Engagement on proposed regulation changes took place throughout March 2023. The engagement revealed a wide range of views on how to ensure safe access to opioids (**see attached draft Summary of Engagement document**).

6. Following this engagement there are some regulation changes that can now be progressed to manage immediate risks and address issues within regulation. There were other regulation changes that may be potentially beneficial, but further analysis is required to determine if these should be implemented.

7. The review also identified other system improvements are needed to ensure safer access to all controlled drug medicines. These include improved monitoring capabilities, better transparency of prescribing information, stronger clinical guidance on appropriate prescribing practice, and a more flexible mechanism than regulation for establishing prescribing rules.

8. A larger work programme is required to develop improvements in these areas and will need to be done alongside work to progress the Therapeutics Products Bill.

Recommendations

We recommend you:

a)	**Note** that concerns have been raised about an increased risk of opioid harm as a result of amendments made to prescribing regulations in December 2022	**Noted**
b)	**Note** that a review of existing opioid controls has identified several controls that require improvement to ensure safe access to opioids	**Noted**
c)	**Note** that amendments to prescribing regulations are required to address short term risk of inappropriate prescribing of opioids	**Noted**
d)	**Note** that these proposals have been widely engaged on with relevant stakeholders	**Noted**
e)	**Agree** to amend the Misuse of Drugs Regulations 1977 to reduce the maximum period of supply (prescription length) for opioids to 1-month	**Yes/No**
f)	**Agree** to amend the Misuse of Drugs Regulations 1977 to align controlled drug prescribing limits for each profession	**Yes/No**
g)	**Agree** to seek approval from Cabinet to amend the Misuse of Drugs Regulations 1977 in accordance with the above recommendations	**Yes/No**
h)	**Note** that Manatū Hauora will progress a wider work programme to explore ways to improve the controls identified in the review	**Noted**

Dr Diana Sarfati
Director-General of Health
Te Tumu Whakarae mō te Hauora
Date: 1 May 2023

Hon Dr Ayesha Verrall
Minister of Health
Date:

Improving safe access to opioids

Background

Regulation change in 2022

1. In December 2022, the Misuse of Drugs Amendment Regulations 2022 (the amendments) increased the amount of Class B controlled drugs that certain professions could **prescribe** at one time to a maximum of **3 months'** supply. The limit on the amount of a Class B controlled drug that can be **dispensed** at one time remains unchanged at **1 months' worth**.
2. This increase only applies to electronic prescriptions issued by authorised prescribers through the New Zealand ePrescription Service (NZePS).
3. This change was made to increase access by reducing the frequency a patient would need to obtain a prescription for their medicines when dealing with a chronic condition.
4. The primary intent of the amendments was to increase access to ADHD medicines. The previous limits caused difficulties for ADHD patients in accessing their medicines and unnecessarily increased General Practitioner and mental health practitioner workloads.
5. In addition to the Regulations, there are also restrictions placed on access to Class B controlled drugs through the Pharmaceutical Schedule (the Schedule), which is managed by Pharmac. The Schedule provides subsidisation criteria that limits the amount of Class B controlled drugs that may be dispensed at one time. For Class B opioids there is a default dispensing limit of **10-day** lots.
6. Pharmac began consulting on changes to the Schedule to align with the amendments in December 2022. This led to more awareness of the changes and a perception that they might increase the risk of unsafe opioid access.
7. Following the concerns raised about the impact on opioid access, Pharmac agreed to suspend any changes to the Schedule until a review of opioid controls could be completed. This review has identified several controls as needing improvement to manage safe access to opioids.
8. There is an exception to the 10-day dispensing limit in certain cases. Subsidised Class B opioids can be dispensed in monthly lots if the patient certifies that they meet requirements such as having limited physical mobility, or they live more than 30 minutes from a pharmacy. This exception is commonly used, which means many patients currently receive funded Class B opioids in monthly lots.
9. The current restrictions in the Schedule mean that the amendments have had limited impact on how most Class B controlled drugs are prescribed, in that the changes only affect unsubsidised prescriptions at this time.

Implications for ADHD medicines

10. Concerns have been raised in the sector that delaying Schedule changes due to opioid risk is unnecessarily impacting patients with ADHD.

11. Upon completion of the review Manatū Hauora notified Pharmac that any changes to the Schedule to improve access to ADHD medicines can now be progressed, but that the status quo should remain for opioids until the regulations are settled.

Why have the 2022 amendments raised concerns?

12. The primary concerns about these changes relate to the increase in the amount of Class B opioids that can be prescribed under the new regulations.

13. There are two main risks that some prescribers see from the ability to prescribe 3 months of a Class B opioid:

    a. diversion of medicines – where the drug is prescribed to a person with a legitimate need but is then passed on to others without a legitimate need

    b. increased risk of addiction arising from longer prescriptions.

14. Some practitioners are concerned that prescribers may behave inappropriately when placed under pressure. Increased pressure could come from their workload or directly from a patient. There is a concern that patients, particularly those already with an opioid addiction, will demand longer prescriptions when they become aware that the regulations allow it.

15. This was an existing risk prior to the amendments, as patients can apply the same pressure to demand repeat prescriptions indefinitely.

16. Opioids are also relatively inexpensive medicines, so cost is not considered a significant barrier to prevent patients from accessing 3 months' worth of unsubsidised opioids. Patients can also currently access 3-month prescriptions where Pharmac will subsidise the first month.

Review of opioid access

17. The Safe Access to Opioids Working Group (the Working Group) was established to review the existing opioid controls to ensure they are effectively managing the risk of opioid misuse and enabling safe patient access.

18. The Working Group is made up of representatives from Manatū Hauora, Te Aka Whai Ora, Te Whatu Ora, Pharmac and the Health Quality and Safety Commission. The first meeting was held on 25 January 2023.

19. Through the review, the following controls have been identified as needing improvement to manage safe access to opioids:

    a. amending opioid prescribing regulation to be more in line with best practice and enable practitioners to prescribe appropriately

    b. more comprehensive monitoring capability, including further investment to take advantage of technology advances

    c. in the longer-term, a better mechanism for establishing prescribing and dispensing rules and guidelines for high-risk medicines.

20. The Working Group recommended further engagement with the sector to assess what changes would be appropriate.

Engagement on changes to opioid regulation

21. The immediate consideration of the opioid review was to manage the short-term risk of opioid harm, given the amendments in 2022. The engagement provided an opportunity for interested stakeholders to express their views on opioid access and submit feedback on the proposed regulation changes.

22. Throughout the engagement period, **14-31 March 2023**, we received 101 individual submissions, 7 submissions from organisations and had 35 participants across 2 web-hui.

23. A range of groups were represented across the engagements including GPs, pain specialists, academics, nurse practitioners, pharmacists, oncologists, hospice workers, consumer groups, mental health specialists and service users.

24. The organisations that made submissions were:

- Accident Compensation Corporation
- National Association Opioid Treatment Providers
- Clinical Advisory Pharmacists Association
- Third Age Health
- The Royal Australian and New Zealand College of Psychiatrists
- Health and Disability Commission
- The Royal New Zealand College of General Practitioners.

Overview of submissions

25. The submissions received in this engagement were varied and nuanced, illustrating the complexity of ensuring access to opioids while managing the associated risks.

26. Some were concerned with safety and therefore want to strengthen regulation. Others were concerned with access and do not want more barriers to patients receiving their medication. Others do not want more regulatory constraints on their clinical decision making.

27. The majority of submissions expressed that changes to regulations are warranted however there were many views on how this should be done.

28. This engagement has also revealed that there is confusion among practitioners on existing prescribing and dispensing regulations. This demonstrates the need for clear guidance and engagement with the health sector to ensure practitioners are aware of the restrictions and their obligations when prescribing medicines.

We engaged on several regulatory changes

29. The online engagement asked stakeholders to provide their views on opioid access generally and whether they felt regulation change was necessary. They were also asked to comment on several proposed changes to the Regulations which might better manage risks associated with opioid access in the short to medium term:

a. return the prescribing limit for **Class B opioids to 1-month**

b. **require a peer review** process to prescribe more than 1-month total of opioids (including repeat prescriptions)

c. **align prescribing limits** for all prescribers of Class B and C controlled drugs

d. create a specific **dispensing limit for opioids**, which would remove the need for the 10-day default dispensing restrictions within the Pharmaceutical Schedule.

Regulation changes that will improve safe access to opioids

Should regulation change be progressed?

30. This engagement has confirmed that two of the regulatory proposals should be progressed, these are outlined below. The other proposals require further development and consultation to determine if they are necessary.

31. Participants in the engagement confirmed that while these regulation changes can be made, they are unlikely to be sufficient to deal with all issues related to safe opioid access. Even if regulation change is progressed quickly, further work must continue to ensure long term measures are put in place to manage access safely.

Reduce the prescribing limit for Class B opioids to 1-month

32. The prescribing limits in Regulations are intended to provide the maximum amount of flexibility to enable prescribers to use their expert clinical judgement when prescribing for their patients.

33. Practitioners with prescribing authority are required to ensure that they meet their professional standards and always act in the patients' best interests. Regardless of what maximum limit is within regulation, practitioners should only be prescribing what is appropriate for the individual patient.

34. The current prescribing limit of 3-months is inappropriate for most situations where opioids are prescribed. Opioids are generally indicated for moderate to severe acute pain and for cancer pain. They are not recommended for chronic non-cancer pain due to concerns over long-term efficacy and safety of treatment, including the risk of abuse, misuse, and dependence.

35. The majority of submissions support reducing the prescribing limit for opioids to 1 month. Some of the potential benefits outlined in submissions include:

a. reduced risk of harm from increased quantity of opioids being prescribed

b. will require more regular review of prescriptions to ensure that medication and dosage is appropriate

c. less wastage from unused opioids.

36. This change creates a reasonable limit for prescribing opioids. Prescribers retain some flexibility, and it mitigates the risk of excessive amounts of opioids being prescribed at one time.

37. We heard throughout the engagement that any increase in restrictions for opioids should not undo the increased access to ADHD medicines that was enabled by the 2022

amendments. Having a specific limit for opioids will allow the other Class B drugs to continue to be prescribed for 3 months.

38. Some opioids are currently scheduled as Class C within the Misuse of Drugs Act, this change will apply to those as well resulting in a prescribing limit of 1 month for **all** opioids.

39. There were views expressed during engagement that a limit of 1 month was still inappropriate for prescribing opioids, as in most cases prescriptions should be limited to a few days, often following an acute event such as an injury or surgery. However, lowering the prescribing limit for opioids any further risks significantly restricting patient access. Ensuring prescribing behaviour remains appropriate for each patient is better managed through sophisticated monitoring capabilities and stronger guidance from professional bodies.

Align prescribing limits for prescribers of controlled drugs

40. The Regulations place specific limits on controlled drug prescribing for each profession. For example, a nurse practitioner can prescribe a Class C controlled drug for a period of up to 3 months whereas a designated pharmacist prescriber can prescribe a Class C controlled drug for up to 3 days.

41. These different limits have been criticised by practitioners as arbitrary, impractical and not reflective of clinical capabilities or the risks associated with prescribing. There is also a significant impact on patient access when certain prescribers are more limited in their ability to prescribe. This impact on access is inequitable as it particularly affects those who live in rural or remote areas.

42. The amendments in 2022 aligned prescribing limits for Class B drugs however did not do the same for Class C drugs.

43. A majority of submissions supported aligning controlled drug prescribing limits for all prescribers of controlled drugs. We heard that if a prescriber is deemed capable of prescribing a certain drug, then the same prescribing amount limit should apply.

44. Some submissions expressed concerns over increasing prescribing limits for certain professions, especially for opioids. However, a limit of 1 month for all prescribers provides an appropriate balance of safety and access.

45. Aligning these limits will require a significant increase in the maximum amounts for some prescribers, for example a pharmacist prescriber will be able to prescribe up to 3 months of a Class C drug instead of 3 days.

46. While this amendment would increase the maximum amount of controlled drug that can be prescribed by some prescribers it will not change which types of controlled drugs that can be prescribed.

47. The amendments in 2022 created an irregularity in the regulations where some prescribers can prescribe more of a Class B drug than a Class C drug. Aligning prescribing limits will enable this to be addressed.

Proposals not to be progressed at this stage

Peer review process for long-term opioid prescribing

48. We heard that requiring a peer review process for repeat opioid prescribing could reduce the risk of inappropriate prescribing. Similar review requirements have been adopted in some jurisdictions currently dealing with significant opioid harm, such as Australia.

49. However, we also heard that this would likely create additional barriers to accessing opioids through increased costs and delays, particularly for those patients who live in areas with limited access to prescribers. There were also concerns about the workability of a peer review process including the increased workload on a workforce already under significant pressure.

Dispensing limit for opioids

50. Under the Regulations, the maximum amount of controlled drug that can be dispensed at one time is a quantity sufficient for use for 1 month.

51. Given that an appropriate amount of opioid to be dispensed is usually less than 1 months' worth, we proposed that a lower limit be created specifically for opioids. The proposal was to reduce this dispensing limit in regulation to align with the 10-day default dispensing limit within the Schedule.

52. We heard that a lower dispensing limit for opioids would be effective in reducing risk of harm, but there was no consensus on what that limit should be.

53. However, submissions also pointed out that any limit specific to opioids would also require broad exemption criteria for the wide variety of cases where larger dispensing amounts would be appropriate.

54. Reducing the dispensing limit would also negatively impact those who do require long-term opioid use and would lead to inequitable access to treatment for those living in rural or remote areas.

55. Prescribers have the ability to determine the appropriate dispensing schedule for each patient. Inserting a more restrictive limit would significantly inhibit their ability to use their professional judgement to determine what is appropriate for their patient.

Regulation changes are first step in larger work programme

56. The review of opioid access identified that the proposed regulation changes will manage some short-term risk, but improvements to other controls will likely have a greater impact on ensuring safe access to opioids.

57. Furthermore, these controls have a wider influence on safe access to all medicines.

Monitoring and enforcement improvements

58. Medicines Control is a regulatory team within Medsafe that oversees the local distribution chain of medicines and controlled drugs within New Zealand. This includes monitoring how controlled drugs are prescribed.

59. Currently, Medicines Control will only become aware of inappropriate prescribing if someone reports a concern about a practitioner or organisation, or in response to a trigger (for example through information identified during an audit process). This means that inappropriate prescribing can go on for some time before it is reported, or it can go unreported.

60. The Working Group identified the need for improved monitoring, to manage compliance with best practice, as essential for managing safe access to opioids.

61. Medicines Control does not currently have access to tools to easily monitor and identify inappropriate prescribing in real time. Work is in progress to implement tools that will enable Medsafe to monitor the prescribing data more effectively, which is expected to be completed by June 2023.

62. The Medicines Data Repository (MDR) is a database of prescribed and dispensed medicines information, currently managed by Te Whatu Ora. It is based on real-time information received directly from the NZePS.

63. Use of the MDR will enhance Medsafe monitoring capabilities by providing:

    a. a single source for prescribing data on all medicines and controlled drugs (NZePS data),

    b. real-time data,

    c. the ability to readily search large quantities of data across individuals, prescribers, pharmacies and medicines.

64. Real-time information on prescribing behaviours is essential to identifying inappropriate prescribing before significant harm is caused.

65. However, further investment is required to achieve more comprehensive monitoring. Manatū Hauora is committed to a more sophisticated level of monitoring capability and is exploring how resources could be allocated to achieve this.

A better mechanism for prescribing rules

66. The prescribing regulations in the Misuse of Drugs Regulations were created to provide extra protections for medicines that are considered to have a high risk of causing harm, including dependence and abuse.

67. These regulations were developed to restrict access to potentially harmful substances, rather than facilitating safe access to important medicines. The restrictions set out within the regulations are also frequently criticised for being arbitrary, impractical and not reflective of clinical views.

68. Changing regulations also requires an extensive amendment process involving consultation, Ministerial agreement, drafting new regulations by Parliamentary Counsel Office, and approval by Cabinet.

69. Frequent amendments are necessary to these Regulations to adapt to changing models of care, best prescribing practices, access to new medicines and technology.

70. There is an opportunity for significant change to the mechanism used for prescribing and dispensing rules through the new regulatory regime being proposed by the Therapeutic Products Bill (the TPB).

71. Under the new regulatory regime, the Therapeutics Products Regulator (appointed by the Director-General of Health) will have the authority to make prescribing and dispensing rules. These rules will have the effect of secondary legislation.

72. When the Therapeutics regulatory regime comes into effect, the setting of prescribing and dispensing authority will be moved to the responsible authorities (professional regulators) under the Health Practitioners Competence Assurance Act 2003.

73. There is an option in this future state to allow the regulators of the professions and the Therapeutics Products Regulator to use this mechanism to develop rules for managing high risk medicines, such as opioids.

74. This mechanism would be more appropriate than regulation for several reasons:

    a. **More responsive**: the rules would be created under the authority of the Therapeutics Products Regulator; the amendment process would be faster.

    b. **Better for patients**: the rules would be created to ensure safe access to opioids, which means that the impact on patients would be central to any restrictions.

    c. Allows a **more flexible** approach to prescribing authority that could enable a clinical review process for prescribing outside of normal parameters.

    d. Rules would be developed by those with the relevant clinical skills and experience; this would provide practitioners with the most up to date direction on **best practice**.

Next steps

75. If you agree to the proposed regulation changes, we will provide you with a draft Cabinet paper seeking agreement to the amendments.

76. Manatū Hauora will continue to prioritise improvements to monitoring capabilities and will update you on progress in the weekly report.

77. A work programme will progress to explore ways to make larger, system wide improvements to safe opioid access, including a new mechanism for prescribing rules.

78. The summary of engagement will be published on the Ministry of Health website once the final version has been reviewed by your Office, likely to be June 2023.

ENDS.

Minister's Notes

MINISTRY OF HEALTH
MANATŪ HAUORA

DRAFT Safe Access to Opioids: Engagement Summary

TBC (May) 2023

Contents

1 INTRODUCTION

1.1 Context

The Ministry of Health (Manatū Hauora) is reviewing the controls and safeguards for the prescribing of opioids to ensure they are fit for purpose, in both managing the risk of inappropriate prescribing and ensuring adequate patient access to these medicines.

A number of controls and safeguards exist to manage the risk of opioid use. These include regulations that set out prescribing authority, clinical guidance that determine appropriate practices, monitoring systems to review potential inappropriate prescribing, and professional sanctions where inappropriate prescribing occurs.

Manatū Hauora established a cross-agency working group (Safe Access to Opioids Working Group) to help assess the potential risk of opioids in New Zealand and develop potential options to improve the regulatory system.

Engagement document

On 14 March 2023, Manatū Hauora released an engagement paper, *Safe Access to Opioids – Engagement document*, for public engagement to inform the review.

The engagement paper sought feedback on possible approaches to regulation, as well as options that could support regulation. Manatū Hauora sought feedback on the following options:

- Option 1: no regulatory change
- Option 2: strengthen guidance to encourage good prescribing practice
- Option 3: strengthen guidance and change regulations. These regulatory changes are to:
    i. reduce the prescribing limit for Class B opioids to 1 month (for both electronic and physical prescriptions) with an exemption for prescribing of opioids for cancer patients and those in palliative care
    ii. require a peer review process for repeat opioid prescriptions for non-cancer pain
    iii. ensure appropriate prescribing limits within the regulations for all prescribers of controlled drugs, including opioids
    iv. insert a 10-day, or similar, dispensing restriction specific to opioids, if this rule is removed from the Pharmaceutical Schedule.

1.2 Why now?

In December 2022, the Misuse of Drugs Amendment Regulations 2022 (the amendments) came into effect. The amendments made several changes to controlled drug prescribing regulations. One of the changes allowed Class B controlled drugs to be prescribed for up to 3 months with up to 1 month dispensing, when prescribed electronically through the NZ ePrescription Service (NZePS) by any prescriber with authority to prescribe them.

This change was intended to improve access to Class B controlled drugs for people with chronic conditions. The increase in the maximum amount was intended to provide more flexibility for practitioners to prescribe what is appropriate for their patients.

In response to concerns that were raised after the regulatory changes were made, Manatū Hauora set up a working group to review the current controls to see if they are fit for purpose, in both managing the risk of opioid misuse and ensuring appropriate patient access to these medicines. The review found some gaps in existing controls that may be increasing the risk of opioid harm. Some of these gaps could be addressed by regulatory change.

2 Summary of engagements

2.1 Engagement Process

Manatū Hauora used various methods in March 2023 to enable a wide range of people to participate and provide feedback on the options to address the risks of harm from unsafe access to opioids. Manatū Hauora published the engagement paper on its website. Participants could make submissions via an online link or by email.

Consultation closed on 31 March 2023.

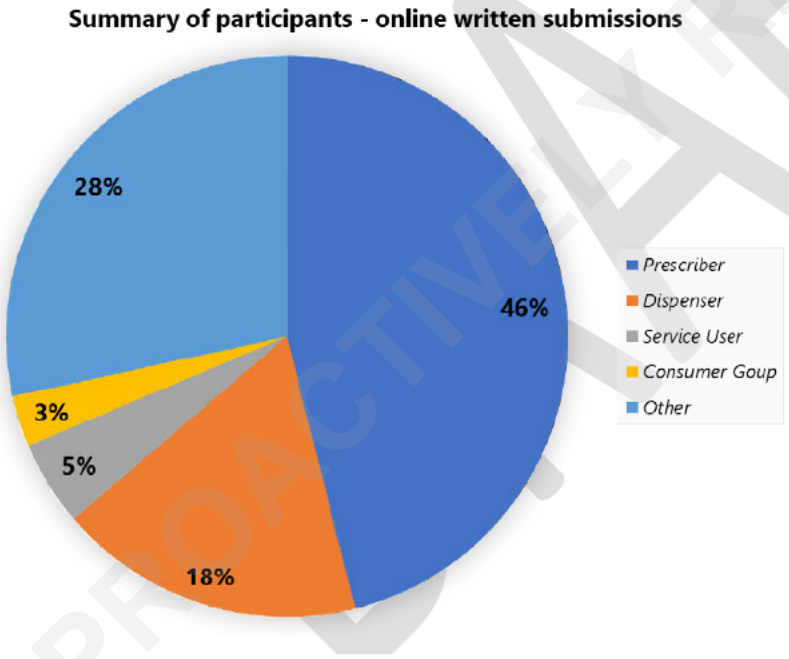
Online web-hui

Two web-hui were held on 22 March and 28 March 2023. Participants for the web-hui largely consisted of individual prescribers, dispensers, and organisation representatives that would be affected by the changes to prescribing and dispensing limits.

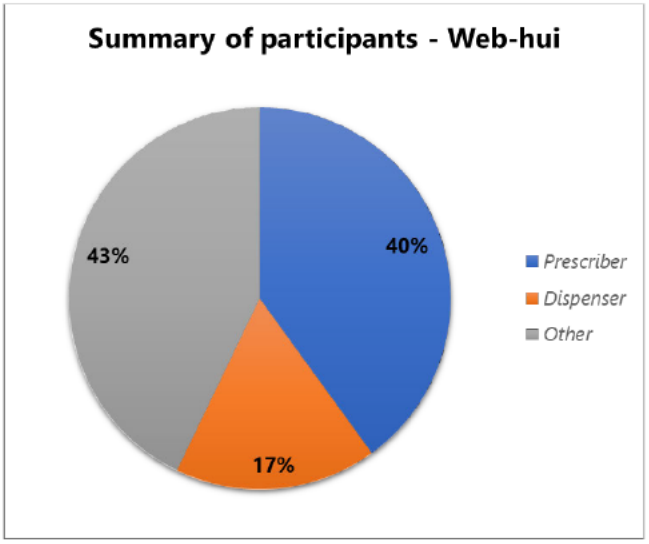
2.2 Summary of participants

Summary of participants from individual submissions (online and email)

Individual submissions consisted of 101 responses and came from prescribers (47), dispensers (18), service users (5), consumers (2), and others (29), some of whom worked in or managed services that prescribed or dispensed opioids.



Web-hui participants consisted of prescribers (14), dispensers (6) and others (15) who were people working in, or managing, services that prescribe or dispense opioids.



Seven organisations made submissions:

- National Association Opioid Treatment Providers (NAOTP)
- Accident Compensation Corporation (ACC)
- Clinical Advisory Pharmacists Association (CAPA)
- Third Age Health (TAH)
- Health and Disability Commission (HDC)
- The Royal Australian & New Zealand College of Psychiatrists (RANZCP)
- The Royal New Zealand College of General Practitioners (RNZCGP)

Participants' interest in the opioid's regulations

Participants were interested in the changes to prescribing and dispensing limits because they:

- are a prescriber or a dispenser
- are a specialist in pain medicine, palliative care, Addiction, Forensic Psychiatry
- manage a service such as General Practitioner service or a Pharmacy
- are concerned about the changes that came into effect in December
- have lived experience in opioid use for chronic health conditions.

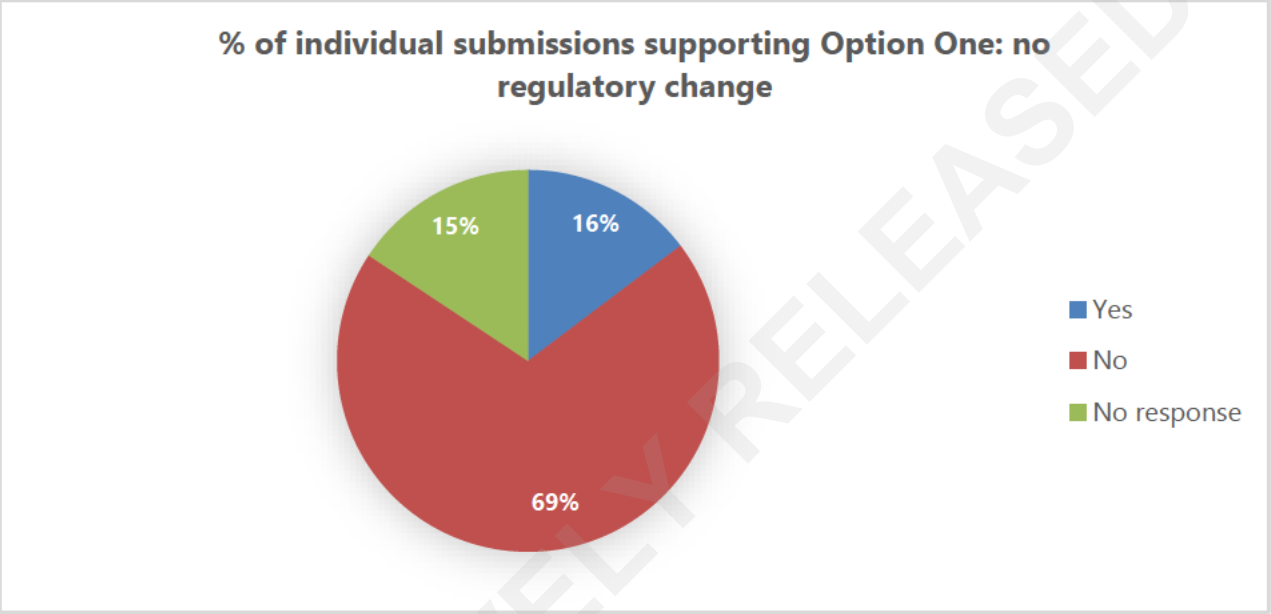
3 Summary of feedback on options

3.1 Option One - no regulatory change

Is Option One sufficient for balancing access to opioids with potential risk of harm?

Under this option, opioids will continue to be able to be prescribed for up to 3 months and dispensed for up to 1 month at a time. This option will not address any concerns over the 10-day default dispensing limit for opioids being removed from the Pharmaceutical Schedule.

The following pie chart reflects individual submissions only. None of the national organisations' submissions support this option.



The majority of submissions do not support this option. Submissions were concerned that Option One does not adequately balance the risks of harm (to individuals from prescribed opioid dependence and to the community from increased quantities of prescribed opioids in the community) against access to opioids for those who need them, except for people receiving medication for ADHD (e.g. stimulants), Opioid Misuse Disorder (e.g. methadone), or opioids used for anxiety, agitation or distress (e.g. benzodiazepines).

Submissions noted that longer prescription and dispensing periods are beneficial for reducing barriers to access. In particular, because of the cost and challenge for those in rural areas or without independent transport, the cost of repeat scripts, and the cost of two months of prescription as the funding model only covers 1 month of prescribed opioids. Also, longer timeframes provide flexibility for clinicians to use their clinical judgement and tailor their approach to the unique needs and circumstances of the person in their care.

We heard that longer prescription and dispensing timeframes might be appropriate for cancer and/or palliative care settings. We also heard that regular review of the individual's pain experience is an important part of ensuring their pain is being appropriately managed, taking opioids for 3 months suggests the opioid is ineffective, prolonged use of opioids increases health risks and reduces health benefits from the medication, and prescribing and dispensing timeframes reduce prescribers' focus on the patient's needs.

Submissions were concerned that longer prescription and dispensing timeframes can lead to stockpiling – intentionally or unintentionally. The greater the quantity of opioids in the home, the greater the risk of opioid abuse and diversion. Larger quantities of opioids in pharmacies (to ensure supply) increases security risks and stockpiling can also lead to wastage when opioids are unused and need to be disposed. Submissions also noted that 1 month prescribing restriction is why New Zealand is not experiencing the surge in opioid prescribing and related dependence and mortality that has occurred in other western countries.

We also heard that the current prescribing and dispensing timeframes are sufficient, provided guidance and education are improved.

Submissions suggested using electronic prescribing of controlled drugs to help reduce fraud and increase visibility of what is being prescribed and dispensed. Increased visibility of what is being prescribed and dispensed, through shared electronic prescribing systems, would help reduce the risk of individuals requesting different dispensers dispense the same script.

This option does not address other concerns that were raised, such as:

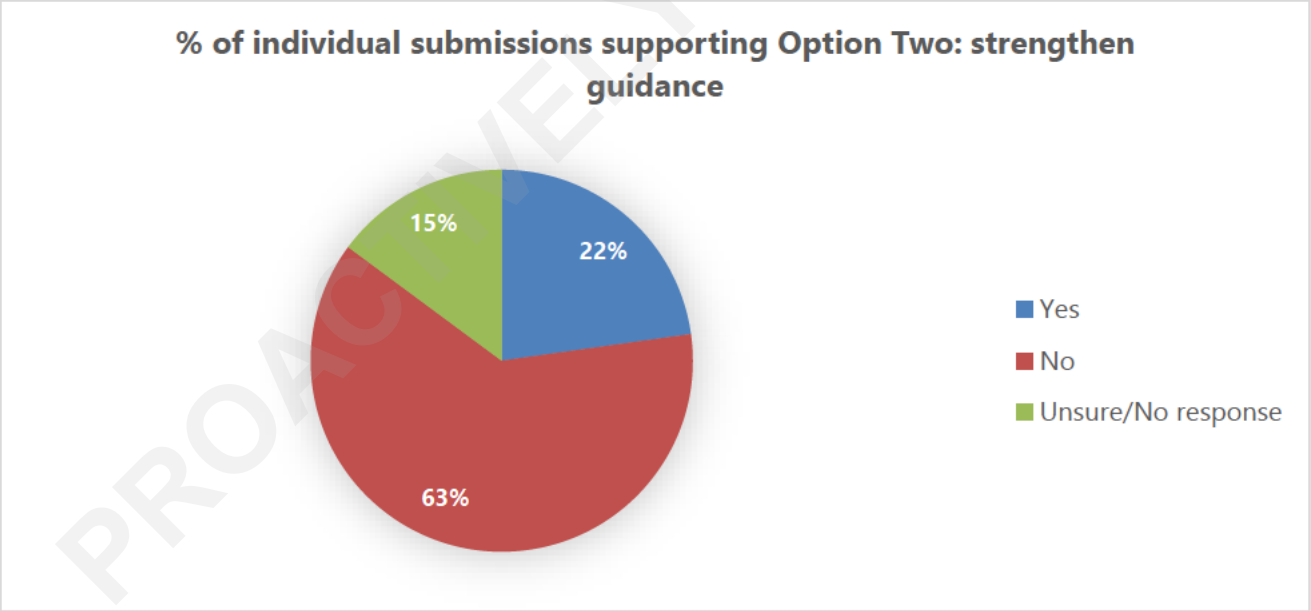
- this option makes Class B drugs more accessible than Class C e.g. products containing codeine
- inconsistent prescriber categories limit patients' equitable access to treatment.

We noted there appeared to be some confusion about current prescribing and dispensing limits and whether we proposed increasing the current limits to 3-month prescription with 1-month dispensing limits, or whether we proposed reducing them to previous limits of 1-month prescription with 10-day dispensing limits.

3.2 Option Two - strengthen guidance

Under this option, opioids will continue to be prescribed for up to 3 months and able to be dispensed for up to 1 month at a time. Clinical guidance for prescribing and dispensing will be developed to guide appropriate prescription and dispensing decisions and practice by clinicians. This option will not address any concerns over the 10-day default dispensing limit for opioids being removed from the Pharmaceutical Schedule.

The following pie chart reflects individual submissions only. One of the national organisations' submissions supports this option.



The majority of submissions do not support Option Two. Submissions noted that, while clinical guidance is beneficial, it will not adequately address the risks of harm from opioid prescribing. We heard support for setting prescribing limits in regulations rather than relying on the Pharmaceutic Schedule (which are funding rules and which can be set aside by other funders or by patients who may be willing to pay for higher quantities).

We heard concerns that guidance would not provide feedback on prescriber behaviour, address inequitable access to pain resources for pain management, provide transparency on patterns of opioid use, or educate prescribers on pain management. We also heard that clinical guidance should aim to minimise harm and not restrict access to opioids, should focus on improving health literacy on safe use of medicine (rather than just prescriber literacy), and should be informed by experts in the management of opioid dependency.

Submissions suggested clinical guidance should include: potency of opioid, the clinical indications, duration of treatment, methods for avoiding and managing dependency, evidence of education provided to patients on the risks of opioid dependence, and information about preventing opioid dependence and the side effects of long-term use.

Submissions noted that clinical guidance can be less effective due to lack of timely updates, varied use and application within and between regions and prescriber professions, and the fragmentation of health services between regions and professional bodies.

Submissions also noted that:

- prescribing and dispensing rules should embrace clinical best practice
- more direct support for practitioners prescribing opioids could be beneficial, such as additional funding for practices focused on reducing polypharmacy/opioid use, clearer pathways/criteria for referrals to specialist pain services and peer support groups focused on opioid use
- prescribers should require training before undertaking prescribing to understand appropriate behaviours and should have frequent refresher professional development. There should be education on de-prescribing to assist post-surgery patients.
- the frequency of prescribing ADHD medication is a burden to primary care services and the 2-year psychiatric review presents a barrier for patients
- we should move away from system-centred care to person-centred care and prioritise each individual and their needs accordingly
- any change must occur in conjunction with Pharmac funding changes, as the current situation where patients who can pay have greater access is inequitable and unfairly penalises many of the patients the legislation seeks to help
- there is a risk of addiction with medication that is not classified as opioids.

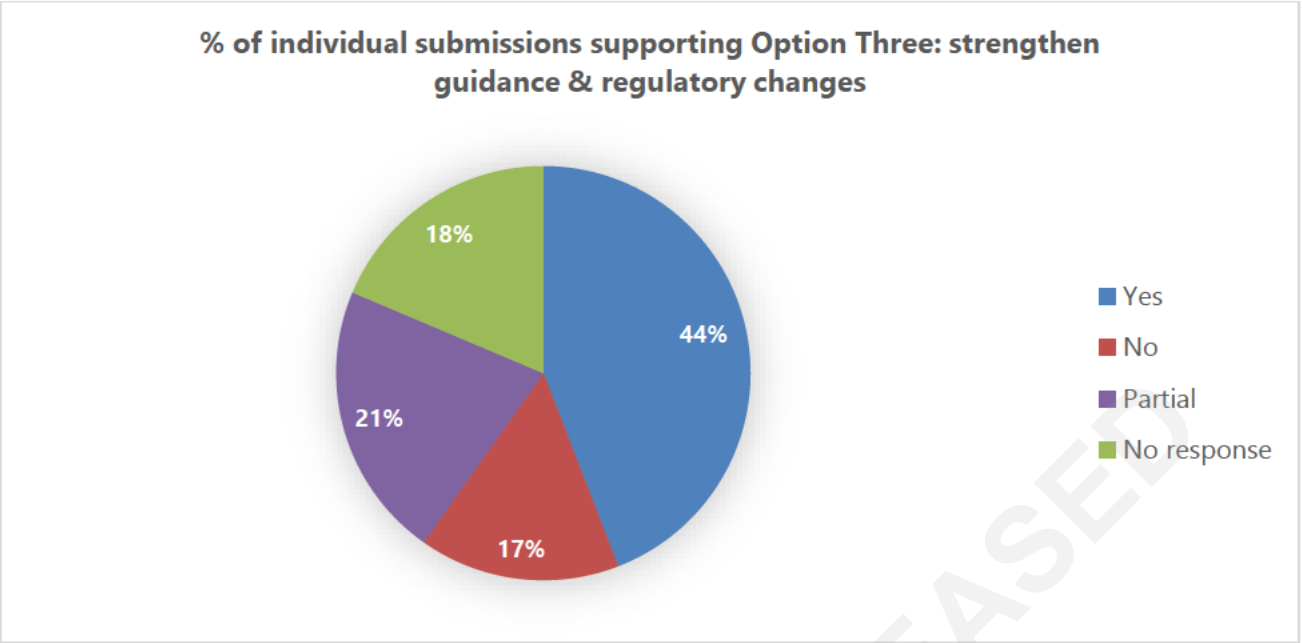
3.3 Option three - strengthen guidance and change regulations

Under this option, Class B opioid prescribing limits will be limited to a maximum of 1 month with dispensing limits of less than 1 month. The prescribing limit would include exemptions for cancer patients and those in palliative care. Opioid prescribing will include a peer review process and prescribing restrictions will be more aligned between prescribers.

The engagement paper asked for general feedback on Option Three and specific feedback on each aspect of Option Three.

3.4 Do you agree with the proposed regulatory changes (option 3)? Why or why not?

The following pie charts reflect individual submissions only. Six of the seven national organisations' submissions support this option and the web-hui participants generally supported regulatory change.



The following summarises submissions from individuals, national organisations and web-hui participants.

Of those who responded to this question, the majority of submissions agree that decreasing the length of prescription and dispensing timeframes through a legal tool, such as regulations, was the best way to minimise the risk of inappropriate prescribing of, or inappropriate access to, opioids. This would, in turn, minimise the risks of harm to the community from increased quantities of opioids in the community and from wastage of unused, dispensed opioids. Submissions noted that an advantage of legislation is that is enforceable.

We heard that limited dispensing frequencies and prescription durations promote regular interactions between patients and their healthcare team (pharmacist, prescriber, and/or medical centre) and provide opportunities for informal checkpoints as part of continued and collaborative health care. Loss of these regular interactions may weaken patient-provider relationships, leading to poorer outcomes and greater risk of uncontrolled and unsupported use of Class B controlled drugs.

The range of medications and their respective indications for treatment, within the Class B Controlled Drug classification, is extensive and not equivalent in terms of the potential for addiction, overdose, or other negative outcomes.

Submissions noted that increasing access to opioid medication by not reducing prescribing and dispensing limits needs to be accompanied by increased access to, and resourcing of, specialist pain clinics, addiction rehabilitation treatment, and acute opioid overdose medication.

Submissions had consistent concerns about aspects of Option Three, regardless of whether they agreed or disagreed to the option in general. These related to exemptions, prescribing limits, dispensing limits, peer review and alignment of prescribing restrictions across prescribers. This feedback has been included in the summary of submissions against each sub-question for Option Three.

We heard conflicting views about whether the 3-month prescribing and 1-month dispensing restrictions increase or decrease New Zealand's risk of a prescription opioid crisis. While some submissions said more restrictive limits may have contributed to why New Zealand is not currently experiencing the prescription opioid crisis evident in other countries (e.g. Australia and the United states of America), other submissions said more restrictive limits reduce access to appropriate pain medication, which increases the risk of growing misuse.

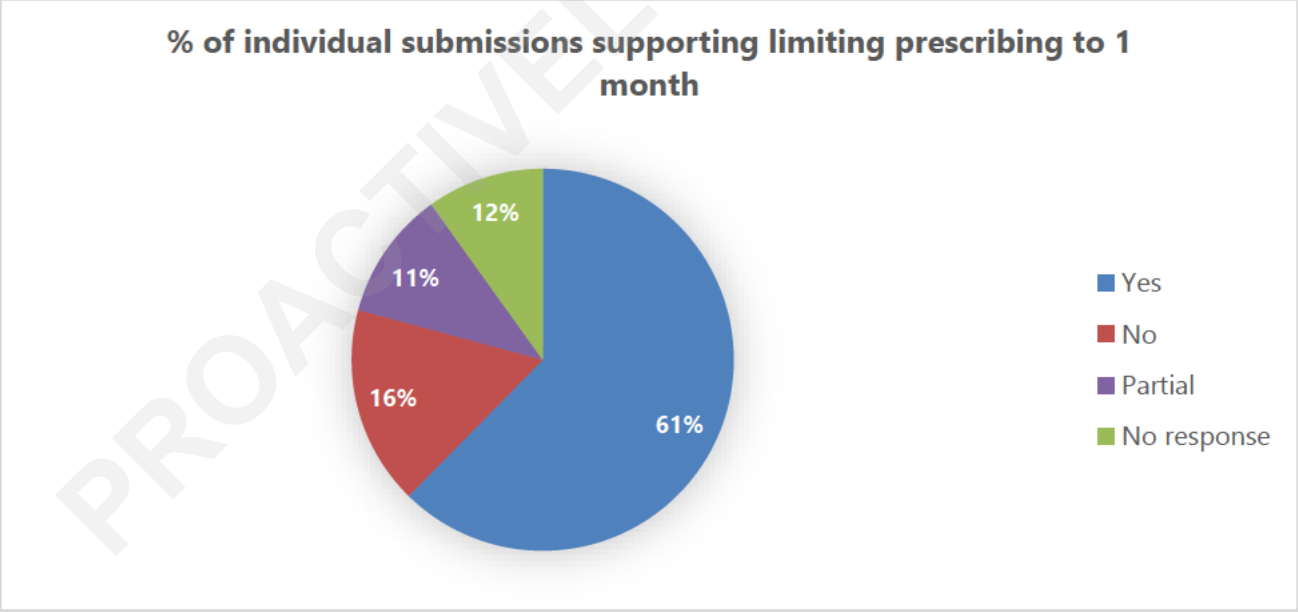
Submissions also noted the body of evidence showing larger opioid prescription limits increases the risk of people becoming new, persistent, opioid users, in particular after surgery and other medical procedures. Evidence also shows Māori and Pacific populations are disproportionally affected by risks of harm associated with opioid addiction.

Submissions that disagreed with Option Three identified that this option reduces prescribing and dispensing flexibility for ADHD and methadone for substance dependency, and it encourages prescribers to fixate on limits rather than patient needs. We heard that the clinical expertise of clinicians is the best way to ensure appropriate prescribing that is specific to the pain context and needs of each patient.

Alternative ways to manage the risk of inappropriate prescribing were suggested, such as:

- focus on opioid plans
- keep the current prescribing and dispensing limits and use a scale of restrictions depending on the potency of the opioid
- form an opiate steering or review group, in liaison with the addiction services, to aid in identifying patients at risk of inappropriate use
- identify variations in potential for addiction, overdose, or other negative outcomes against the sub-classifications within the Class B schedule
- develop systems to support comprehensive gathering and evaluation of data across the various interactions and stages of a patient's journey to better understand the situation of opioid use and harm, and to inform future improvements
- strengthen relationships between prescribers and pharmacists to work together to conduct regular medication reviews, reduce polypharmacy and manage pain relief options
- develop a detailed approach towards integrated monitoring and stewardship to ensure compliance with good clinical practice
- include injectable buprenorphine for opioid dependence in regulations.

3.5 Should opioid prescribing be limited to 1 month's supply?



Most responses to this question support reducing the prescribing limit to 1 month.

We heard that reducing the prescribing limit is a way to reduce the risk of community harm from increased quantity of opioids in the community, and to reduce wastage from unused prescribed opioids. Submissions noted that prescription limits ensure regular review of repeat prescriptions. This ensures that prescriptions are appropriate to the needs of the patient, and that opioids are generally reserved for moderate to severe acute pain due to concerns over the long-term efficacy and safety of treatment, including the risk of abuse, misuse and dependence. A shorter duration of supply also 'catches' human error, e.g. if a script was mistakenly given a long duration of supply, this would be limited to 1 month.

Whether agreeing or disagreeing with Option Three, we heard that prescribing limits need to allow flexibility for clinicians to prescribe quantities appropriate to the patient's needs and circumstances. But this might discourage prescribing decisions based on patient need, could increase barriers to access, and could encourage understanding about the dangers of prescribed opioids.

There were conflicting views on the circumstances under which 1-month prescribing limits would be appropriate.

We heard concerns that a 1-month prescribing limit might be too restrictive as it could reduce access to opioids for chronic conditions, cancer patients, those in palliative care, or those in opioid substance treatment. For example, a 1-month prescribing limit adds extra costs for repeat prescriptions and collection of collect medication. Submissions noted that, for stimulants for ADHD, it is cheaper to pay for 2nd and 3rd repeats than to pay for a GP script. In addition, a 1-month prescribing limit increases the risk that patients may be without pain medication for a few days. Some submissions suggested exemptions should be made for those living in remote areas or for stimulants such as methylphenidate / dexafetamine used for ADHD.

We heard that a 1-month prescribing limit might be appropriate for short term use, such as post-surgical patients or for acute pain. We also heard that a 1-month prescribing limit is not restrictive enough and that the limit should be considerably less than 1 month, in particular, for acute pain and for the first prescription of Class B opioids.

There were concerns that a 3-month prescribing limit could suggest pain is being inappropriately managed and increases the risk of opioid dependency. It also creates the impression that prescribed opioids are safe. It was suggested that, when opioids are prescribed, clinicians need to ensure that patients are aware that opioids can be addictive and should be treated differently to other medications.

Submissions raised concerns with the workability of reducing prescribing limits and the availability of prescribers for patients who may need extended treatment.

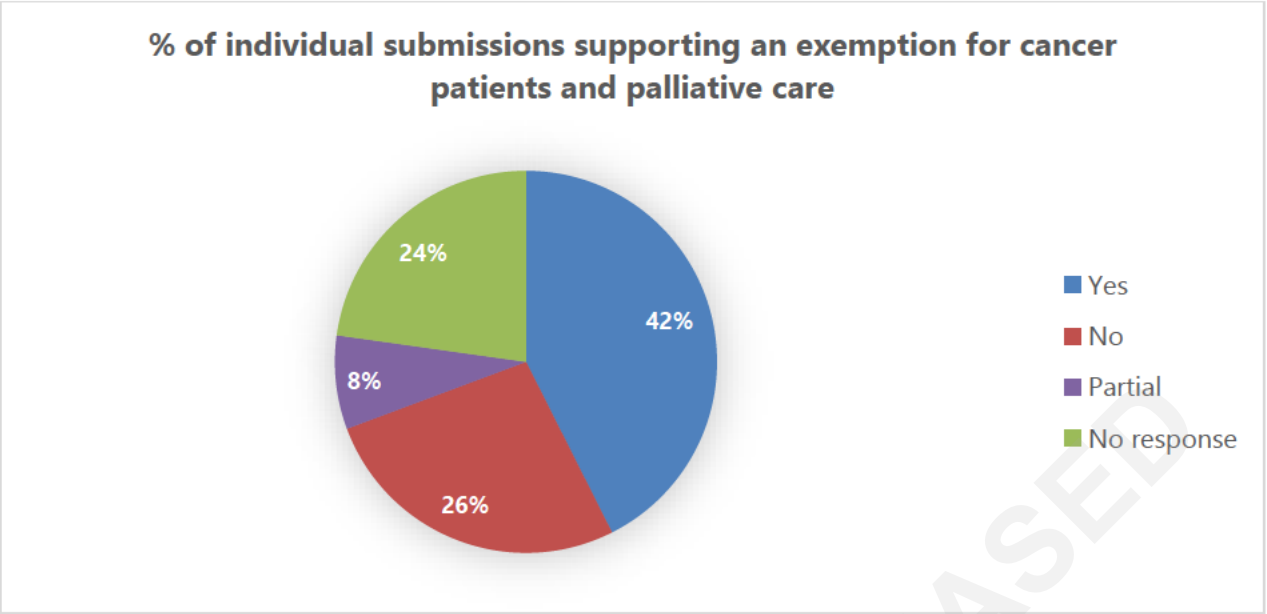
Some submissions suggested additional measures that were outside the scope of this question or the other options, such as:

- Use of an electronic opioid prescribing portal with useful guidance as opioids are prescribed for different conditions, acute pain, chronic non-cancer pain, cancer pain, palliative care
- Establish initiatives that are evidence-based and support patients, who have been using opioids long-term for non-cancer pain, to transition off these medicines.

There appeared to be confusion about the current prescribing limits and dispensing limits set in regulations. Some submissions thought current prescribing limits are 3 months and dispensing limits are 10 days. Some submissions seemed to think that a maximum 3-month prescription means 3 months' worth of opioids being dispensed at once.

3.6 Should there be an exemption for cancer patients and those in palliative care?

Further question: How would this impact the ability of prescribers to care for their patients?



We heard that an exemption should be considered for a range of circumstances: other stable long-term pain conditions that are being well-managed, stimulants, opioid substitute treatment, narcolepsy and related conditions requiring dexamphetamine, and those under supervised care. An exemption should also be considered for circumstances that create a barrier to access, e.g. inability to access pharmacist or medical services, cognitive or physical barriers, remote location, and cost of prescription for more frequent visits to a pharmacy.

Not all submissions agreed with this extended coverage for an exemption, or even that there should be an exemption for cancer patients and those in palliative care. Submissions noted that cancer patients and those in palliative care are less likely to benefit from an exemption and that best practice is to review symptoms and patient needs to frequently review their dose, and that clinicians are best placed to assess patient needs and identify the appropriate length of prescription. Submissions also noted that the proposed exemption increases the risk of oversupply, wastage, and community harm.

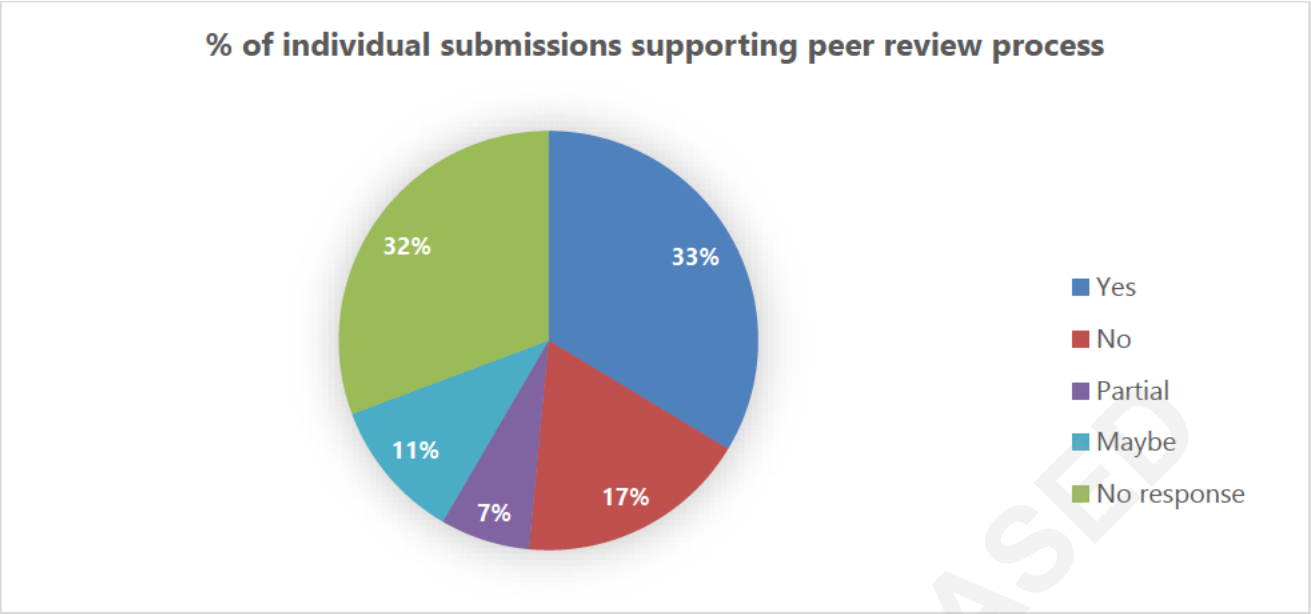
We heard that, while there might be instances when longer prescriptions might be appropriate for cancer and palliative care, a blanket exemption is not appropriate.

It was noted that, for an exemption to work, it will require better information-sharing systems, e.g. all pharmacies having information about patient diagnosis, including diagnosis clarification and electronic medications records. We heard an alternative approach to improve access to opioids for cancer patients and those in palliative care could be to separate the requirements for long-term treatment and improvements through the electronic prescribing process.

3.7 Would a peer review process for repeat opioid prescriptions reduce the risk of inappropriate prescribing?

Further Questions: **Would implementing this create a significant barrier to access?**

Are there implementation issues with this proposal?



We heard that a peer review process could reduce the risk of inappropriate prescribing and would also create additional barriers to accessing opioids for those who needed them. In particular, by creating additional costs to patients, exacerbating existing access inequity for some patients through cost and where there is limited access to prescribers beyond primary prescriber (e.g. Māori, those in rural or remote areas), delaying access to opioids if peer reviews are not timely, and impact on patient care if this is added to the workload of an already over-worked and under-resourced workforce.

We heard concerns about the workability of a peer review process. In particular, the likely increased pressure on an already overworked workforce (especially, but not only, in addiction and pain services), the need to fund the process, the impact on timeliness of decisions about what to prescribe, and how to monitor and audit it.

Support for the peer review process identified that it:

- would support prescribers needing advice about the use of opioids for chronic pain, as they would have access to pain specialists with experience of specific setting, e.g. palliative medicine specialists
- could support prescribers to explain their decisions to patients.

Submissions noted that some practitioners may already be using some form of peer review.

We heard that a peer review process would be unlikely to reduce the risk of inappropriate prescribing because of pressure from patients who know a longer prescribing period exists, that guidelines and auditing are sufficient to reduce the risk of inappropriate prescribing, and that a peer review process could negatively impact GP/patient relationships. Submissions were also concerned about the impact on patients coming off opioids when there are issues with pain clinics.

Submissions made suggestions about the design of the peer review process or alternative mechanisms to ensure appropriate prescribing and dispensing, such as:

- using prescribing data to identify outliers and using a peer from a different practice or sector to intervene
- allowing prescribing pharmacists to review the medications with the patient and work collaboratively in the practice to provide monthly prescriptions would have better outcomes for patients and better manage wastage
- requiring a diagnosis on prescriptions so prescribers can be audited
- encouraging clinicians to adopt a checking system that best suits their practice
- ensuring prescribers can see what others are doing in 'real time' before they prescribe, which would

improve prescribing practice and help audit prescribers

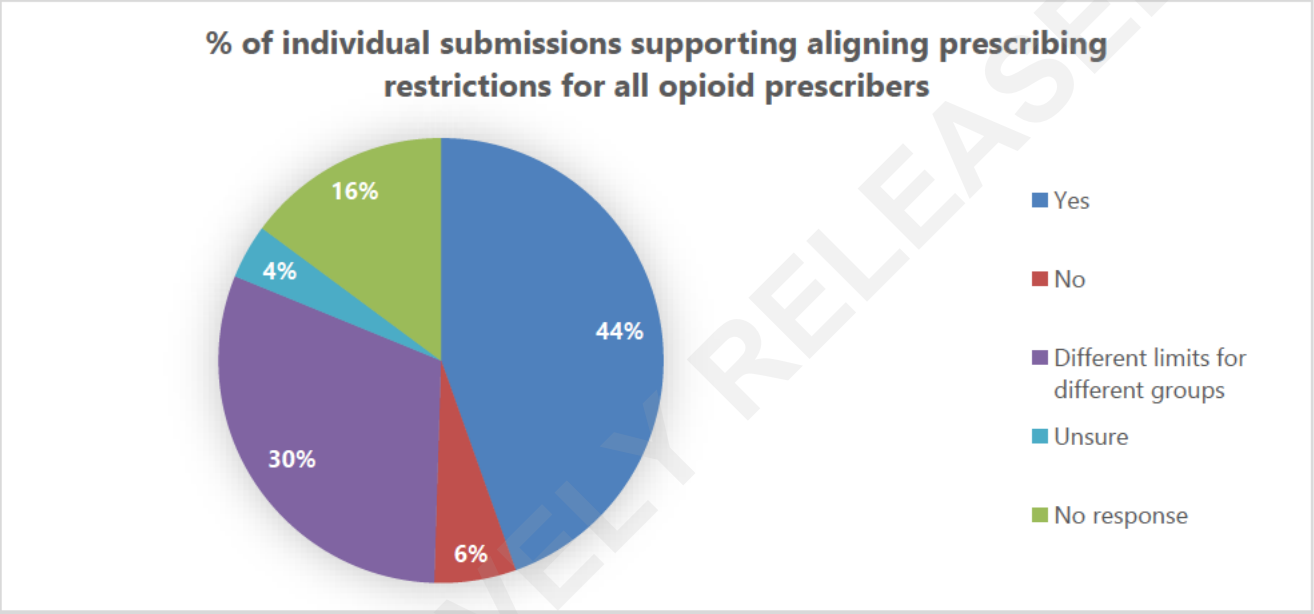
- using the regulations to ensure scripts cannot be filled prematurely, which will prevent over-prescribing
- focusing on prescribers adhering to best practice and guidelines rather than using legislation.

Submissions noted that, in other countries where there is an opioid crisis, the trend is to restrict access to opioids.

3.8 Should we align the prescribing restrictions for all opioid prescribers?

Further Questions: **Should some prescribers have lower limits for prescribing opioids?**

Should there be different limits for different groups of prescribers?



Of those that responded to this question, a small majority support aligning prescribing restrictions for all opioid prescribers, in particular for general practitioners, nurse practitioners and pharmacist prescribers. We heard that having different prescribing restrictions for different professions increases inequitable access to medicines (particularly for those in rural or remote locations who have less access to specialist services), increases inequitable prescriber practice, and is particularly problematic for prescriber pharmacists who can only prescribe for 3 days (which can adversely impact continued patient care, e.g. in mental health, as a doctor needs to do the controlled drug prescription and this can be time-consuming and cause delays). Aligning prescribing restrictions by profession would also decrease GPs' workloads. It could also reduce the risk of some of those with addictions taking advantage of the system, if all prescribers have appropriate knowledge and expertise about the use of opioids and provided prescribing is monitored.

Submissions noted that prescribers' scopes of practice have changed since this legislation was created and that a health system using a multi-disciplinary model should have the same prescribing restrictions across prescribing professions. It was also noted that current limits do not have a clear rationale based on risk or safety.

We heard that prescription limits should be aligned with safety and clinical considerations. Decisions on prescription limits should be made by clinicians based on best practice and clinicians should have the flexibility to adjust prescriptions to the unique needs and circumstances of patients. Where people are managing substance use disorder, the service should be patient-centric and flexible to allow access to sufficient opioids for pain management.

Submissions that supported having lower or different limits noted that prescribing restrictions should be based on training, experience, clinical guidance and scope of practice, and that the risk of inappropriate prescribing comes from prescribers working outside their scope of practice. The following groups were

identified as being appropriate to have lower limits: secondary care prescribers (hospital prescribers), midwives, nurse practitioners and pharmacist prescribers. The following groups were identified as being appropriate to have higher limits: fully trained supervisors, pain specialists, primary care managing long-term pain, palliative care physician, chronic pain specialists, and oncologists. Dentists were identified as appropriate to have lower limits and, conversely, as appropriate to have higher limits. We heard prescribers managing substance use disorder might be appropriate to have an exemption.

Submissions were concerned that having different limits for different groups of prescribers is unworkable. It increases access barriers for patients who have limited access to specialist services, it could be unworkable in secondary care, e.g. how to differentiate between surgeons and registrars, and repeat clinic visits for patients on long-term treatments are usually with registrars rather than the consultants.

We also heard that short term acute pain prescriptions should be restricted to less than 7 days.

Whether supporting or not supporting alignment of prescribing restrictions, submissions recognised that:

- prescribing limits should be consistent across different prescribing methods (e.g. electronic or paper-based)
- it is inappropriate to have tighter restrictions on Class C opioids than on Class B opioids. Some felt they should have the same prescribing restriction, others felt that Class B should have tighter prescribing restrictions.

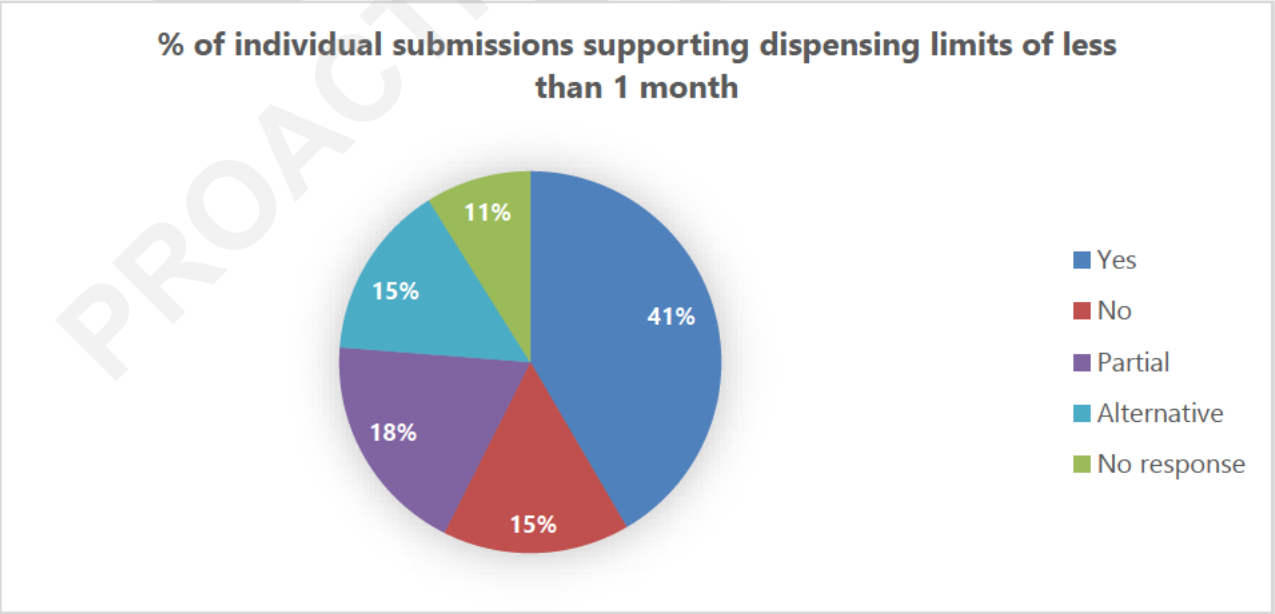
Submissions noted that regulations can't be updated quickly enough to align with risks from a quickly changing drug market.

Submissions made additional suggestions:

- use some form of audit and compliance (or peer review) to support identification of inappropriate prescribing
- enable pharmacist prescribers to be able to move into Opioid Substitution Treatment (OST) prescribing in the future, given significant medical practitioner shortages.

3.9 Should opioids have dispensing limits of less than 1 month?

Further Question: Is the 10-day default dispensing limit appropriate



The majority of submissions support or partially support having a dispensing limit of less than 1 month. While there was a strong preference for a limit of 10 days, submissions also suggested 3 days, or multiples of 7 days. Submissions noted that 7 days is used in palliative care as it helps with workflow and for managing short courses of medicine and dose reductions.

We heard that reduced dispensing limits would support: reducing the risk of harm to the community from diversion, theft, oversupply and wastage, increasing patient awareness of the seriousness and potential for harm associated with opioids; prompting patients to consider the need for continuing the medication; providing dispensers with an opportunity to monitor if the patient's pain is resolved; and reducing the risk of stock shortages and storage issues at pharmacies. Submissions noted that, in palliative care, it may be appropriate for facilities to receive more than a 10-day supply of medication if access to a pharmacy is restricted, as palliative care facilities may not have capability to hold sufficient stock.

Submissions made suggestions related to implementation of a 10-day dispensing limit:

- Where three-months' supply is appropriate, monthly supply through dispensing could be enabled with access exemptions where needed.
- Enable prescribers to determine the period of supply, and require the number of units (e.g. tablets, ampoules) is specified, if the prescription is for unscheduled use.

We also heard concerns that reducing the dispensing limit will negatively impact those who require opioids for long-term/chronic conditions and has the potential to increase inequitable access to treatment, especially for those living in rural or remote areas.

Submissions noted that, currently, the Pharmaceutical Schedule allows for individual patient exemptions to the 10-day rule, thereby enabling access and flexibility in complex situations. If dispensing rules are set in regulations, the ability to make context- and patient-specific exceptions would be lost.

The following were suggested, as alternatives to setting dispensing limits:

- use health practitioners' discretion to identify appropriate dispensing periods, e.g. a pharmacist could decide if longer dispensing is appropriate if the dose is stable.
- use funding rules or guidelines instead of regulations to set dispensing limits.

4 Additional questions for feedback

4.1 What do you think are the main risks or gaps in opioid regulation that need to be addressed? Are there specific issues you are aware of?

Submissions noted the following risks and gaps in opioid regulations, some of which were also noted in responses to questions about the three options.

Monitoring

- A peer review process would help long-term prescriptions to be assessed for inappropriate prescribing.
- Lack of electronic prescribing and monitoring means the current system does not allow for prescribers to have transparency on what opioids their patients are taking, which makes it easier for patients for shop-around for opioids.

Funding

- The Pharmaceutical Schedule, which are funding rules, should not be the control mechanism for dispensing, and that the control mechanism needs instead to be defined in legislation (with the funding rules aligned with that).
- Misalignment of funding where people can pay for 1 month of opioids if they can fund themselves.
- The funding model doesn't reflect the non-pharmacological management of pain and doesn't allow enough time for complex chronic pain patients to be seen and assessed at primary care services.

Pain management services

- Lack of (and referral to) pain services to implement de-prescribing clinics, especially for continued opioid prescribing following surgery or hospital stay.
- Lack of opioid substitution treatment programmes.
- Lack of opioid management plan.

Education

- Lack of education for patients, family, carers and the public about safe use of opioids, returning unused drugs, and the harm of long-term opioid use. Especially where family members are legally appointed to make decisions for an individual and are fearful of reducing opioids in case it increases pain for that individual.
- The needs of elderly and people with chronic conditions are increasing along with the reliance on others to manage medication. Opioid education for health care staff working with complex groups, such as people that are frail, have multiple comorbidities and multiple medications charted, is an area of opportunity. Care plans specifically for managing opioids in aged residential care (ARC) could be a solution to current problems, e.g. managing multiple specialists' involvement, high turnover of ARC staff.
- Opioid and pain management for patients with cognitive/communication impairment could benefit from an education focus.
- Lack of clinical guidance and training on prescribing opioids.

We heard concerns about regulations achieving the balance between flexibility of access, especially for ADHD medication, and the risks of harm to the community from larger quantities of opioids, which could result in stockpiling of unused opioids, diversion and misuse in the community. We also heard concerns about different groups of prescribers having different prescribing limits.

There were concerns that prescribers' fear of the risk of harm from prescribed opioids may be creating barriers to those who need opioids for pain, and, conversely, that prescribers may not be taking the harm of

opioids seriously when prescribing.

4.2 If you are a prescriber, what do you need to ensure you can continue to provide safe access to opioids to service users?

This question received 56 responses with suggestions.

We heard that there needs to be greater consistency across prescribers for Class B and C opioid prescribing and the length for which they are prescribing, especially (but not limited to) pharmacist prescribers and nurse practitioners. This is to ensure equitable access for service users. We also heard we need to have consistency between electronic and physical prescriptions to reduce inequity between community-based and hospital-based prescribers.

Submissions made suggestions about dispensing timeframes, education, long-term/chronic care, funding, information sharing and relying on clinical best practice as the control to manage risks of inappropriate prescribing. We heard that prescribers need more autonomy to make decisions in the best interests of their patients, specifically in relation to safeguarding and pastoral review of practice to acknowledge potential risks to patients, providers, and the wider community.

Submissions raised the need for an improved electronic prescribing system that aids patient management, is accessible within hospital databases, and creates overall transparency across the system.

We also heard that access to atypical opioids (buprenorphine, tramadol and tapentadol) needs to be improved as safer options, that there needs to be more education for junior prescribers to ensure safe prescribing, and there needs to be increased funding for GPs and pharmacies to enable cost reduction.

4.3 Do you have any comments on the long-term proposal to explore how prescribing and dispensing rules could be incorporated into the Therapeutics Products regulatory regime?

We received 43 submissions with suggestions for the Therapeutics Products regulatory regime. These comments have been shared with the Therapeutics Products Bill Review.

4.4 Is there anything else you would like us to consider

We received 55 responses to this question. Responses were wide-ranging and raised points also noted in responses to questions about the three options.

Submissions raised the following additional concerns:

- Improve funding to support the assessment and management of complex chronic pain conditions and non-pharmacological pain management in primary care. Improve funding and access to multi-disciplinary chronic pain management at secondary and tertiary levels, and funding for deprescribing clinics targeting persistent opioid users.
- The delay of the proposed changes to the Pharmaceutical Schedule has adversely impacted many people living with ADHD whose access to long-term medications remain high, but with access barriers. The current requirements for 1-monthly prescriptions for long term medications methylphenidate and dexamfetamine for ADHD and associated conditions make access difficult for patients and their whānau, add unnecessary cost and time for whānau and extra work for the GP, prescriber and pharmacy. The guidance/gazette/public funding for methylphenidate prescribing is confusing and does not prevent inappropriate prescribing. Opioids and stimulants (for ADHD) should have separate prescribing and dispensing limits.
- Create a change to existing practice to allow for a greater focus on human rights and remove stigmatisation from education and training to ensure all service users are treated equitably.
- There is no mention of other options for mitigating potential harm (for example, increasing the availability of naloxone).

- The engagement paper used a simplistic and stigmatising framework which should not frame development of options to reduce the risk of harm while ensuring people have access to appropriate pain management. In addition, the engagement period was too short to consider the issue fully.
- Submissions requested a transparent and thorough consultation process before similar changes are considered for implementation, a request for appropriate use of terminology, and consistent messaging.
- Harm from opioids is not just about tolerance/dependence. It is also about respiratory depression, constipation and poorly managed pain and diversion. Rules to access them need to be correspondingly strong.
- Following the enactment of the Misuse of Drugs Amendment Regulations 2022, prescribers and dispensers nationwide reported unclear, delayed, inconsistent information from authorities such as Manatū Hauora and Pharmac. Health professionals and the public encountered conflicting and contradicting advice, and at times were unable to contact Manatū Hauora for any comment whatsoever. These authorities should be trusted to provide timely and reliable guidance during situations such as policy or legal reform, to support the application of current law, best clinical practice and prevent avoidable harm. Any subsequent changes to law, policy and practice are accompanied by a comprehensive communication plan across relevant sector organisations. A comprehensive communication plan would facilitate certainty and transparency to those who intersect with the legislation. Updates should be prompt, concise and consistent, incorporating domains such as Manatū Hauora, Te Whatu Ora, Pharmac, Medsafe, Te Hiringa Hauora– Health Promotion Agency, the Health Quality & Safety Commission, and relevant health professional registration boards and/or councils.
- Representative organisations that made submissions expressed a desire to be involved in further engagement and development of solutions.