Minister of Health

Amendments to prescribing regulations for controlled drugs

4 September 2023

These documents have been proactively released by the Ministry of Health on behalf of the Minister of Health, Hon Dr Ayesha Verrall.

Title of Cabinet papers:

- Amendments to prescribing regulations for controlled drugs

Titles of minutes:

- Report of the Cabinet Social Wellbeing Committee: Period Ended 21 July 2023 (CAB-23-MIN-0313)
- Amendments to Prescribing Regulations for Controlled Drugs (SWC-23-MIN-0086)

Some parts of this information release would not be appropriate to release and, if requested, would be withheld under the Official Information Act 1982 (the Act). Where this is the case, the relevant sections of the Act that would apply have been identified. Where information has been withheld, no public interest has been identified that would outweigh the reasons for withholding it.

Key to redaction codes:

s9(2)(a): to the privacy of individuals

Out of scope of the subject of this proactive release.

CAB-23-MIN-0313

Cabinet

Minute of Decision

Report of the Cabinet Social Wellbeing Committee: Period Ended 21 July 2023

On 24 July 2023, Cabinet made the following decisions on the work of the Cabinet Social Wellbeing Committee for the period ended 21 July 2023:

Out of scope

SWC-23-MIN-0086 **Amendments to Prescribing Regulations for Controlled Drugs** CONFIRMED
Portfolio: Health

Out of scope

Rachel Hayward
Secretary of the Cabinet

SWC-23-MIN-0086

Cabinet Social Wellbeing Committee

Minute of Decision

Amendments to Prescribing Regulations for Controlled Drugs

Portfolio **Health**

On 19 July 2023, the Cabinet Social Wellbeing Committee:

1 **noted** that the Misuse of Drugs Regulations 1977 establish different maximum periods of supply for controlled drug prescriptions for each profession;

2 **noted** that different maximum periods of supply can restrict access to important medicines for some patients and cause difficulties for some professions to provide necessary care;

3 **agreed** to amend the Misuse of Drugs Regulations 1977 to establish a maximum period of supply for non-opioid Class B and Class C controlled drugs of three months for medical practitioners, nurse practitioners, designated prescriber nurses, designated prescriber pharmacists, midwives and dentists;

4 **agreed** that the above new maximum period of supply will apply to both physical and electronic prescriptions;

5 **noted** that a period of supply limit of one month for controlled opioids provides a balance between safety and access, and supports regular clinical review;

6 **agreed** to amend the Misuse of Drugs Regulations 1977 to establish a period of supply limit for all opioids classified under the Misuse of Drugs Act 1975 of one month for medical practitioners, nurse practitioners, designated prescriber nurses, designated prescriber pharmacists, midwives and dentists;

7 **agreed** to amend the Misuse of Drugs Regulations 1977 to allow the relevant Medical Officer of Health to authorise a maximum period of supply of up to three months for specified prescribers under section 24A of the Misuse of Drugs Act 1975, to maintain access to Opioid Substitution Treatment;

8 **invited** the Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to give effect to the above decisions.

Rachel Clarke
Committee Secretary

Attendance (see over)

Present:
Hon Kelvin Davis
Hon Grant Robertson
Hon Dr Megan Woods
Hon Jan Tinetti (Chair)
Hon Willie Jackson
Hon Peeni Henare
Hon Kieran McAnulty
Hon Ginny Andersen
Hon Barbara Edmonds
Hon Jo Luxton

Officials present from:
Office of the Prime Minister
Officials Committee for SWC

In Confidence

Office of the Minister of Health

Cabinet Social Wellbeing Committee

Amendments to prescribing regulations for controlled drugs

Proposal

1 This paper seeks agreement to amend the Misuse of Drugs Regulations 1977 to improve safe access to controlled drug medicines.

Relation to government priorities

2 The proposals are in line with the Government's priorities of providing equitable and safe access to health care services.

Executive Summary

3 In early 2023, Manatū Hauora began a review to examine whether current controls that manage prescribing, including regulation, were appropriate to enable safe access to opioid medicines. The review followed concerns being raised by some clinicians that amendments to prescribing regulations in 2022 [CAB-22-MIN-0526] may have increased the risk of harm from inappropriate prescribing of opioids.

4 The proposals in this paper respond to the following issues with current prescribing regulations identified through the review:

4.1 current prescribing limits for controlled drugs are complex, arbitrary, a barrier to accessing health services, and for some prescribers not reflective of their competence

4.2 the amendments in 2022 created a prescribing limit for opioids that is not appropriate.

5 To address these issues, I am seeking Cabinet's agreement to amend the Misuse of Drugs Regulations 1977 to:

5.1 establish a consistent maximum period of supply for Class B and C controlled drugs that are not opioids, of 3 months, across all controlled drug prescribers for both physical and electronic prescriptions

5.2 establish a maximum period of supply for Class B and C opioids of one month.

6 Both proposals in this paper will provide a more reasonable regulatory framework for prescribing controlled drugs, which acknowledges that these drugs are essential components of health care for many people, but that caution is needed when prescribing them.

Background

Misuse of Drugs Regulations 1977 strictly limit access to controlled drugs

7 Controlled drugs are classified within the schedules of the Misuse of Drugs Act 1975 by their potential risk of harm, as either A (very high-risk), B (high-risk), or C (moderate risk).

8 The Misuse of Drugs Regulations 1977 (the Regulations) set out the requirements for prescribing and dispensing controlled drugs and provide explicit standards for controlled drug prescriptions. The Regulations were created to provide additional controls for medicines that are considered to have a high risk of causing harm, including dependence and abuse.

9 The Regulations set limits for how much of a controlled drug each type of prescriber can prescribe, on a single prescription. This limit is known as the maximum period of supply.

10 The maximum period of supply is different for each type of prescriber and for each Class of controlled drug. A prescriber should issue prescriptions for less than the maximum period if that is more clinically appropriate. Although the maximum period of supply provides a control on a single prescription, the Regulations do not prevent a prescriber from issuing repeat prescriptions indefinitely.

11 Medical practitioners, nurse practitioners and dentists are authorised to prescribe any Class of controlled drug under the Regulations (except for some subsets of controlled drugs that require Ministerial approval to prescribe).

12 Designated prescriber nurses, designated prescriber pharmacists and midwives are only authorised to prescribe specific controlled drugs that are listed in their respective schedules within the Regulations. These schedules contain a combination of Class B and C controlled drugs, primarily opioids and benzodiazepines.

13 The current period of supply limits for Class B and Class C controlled drugs under the Regulations are as follows:

Profession	**Maximum period of supply (length of prescription)**	
	Physical prescription	**Electronic prescription (through NZePS)**
Medical practitioners: - Class B - Class C	 1 month 3 months	 3 months 3 months
Nurse practitioners: - Class B - Class C	 1 month 3 months	 3 months 3 months

Midwives: - Class B - Class C	 1 month 1 month	 3 months 1 month
Designated prescriber nurses: - Class B - Class C	 7 days 7 days	 3 months 7 days
Designated prescriber pharmacists: - Class B - Class C	 3 days 3 days	 3 months 3 days
Dentists: - Class B - Class C	 7 days 7 days	 7 days 7 days

These prescribing limits were recently amended in 2022

14 On 22 December 2022, the Misuse of Drugs Amendment Regulations 2022 (the 2022 amendments) came into effect. The 2022 amendments removed regulatory barriers to electronic prescribing and improved patient access to certain controlled drug medicines [CAB-22-MIN-0526].

15 One of the impacts of the 2022 amendments was to increase the maximum period of supply for Class B controlled drugs to 3 months, when prescribed electronically through the New Zealand ePrescription Service (NZePS).

16 This change was made to improve access to medicines for those with chronic conditions by reducing the frequency a patient would need to obtain a prescription for their medicines. The decision to limit this increase to electronic prescriptions was due to the increased oversight and security provided by the NZePS compared to physical prescriptions.

17 The 2022 amendments increased the maximum period of supply for all Class B controlled drugs, which included many opioids (such as fentanyl and morphine). While the 2022 amendments took effect in December 2022, there has been no indication that prescribing behaviour was impacted. This is likely due to other controls that limit prescribing amounts for opioids, such as professional standards and funding criteria set by Pharmac.

A review of opioid controls took place in early 2023

18 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.

19 Manatū Hauora conducted a review of opioid controls (the review) following the concerns raised by some clinicians about the impact of the 2022

amendments on the prescribing of opioids. Most opioid medicines currently approved in New Zealand are Class B controlled drugs.

20 The intent of the review was to determine whether the existing controls are effectively managing the risk of opioid harm and enabling safe patient access.

21 As part of this review, a cross-agency working group (the Working Group) was established. This working group was made up of representatives from Manatū Hauora, Te Aka Whai Ora, Te Whatu Ora, Pharmac and Te Tāhū Hauora | Health Quality and Safety Commission.

The review identified improvements for opioid controls

22 Through the review, the Working Group identified the following controls as needing improvement to manage safe access to opioids:

22.1 amending prescribing regulation to be more in line with best practice and supporting practitioners to prescribe appropriately

22.2 more comprehensive monitoring capability, in the short-term to assess the consequences of dispensing larger amounts of medication, and in the long-term further investment to take advantage of technology advances

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

23 This paper outlines the necessary amendments to prescribing regulations identified in the review.

Engagement with the sector on these proposals

24 Some of the clinicians who raised concerns over the 2022 amendments expressed that they should have been consulted during development of the amendments.

25 As part of the review, engagement with the health sector took place throughout March 2023. This provided an opportunity for interested stakeholders to express their views on opioid access and submit feedback on several proposed regulation changes.

26 The submissions received in this engagement were varied and nuanced, illustrating the complexity of ensuring access to opioids while managing the associated risks. The feedback informed the development of the proposals in this paper.

Analysis

The proposals seek to establish reasonable prescribing limits for all controlled drug prescribers

27 The proposals in this paper seek to ensure that prescribing regulations are enabling safe access to controlled drug medicines.

28 I propose the following amendments to the Misuse of Drugs Regulations 1977:

28.1 for all non-opioid Class B and C controlled drugs, establish a consistent maximum period of supply, of 3 months, for all controlled drug prescribers

28.2 create a maximum period of supply for all Class B and C opioids, of one month, for all controlled drug prescribers.

29 The maximum periods of supply within the Regulations are not guidelines for clinical practice. Setting a particular limit does not suggest that this is always an appropriate amount to prescribe a patient. The limit should allow the prescriber to use their own clinical judgement.

30 Practitioners with prescribing authority are required to ensure they meet their professional standards, codes of conduct, and always practise in patients' best interests. Regardless of what the maximum limit is within regulations, practitioners should only be prescribing an amount that is appropriate for the individual patient.

Establish consistent controlled drug maximum periods of supply for all prescribers of controlled drugs

31 The Regulations establish different maximum periods of supply for each profession. There is a significant impact on patient access when certain prescribers are more limited in their ability to prescribe. This particularly affects those with limited access to specialist services, such as those in rural or remote areas.

32 The Regulations should seek to balance the need to mitigate risk of harm while also enabling practitioners to provide services to their patients. For some controlled drug prescribers, the lower limits in the Regulations create barriers to care for their patients and are not reflective of the service they need to provide. For instance, pharmacist prescribers have expressed the difficulties caused by a prescribing limit of 3 days when they are the primary prescriber for their patients.

33 Therefore, I propose that the Regulations be amended to establish a maximum period of supply of 3 months for all non-opioid Class B and C controlled drugs, including both physical and electronic prescriptions. This maximum period of supply of 3 months would apply to all controlled drug

prescribers: medical practitioners, nurse practitioners, midwives, designated prescriber nurses, designated prescriber pharmacists and dentists.

34 Increasing the maximum periods of supply for designated prescribers, midwives and dentists recognises the competencies of these professions to determine appropriate prescribing amounts within a reasonable framework. It also reflects the confidence that responsible authorities (i.e., professional regulators such as the Pharmacy Council) have in upholding high standards within their professions.

35 For these prescribers this change will primarily impact benzodiazepines (often used to treat anxiety or insomnia). The maximum periods of supply are not indicative of a recommended length of prescription for specific drugs, they are the maximum amounts allowed by law. Clinical guidance and professional standards set by the responsible authorities are more appropriate controls on practice.

36 This proposal will not affect which specific drugs that can be prescribed by designated prescriber nurses, designated prescriber pharmacists and midwives.

Create a maximum prescribing limit of one month for all opioids

37 The current regulations set prescribing limits for each Class of controlled drug, rather than for individual types of drugs.

38 This presents an issue when certain drugs or types of drugs within a Class have different applications and risk profiles in a clinical setting. A single limit for all drugs within a Class is not always appropriate and can place unnecessary barriers to accessing some medicines.

39 Three months is not an appropriate limit for opioids. 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.

40 I propose that the Regulations be amended to insert a maximum period of supply for all controlled drugs that are Class B and C opioids, of one month. This change sets a reasonable limit for prescribing opioids.

41 For Class B opioids, this will return the limit to what it was prior to the 2022 amendments. However, the limit of one month will apply across all controlled opioid prescribers. Examples of Class B opioids affected by this change are fentanyl, morphine, oxycodone and methadone.

42 For Class C opioids, this change represents a decrease in prescribing limits for medical and nurse practitioners, and an increase for other controlled opioid prescribers. Examples of Class C opioids affected by this change are codeine and dihydrocodeine. Tramadol will also be affected by this change when it becomes a Class C controlled drug on 1 October 2023.

43 Setting a maximum period of supply of one month is sufficient to require regular clinical review of ongoing pain management. This will promote consultation and assessment of the patient and the opportunity to reduce opioid use or explore other pain management options.

44 A reduced maximum period of supply will result in less opioids in the community, which lessens the risk of stockpiling and diversion of these drugs to others, as well as less opioid wastage.

An exception for Opioid Substitution Treatment

45 Opioid Substitution Treatment (OST) provides support to people dealing with a dependence on opioids. Specialist OST services are specified by the Minister of Health under section 24A of the Misuse of Drugs Act 1975.

46 A specialist service and the lead clinician of that service must be authorised under section 24A to provide OST services. Section 24A also allows the specified lead clinician to authorise other practitioners within the service to provide OST services. They must also adhere to the New Zealand Practice Guidelines for Opioid Substitution Treatment, issued by the Ministry of Health. This high level of oversight, over both the provider and service user, greatly reduces the risk of inappropriate prescribing of opioids.

47 I propose that the Regulations be amended to provide an exception to the one-month period of supply limit for Class B and C opioids, when prescribed as part of OST. This exception would allow a specified prescriber, under section 24A, to issue prescriptions for up to 3 months when authorised by the Medical Officer of Health responsible for regulating OST services.

The new limits will apply to physical and electronic prescriptions

48 The 2022 amendments created different prescribing limits for physical and electronic prescriptions. This was due to the oversight and security provided by the NZePS, which allowed significantly better monitoring of prescribing behaviour compared to physical prescriptions.

49 Since the 2022 amendments there have been improvements in the Ministry's monitoring capability, which mean different rules for physical and electronic prescribing are no longer necessary.

50 Medsafe monitors prescribing practices within New Zealand. In June 2023, Medsafe gained access to the Medicines Data Repository (MDR) which provides real-time prescribing and dispensing data and enables large quantities of data across individuals, prescribers, pharmacies, and medicines to be searched.

51 Medsafe is working with Te Whatu Ora to implement the new system into their monitoring processes and to scope further improvements to monitoring capability, including the development of tools to support real-time monitoring of prescribing.

Financial Implications

52 There are no financial implications for the Government from the proposals in this paper.

Legislative Implications

53 To enable the proposals in this paper, amendments will be required to the Misuse of Drugs Regulations 1977.

Impact Analysis

Regulatory Impact Statement

54 A Regulatory Impact Statement has been completed and is attached in appendix one.

55 The Ministry of Health QA panel has reviewed the Impact Statement titled "Amendments to improve safe access to opioids" produced by the Ministry of Health and dated 11 July 2023.

56 The panel considers that the Impact Statement **Partially Meets** the quality assurance criteria.

57 The Impact Statement is clear, complete, and consulted. The Impact Statement does not make a convincing case that the regulatory proposals will achieve the desired objectives. However, the improved monitoring and future regulatory mechanisms described in the Impact Statement are likely to address the identified issues.

Climate Implications of Policy Assessment

58 There are no climate implications arising from this paper.

Population Implications

59 Establishing consistent maximum periods of supply for all (non-opioid) Class B and Class C drugs, for all controlled drug prescribers, will reduce barriers to accessing treatment in areas where certain prescribers are unavailable (e.g., medical and nurse practitioners).

60 Māori, Pacific people, disabled people, rural communities, and people with chronic health conditions can all face barriers to accessing medications due to the financial and logistical challenges of obtaining a new controlled drug prescription. Establishing a maximum period of supply of one month for opioids will create a barrier by requiring more frequent appointments with their prescribers. However, this is necessary to support regular clinical review taking place to ensure opioids are still an appropriate treatment.

Human Rights

61 The proposals in this paper are not inconsistent with the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993.

Consultation

62 The following agencies were consulted with: Te Whatu Ora, Te Aka Whai Ora, Pharmac, Te Aho o Te Kahu | Cancer Control Agency, Te Tāhū Hauora | Health Quality and Safety Commission, and New Zealand Police.

Communications

63 The Ministry will work with the relevant professional regulators (responsible authorities) to communicate with all prescribers and dispensers of controlled drugs to ensure they are aware of the new regulations and the implications.

Proactive Release

64 This paper will be proactively released according to standard processes under Cabinet Office circular CO (18) 4, subject to redactions as appropriate under the Official Information Act 1982.

Recommendations

The Minister of Health recommends that the Committee:

1 **note** that the Misuse of Drugs Regulations 1977 establish different maximum periods of supply for controlled drug prescriptions, for each profession;

2 **note** that different maximum periods of supply can restrict access to important medicines for some patients and cause difficulties for some professions to provide necessary care;

3 **agree** to amend the Misuse of Drugs Regulations 1977 to establish a maximum period of supply for non-opioid Class B and Class C controlled drugs, of 3 months, for medical practitioners, nurse practitioners, designated prescriber nurses, designated prescriber pharmacists, midwives and dentists;

4 **agree** that this new maximum period of supply will apply to both physical and electronic prescriptions;

5 **note** that a period of supply limit of one month for controlled opioids provides a balance between safety and access, and supports regular clinical review;

6 **agree** to amend the Misuse of Drugs Regulations 1977 to establish a period of supply limit for all opioids, classified under the Misuse of Drugs Act 1975, of one month for medical practitioners, nurse practitioners, designated prescriber nurses, designated prescriber pharmacists, midwives and dentists;

7 **agree** to amend the Misuse of Drugs Regulations 1977 to allow the relevant Medical Officer of Health to authorise a maximum period of supply of up to 3

months for specified prescribers under section 24A of the Misuse of Drugs Act 1975, to maintain access to Opioid Substitution Treatment;

8 **authorise** the Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to give effect to recommendations in 3, 4, 6 and 7.

Authorised for lodgement

Hon Dr Ayesha Verrall

Minister of Health