



Safe Access to Opioids – Engagement document

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Part One – Introduction

Purpose of this paper

1. This paper seeks your feedback on options to ensure safe access to opioids for people who need them. The Ministry of Health especially want to hear from prescribers and dispensers of opioids, pain specialists, and consumer groups.

How to have your say

2. The Ministry of Health (Manatū Hauora) seeks written and oral submissions on the issues raised in this document by 31 March 2023.
3. You may respond to any, or all, of the options and questions in the engagement paper. Where possible, please provide the reasons for your responses.
4. You can make your submission by using the submission form at consult.health.govt.nz/regulatory-policy/17cc7794.
5. There will also be an opportunity to provide additional feedback at a web-hui on Wed 22 March 2023 5.30pm-6.30pm or Tue 28 March 2023 7.30pm – 8.30pm.
6. If you wish to register your interest in attending the web-hui, or receiving the findings from this engagement, please email safeopioiduse@health.govt.nz by 20 March 2023.
7. Note that your submission may be requested under the Official information Act 1982. If this happens, the Ministry of Health will normally release your submission to the person who asks for it. If you consider there are good reasons to withhold it, please clearly indicate these in your submission.

Summary

8. Some clinicians, including pain specialists, are concerned about recent regulatory changes that increased the maximum amount of opioids that could be prescribed at one time. Further discussions with clinicians and relevant agencies highlighted wider issues with the effectiveness of the controls intended to manage people's safe access to opioids.
9. The Ministry reviewed these 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, but there are also opportunities for system improvements.

Focus of this engagement process

10. The Ministry of Health is considering what controls and safeguards are needed for the prescribing of opioids. We want to ensure that all those who need prescription opioids have reasonable access to them, while maintaining appropriate controls to mitigate their risk of harm to the public.
11. This document seeks feedback on possible approaches to regulation, as well as options that could support regulation.
12. The Ministry of Health seeks feedback on the following options:
 - 12.1 Option 1: no regulatory change
 - 12.2 Option 2: strengthen guidance to encourage good prescribing practice
 - 12.3 Option 3: strengthen guidance and change regulations
13. The Ministry of Health seeks your feedback on the risks associated with current controls on opioids, the proposed options, and their implementation. Your feedback will be used to inform the Ministry of Health's advice to Ministers on addressing risks of harm from unsafe access to opioids.

Timeframes for engagement

14. Submissions on the options in this document are due before 5pm on **31 March 2023**.

Background

15. The Medicines Act 1981 and the Misuse of Drugs Act 1975 regulate the prescribing, supply and possession of drugs. Specific limits for prescribing controlled drugs are provided in the Misuse of Drugs Regulations 1977 (the Misuse of Drugs Regulations).
16. In December 2022, the Misuse of Drugs Amendment Regulations 2022 (the amendments) came into effect. These amendments made several changes to controlled drug prescribing regulations. One of these changes allowed Class B controlled drugs to be prescribed for up to 3 months with up to 1 months dispensing, when prescribed electronically through the NZ ePrescription Service (NZePS), by any prescriber with authority to prescribe them.
17. This change was intended to improve access to Class B controlled drugs for people with chronic conditions. The increase in the maximum amount provides more flexibility for practitioners to prescribe what is appropriate for their patients.
18. Clinicians have raised concerns that this prescription length might increase the quantity of opioids being prescribed and could increase the risk of opioids being accessed inappropriately. For example, some patients, particularly those already with an opioid dependence, may request longer duration prescriptions.

19. A number of controls and safeguards exist to manage the risk of inappropriate access to opioids. These include regulations that set out prescribing authorities, clinical guidance that sets out appropriate practices, clinical support systems in provider settings, monitoring systems to review potential inappropriate prescribing, and professional sanctions where inappropriate prescribing occurs.
20. The Ministry's review identified the following controls need improvement:
 - 20.1 amending opioid prescribing regulation to be more in line with best practice,
 - 20.2 more comprehensive monitoring capability, including further investment in technology,
 - 20.3 in the longer-term, a better mechanism for establishing prescribing and dispensing rules and guidelines for high-risk medicines.
21. The proposed regulation changes, which the Ministry is seeking feedback on, are discussed later in this document.
22. The amendments in 2022 impacted prescribing limits for all Class B controlled drugs, which includes stimulants that are prescribed for patients with ADHD. This review is focused on addressing risks associated with opioid access, so does not include ADHD medicines.
23. Improving access to ADHD medicines is being explored in a separate process.

Monitoring is being strengthened

24. From June 2023, the Medicines Data Repository (MDR) will be utilised by Medsafe (the medicines regulator). The new monitoring system will provide Medsafe¹ the capability to more rapidly identify and respond to prescribing issues.
25. The monitoring system will enable searches of real-time data across individuals, prescribers, pharmacies and medicines. This information can be more frequently analysed by Medsafe and shared with Ministry of Health officials and other regulators to take a more proactive approach to compliance monitoring and enforcement.
26. The Ministry of Health will prioritise regular, high-level monitoring of prescription durations, dispensed amounts and equity indicators (by ethnicity). The Ministry is currently exploring, with Medsafe, what will be required to achieve this level of enhanced monitoring.

Future opportunities for setting prescribing rules

27. The Misuse of Drugs Regulations provides specific prescribing and dispensing rules for each class of controlled drug, and each type of prescriber. To ensure

¹ One of the activities of Medicines Control (a unit within Medsafe) is to monitor controlled drug prescribing.

that these rules are appropriately balancing access with safety, these rules need to reflect current clinical views and guidance.

28. It is difficult to keep the Misuse of Drugs Regulations up to date as the process to change legislation takes considerable time and prioritisation over other legislative changes.
29. There is an opportunity to change the mechanism used for setting prescribing and dispensing rules. The Therapeutic Products Bill, recently introduced to Parliament, is intended to provide a modern regulatory regime for therapeutic products in New Zealand.
30. Under this new regulatory regime, the Therapeutics Products Regulator (appointed by the Director-General of Health) will have the authority to make legally enforceable prescribing and dispensing rules. There is an option in this future state to use this mechanism to develop rules for managing high risk medicines, such as opioids. This would offer a more responsive, flexible and patient centred option for managing access.
31. Developing this regulatory system is a long-term opportunity and will involve further consultation.

Part Two – What is the problem?

32. Opioids are important medicines for many people. However, they can also lead to dependence and cause significant harm when accessed inappropriately.
33. Opioids should be prescribed in line with best practice clinical guidelines to ensure appropriate access for patients to manage their pain. They 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 the long-term efficacy and safety of treatment, including the risk of abuse, misuse and dependence.

Existing issues with opioid prescribing regulations

34. The Ministry's review into opioid prescribing identified the following problems that could be addressed through regulation change:

Opioid prescribing limits

35. As a result of the Misuse of Drugs Amendment Regulations 2022, Class B opioids can be prescribed (by any prescriber with authority to prescribe them) for up to **3 months** with up to **1 months dispensing**, when prescribed through the NZ ePrescription Service (NZePS).
36. The ability to prescribe 3 months' supply of a Class B opioid has two main risks:
 - a) Diversion of medicines – where the medicine is prescribed to a person who has a legitimate need but is then passed on to others without a legitimate need
 - b) Increased risk of dependence arising from longer duration prescriptions.
37. Some practitioners are concerned that prescribers may prescribe inappropriately when placed under pressure. Increased pressure could come from their workload or directly from a patient.
38. There is a concern that patients, particularly those already with an opioid dependence, will expect longer duration prescriptions when they become aware that this is possible. This was also an issue prior to the amendments as patients can apply the same pressure for repeat prescriptions.

39. There is also a concern that the process of repeat prescribing may be accompanied by inadequate communication or reassessment, for instance if a patient is prescribed opioids following surgery and the prescription is repeated by subsequent prescribers.

Balance patient access with safety

40. The regulations place strict restrictions on controlled drug prescribing, due to the risk of harm they can cause when misused. However, these restrictions are not always appropriate for all situations.
41. Long term use of opioids, for example, can be appropriate when treating patients with cancer or who are in palliative care. Currently the regulations do not allow prescribers the flexibility to prescribe more opioids in those circumstances.

10-day dispensing limit for Class B opioids

42. A key control on opioid access are the dispensing rules that sit within the Pharmaceutical Schedule. This Schedule, managed by Pharmac, provides subsidisation criteria that limits the amount of Class B controlled drug that may be dispensed at one time. For Class B opioids there is a default limit of **10-day** lots.
43. The dispensing rules in the Schedule are only for funded medicines, which means they do not apply if a person chooses to pay for the drug in full. Opioids are also relatively inexpensive medicines, so cost is not considered a significant barrier to prevent patients from accessing larger amounts of unsubsidised opioids.
44. In December 2022, Pharmac began consulting on aligning these rules with the Misuse of Drugs Regulations. If these changes were implemented the 10-day dispensing limit for Class B opioids would be removed. If this limit, or something similar, needs to be retained it may have to be placed within the Misuse of Drugs Regulations.

Appropriate prescribing limits for each profession

45. The Misuse of Drugs Regulations place specific limits on controlled drug prescribing amounts 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 prescriber pharmacist can prescribe a Class C controlled drug for a period of up to 3 days.
46. The amendments in 2022 have also created a situation where, in some instances, a prescriber is able to prescribe more of a Class B controlled drug than a Class C controlled drug.

47. Prescribers and dispensers have raised concerns that various limits can sometimes be arbitrary, impractical and not reflective of clinical capabilities. There is also a significant impact on a patients access to important medicines when certain prescribers are more limited in their ability to prescribe.

Part Three – Options

Options

48. There are a range of options the government could use to minimise or decrease the risk of inappropriate access, ranging from 'light' education and guidance-based approaches through to regulation change.

Option 1 – no regulatory change

49. Under this option, there would be no change to prescribing or dispensing regulations under the Misuse of Drugs Regulations. This would only be appropriate if the existing regulations are deemed appropriate to ensure safe access to opioids.
50. The Ministry will continue to implement enhanced monitoring as described above and explore, in the long term, how prescribing and dispensing regulations might be better placed under the Therapeutics Products regulatory regime.
51. Under this option, opioids will still be able to be prescribed for up to 3 months and with up to 1 months dispensing.
52. The 10-day default dispensing limit, within the Pharmaceutical Schedule, may be removed (this has been consulted on separately by Pharmac).

Option 2 – strengthen guidance

53. Under this option, Manatū Hauora, along with the other health agencies, will coordinate with responsible authorities and relevant professional bodies to develop and distribute clinical guidance for opioid prescribing and dispensing.
54. Clinical guidance is an important mechanism to influence practitioner behaviour and support them to be confident about how they should prescribe and dispense opioids.
55. A criticism of the existing clinical guidance on opioid prescribing is that it can be fragmented (produced by different bodies), is not updated in a timely way, and doesn't reach all the relevant practitioners.
56. An advantage of this option is that the guidance could, in time, inform the development of parameters for the enhanced real-time monitoring system and would form the basis for future rules on opioid prescribing.
57. As with **option 1** this option will not address any concerns over the 10-day default dispensing limit for opioids being removed from the Pharmaceutical Schedule.

Option 3 – strengthen guidance and change regulations

58. Under this option, the Ministry will strengthen guidance, as per **option 2**, and amend the Misuse of Drugs Regulations to manage short term risk. Manatū Hauora is considering the following regulatory changes, one or all could be progressed if appropriate:
- 58.1 reduce the prescribing limit for Class B opioids to **1 month** (for both electronic and physical prescriptions). This would include an exemption for prescribing of opioids for cancer patients and those in palliative care, to ensure those with long term need have reasonable access to these medicines.
 - 58.2 require a peer review process for repeat opioid prescriptions for non-cancer pain. Similar mechanisms are used in other jurisdictions. This would create an additional check on opioid prescribing to ensure that patients have a legitimate need for further opioid use.
 - 58.3 ensure appropriate prescribing limits within the regulations for all prescribers of controlled drugs, including opioids. This change could allow all prescribers of controlled drugs the same maximum prescription length under the regulations, for each class of drug, or new specific limits for each type of prescriber.
 - 58.4 insert a 10-day, or similar, dispensing restriction specific to opioids to retain limited opioid dispensing if this rule is removed from the Pharmaceutical Schedule.

Part Four – Questions

These proposals are intended to balance the need for access to opioids with the need for preventing the significant harm seen around the world as a result of these drugs. We wish to hear from submitters on all the potential impacts of these proposals.

Your written submission can address any aspect of this paper. However, for clarity we would appreciate it if you could please answer the following questions:

1. Briefly, what is your interest in this topic? Are you a prescriber, service user, practitioner etc? **This is a collaborative response on behalf of the New Zealand Hospital Pharmacy Association (NZHPA), compiled by the NZHPA Medication Safety Special Interest Network.**
2. Is **option 1** (no regulatory change) sufficient for balancing access to opioids with potential risk of harm? **No, NZHPA don't believe the regulations changed in 2022 balance the risk of opioid related harm.**

There is a global opioid crisis and opioids are consistently amongst the top medications involved in incidents and errors. Our biggest concerns with 3 monthly prescriptions would be:

- **opioid dependence,**
- **potential risk of overdosing. There would be increased risk of accidental poisoning/overdose in children with larger quantities of opioids in homes**
- **potential for diversion and stockpiling. Vulnerable patients may be targeted by criminals if they have larger supplies of opioids in the home.**

Community pharmacies have raised concerns about ability/room to store increased supplies to cover 1 month prescriptions, and increased risk of burglary knowing larger quantities will be on the premises.

Without regular review there is also potential for some patients to not have their pain managed effectively.

3. Is strengthened clinical guidance required and would it adequately address the risks of inappropriate prescribing (**option 2**)? **Strengthened national clinical guidance would be welcome and will serve as a strong foundation for opioid stewardship. However, guidance alone will not reduce the risk of overprescribing and inappropriate supply. Therefore option 2 alone will not be adequate.**

Education is a relatively weak intervention to prevent harm, regulation or forcing functions is preferred, and will ensure standards are applied consistently. For example, if you look at the Australia NZ College of Anaesthetists ANZCA position statement issued in 2018 advising against the use of controlled release opioids in the acute setting and then look at prescribing habits post-surgery in local NZ hospitals you can see this position statement education has been relatively ineffective. Long-acting opioids

such as M-eslon and Oxycodone CR continue to be prescribed post-operatively. They are also often prescribed without a clear plan for discontinuing therapy being documented for primary care.

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

- Should opioid prescribing be limited to 1 month's supply? **Yes, opioid prescribing should be limited to 1 month supply. Reasons outlined in question 2 – risks of dependence, overdose, diversion etc.**
- Should there be an exemption for cancer patients and those in palliative care? How would this impact the ability of prescribers to care for their patients? **We would support exemptions for palliative patients and cancer patients if Palliative Care Physicians and Oncologists are supportive of this exemption.**

In main urban areas palliative and cancer patients are usually reviewed by a physician or nurse regularly. Doses are titrated frequently, so the prescription could quickly become out of date. In this case, a 3-month prescription would be excessive and could lead to wastage.

We can see the benefit of 3-month prescriptions for more isolated patients, or areas with reduced palliative care services. An extended period of supply would greatly improve patient's access, and doses could be titrated remotely over telehealth for example.

Exemptions could also be applied to other stable long-term conditions, for example, Opioid Substitution Therapy (OST) patients with a stable dose. Psychiatrists could prescribe extended periods of OST if viewed as appropriate, to reduce the administrative task of re-prescribing each month. Daily dispensing, with limited takeaway doses would continue to limit the potential of opioid related harm in these patients.

- Would a peer review process for repeat opioid prescriptions reduce the risk of inappropriate prescribing? Would implementing this create a significant barrier to access? Are there implementation issues with this proposal? **We would support this in principal but wonder if in practice, it might be time consuming, cumbersome and lead to a delay in patients receiving medicines, and potentially additional costs to the patient having to see another prescriber. Would also be difficult to implement in some rural areas where GPs are practicing in isolation.**

Should we align the prescribing restrictions for all opioid prescribers? Should some prescribers have lower limits for prescribing opioids? Should there be different limits for different groups of prescribers? **We strongly believe the limits should be aligned. We think that doctors, nurses and pharmacist prescribers should be able to prescribe the same quantities. It makes no sense to be different and is confusing for the patients and all involved in the care of the patient. If a prescriber has undertaken the appropriate training and deemed competent to prescribe by their regulatory body, there do not need to be differing restrictions for controlled drug**

prescribing. With increased clinical demand more pharmacists and nurses will be working at top of scope, the legislation needs to support their practice.

Dental prescriptions should remain at 7 days, and not increased to 1 month, as they should only be managing acute not chronic pain.

- Should opioids have dispensing limits of less than 1 month? Is the 10-day default dispensing limit appropriate? **The 10 day limit is appropriate.** Wastage of controlled drugs will increase if patients are dispensed monthly lots of controlled drugs and their condition then changes – not uncommon in palliative care and in pain conditions. There are also stock related issues that will occur if pharmacies have to stock enough controlled drugs for 1 month dispensing: having enough storage space and short dated stock are examples. Pharmacies are also concerned about the safety of holding large quantities of controlled drugs, especially with all the hold ups in the media. Monthly dispensing would mean it would take much longer to identify errors. We had a recent case where a patient was meant to be on m-eslon 20mg BD for 1 week, then decrease to 10mg BD 1 week on discharge from hospital. However the patient was incorrectly prescribed oxycodone CR and subsequently took both the 20mg and 10mg BD at once, so ended up taking 60mg BD morphine equivalent. Monthly dispensing would have taken longer to identify the error.

We also recognise that an extended period 1 month supply for certified or endorsed conditions might be beneficial– e.g. cancer pain.

If the 10 day limit were to change to increase patient access, it would be preferable to change to twice monthly or fortnightly dispensing, e.g. a 14 or 15 day rule. This would reduce patient visits to the pharmacy by 1/3, or 12 visits per year, and have lesser impact on the increased risks of opioid related harm mentioned above. Although this proposal may be viewed as not a significant difference from the 10 day rule and legislatively simpler to maintain the status quo 10 day rule.

Additional questions:

5. 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? **The current mismatch between regulation and funding needs to be addressed. Also the disparity that a pharmacist prescriber can prescribe up to 30 days of class B controlled drugs, but only 3 days of class C controlled drugs.**

There is also the issue that many hospital pharmacies are not able to read barcoded controlled drug prescriptions to date. The dispensing software does not integrate with NZePS yet. It is illegal for hospital pharmacies to dispense from barcoded GP prescriptions without the technological support. For example if a palliative rest home patient needs an ampoule of subcut opioids not readily available in community pharmacies and writes an electronic prescription, which is then printed. Legislative barriers negatively impact timely patient care.

Triplicate CD prescriptions seem to have been removed from primary care without the barcoding technology completely implemented in hospitals.

Please ensure any future legislative changes have the technology fully implemented to support.

6. If you are a prescriber, what do you need to ensure you can continue to provide safe access to opioids to service users? As a group, we have many pharmacist prescribers amongst our members. Pharmacist prescribers need to be able to prescribe more than 3 days of controlled drugs for our patients to ensure timely and safe access to these medicines.
7. 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? The ability of the Therapeutics Products Regulator to develop dispensing rules would be useful. We can see this being beneficial in response to e.g. monitoring information highlighting a particular opioid-related issue.
8. Is there anything else you would like us to consider? Thank you for collating this feedback. We believe patient safety should underpin any decisions made.