MANATŪ HAUORA
MINISTRY OF HEALTH

Aide-Mémoire

Ministerials on recent changes to opioid regulation

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To:	Hon David Seymour, Associate Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

Contact for telephone discussion

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Comment: **Ministerials on opioid regulation changes**

- Your office has recently received several Ministerials from people who are facing new restrictions to accessing their opioid medicines.
- The new restrictions are a result of changes to prescribing regulations for opioids that came into effect in late 2023.
- This aide-mémoire provides you with an overview of these regulatory changes and attached are proposed responses to the Ministerials we have received to date.
- This aide-mémoire discloses all relevant information.

Allison Bennett
Group Manager, Health System Settings
System Strategy and Policy

Ministerials on recent changes to opioid regulation

Context

1. In 2023, changes were made to the Misuse of Drugs Regulations 1977 to ensure more appropriate restrictions on the prescribing limits of opioids. The changes reduced the maximum limit for all opioid prescriptions from **three months** to **one month**.

2. These changes were a result of a review of opioid controls by the Ministry of Health following concerns raised about inappropriate prescribing limits for opioids.

3. Opioids 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. Setting a maximum period of supply of one month ensures regular clinical review of ongoing pain management.

4. However, for some people this change has increased barriers to accessing their pain medicines (opioids). Your office has received several complaints requesting that this change be reversed.

Review of opioid controls

The review was initiated as a result of concerns of opioid harm

5. In December 2022, the Misuse of Drugs Regulations 1977 (the Regulations) were amended to improve patient access to some medicines. One of the changes included in the amendments increased the maximum prescribing amounts for Class B controlled drug medicines.

6. The 2022 amendments increased the amount of Class B controlled drugs that certain professions could prescribe at one time to a maximum of 3 months supply, up from the previous limit of 1 month.

7. 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.

8. Some clinicians, including pain specialists, expressed concerns over how this change might impact the amount of opioids being prescribed (many of which are Class B drugs) and could increase the risk of harm that opioids can cause when accessed inappropriately.

9. Discussions with those concerned, and with relevant agencies, highlighted some existing issues with wider system controls that impact safe access to opioids.

Cross-agency review

10. 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.

11. The Working Group was 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.

12. Through the review the following controls were identified as needing improvement to manage safe access to opioids:

    a. amending opioid prescribing regulation to be more in line with best practice,

    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.

The Ministry of Health engaged on further regulation change based on the Working Group's findings

13. The immediate consideration of the review was to manage any short-term risk of opioid harm. The review identified that the priority was to address prescribing regulations for opioids.

14. Engagement on proposed regulation changes took place throughout March 2023.

15. 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.

16. 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.

17. A summary of this engagement was made available on the Ministry website.

18. The submissions received in this engagement were varied and nuanced, illustrating the complexity of ensuring access to opioids while managing the associated risks. However, the majority of submissions expressed that changes to prescribing regulations for opioids were warranted.

Reducing the prescribing limit for opioids to 1-month

19. 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.

20. 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.

21. A 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.

22. Most submissions supported 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.

23. This change created 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.

The changes have impacted access for some patients

24. The new restrictions on opioid prescribing came into effect on 5 October 2023. The changes were well communicated at the time to the public and through the relevant clinical stakeholders.

25. Your office has recently received several complaints from patients who have become aware of the new restrictions through their health practitioner informing them that they can now only receive a 1-month supply of their medicines. This is understandably frustrating for those patients, especially as there is likely to be a cost increase from requiring a new prescription each month.

There is the potential for improved regulation

26. 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.

27. 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 always reflective of clinical views.

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

29. Frequent amendments are necessary to these regulations to adapt to changing models of care, best prescribing practices, access to new medicines and technology. The existing regulations also do not provide the flexibility to enable prescribing outside of normal parameters when deemed clinically appropriate.

30. The Ministry will be providing advice on future regulatory mechanisms for medicines as part of progressing the repeal of the Therapeutic Products Act.