

Misuse of Drugs Amendment Regulations (No 2) 2023 – FAQs

When do the changes under the Misuse of Drugs Amendment Regulations (No 2) 2023 come into effect?

The Misuse of Drugs Amendment Regulations (No 2) 2023 will come into effect on **5 October 2023**. The amendment regulations can be viewed at

<https://www.legislation.govt.nz/regulation/public/2023/0231/latest/LMS891811.html>

Why have these changes been made?

These changes to regulations are the result of a recent review conducted by Manatū Hauora. The Safe Access to Opioids review focused on the various controls and safeguards that currently exist to manage opioid access, including 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.

Manatū Hauora engaged the sector on regulation changes in March 2023 and the submissions we received informed the final changes. A summary of this engagement can be found here

<https://www.health.govt.nz/publication/safe-access-opioids-engagement-summary>

What do the changes mean for the maximum prescribing period for a controlled opioid?

From 5 October 2023 all opioids classified under the Misuse of Drugs Act 1975 can be **prescribed for a maximum amount that is required for one month of treatment** (regulation 21(5D)(a)). This limit of one month will apply to Class A, B and C opioids.

This limit will apply to all controlled drug prescribers (medical practitioners, nurse practitioners, designated prescriber nurse, designated prescriber pharmacists, midwives, and dentists). However, this does not impact the specific controlled drugs that some groups of prescribers are authorised to prescribe.

What is considered a controlled opioid?

Any opioid listed in the schedules of the Misuse of Drugs Act 1975 will be subject to the opioid prescribing limits in the Misuse of Drugs Regulations 1977.

Examples of commonly prescribed controlled opioids that this will impact in practice include:

<u>Class B opioids</u>	<u>Class C opioids</u>
<ul style="list-style-type: none"> • Alfentanil • Fentanyl • Methadone • Morphine • Oxycodone • Pethidine • Remifentanil 	<ul style="list-style-type: none"> • Buprenorphine • Buprenorphine with naloxone • Codeine • Dihydrocodeine • Tramadol (from 1 October)

How does the exemption for Opioid Substitution Treatment (OST) work?

Providers of Opioid Substitution Treatment (OST) services are regulated under section 24A of the Misuse of Drugs Act 1975. They are subject to separate authorisations and restrictions, these restrictions include the requirement for consumption on premises and where safe, take-away doses in accordance with OST guidelines.

These amendments will allow opioids prescribed as part of OST to be **prescribed for a maximum of 3 months**. This exemption will enable continuity of treatment for service users when required. As with other types of prescribing this is a maximum limit and would not be appropriate in all circumstances.

OST services also adhere to guidance provided by Manatū Hauora. Manatū Hauora is currently updating guidance for OST providers and expects to release it later this year.

What do the changes mean for the maximum prescribing period for a non-opioid controlled drug?

From 5 October non-opioid controlled drugs, classified as Class B or Class C under the Misuse of Drugs Act 1975, can be prescribed for a **maximum amount that is required for 3 months of treatment**.

This limit will apply to all controlled drug prescribers (medical practitioners, nurse practitioners, designated prescriber nurse, designated prescriber pharmacists, midwives, and dentists). However, this does not impact the specific controlled drugs that some groups of prescribers are authorised to prescribe.

Prescribing limits in the regulations are not indicative of a recommended length of prescription for specific drugs, they are maximum amounts allowed by law. Professional standards and guidance set by a

practitioner's responsible authority (such as the Medical Council), colleges and other professional bodies are more appropriate controls on practice.

Has the maximum dispensing amount changed?

No. The maximum dispensing amount for any controlled drug under the Misuse of Drugs Regulations 1977 **is still a quantity not greater than a quantity sufficient for use for a period of one month** (regulation 31).

Prescribers will retain the ability to direct more frequent dispensing intervals when appropriate.

Have the Pharmaceutical Schedule funding rules for Class B controlled drugs changed?

No. Prescribers will still be required to operate within the limits of the Pharmaceutical Schedule managed by Pharmac.

In June 2023, the Pharmaceutical Schedule was amended to allow funding for a 3 month total period of supply for Class B Attention Deficit Hyperactivity Disorder (ADHD) stimulants (such as dexamfetamine and methylphenidate). This will continue to be the case.

For Class B opioids the default dispensing amount will remain at 10 days' supply. Under rule 4.4.2.a of the Pharmaceutical Schedule Rules, one months' supply of a Class B opioid may be supplied if the patient qualifies for single lot dispensing.

What do these changes mean for electronic prescriptions on the NZePS?

These changes will align prescribing limits for electronic (NZePS) and physical prescriptions.

What do these changes mean for the period of validity of controlled drug prescriptions?

Regulation 31 of the Misuse of Drugs Amendment Regulations 1977 defines the restrictions on supply of controlled drugs on prescription, including the period of validity of controlled drugs.

The period of validity for Class A and B controlled drugs (opioids and non-opioids) will remain at 7 days after the Misuse of Drugs Amendment Regulations (No 2) 2023 come into effect on 5 October 2023.

The period of validity for Class C controlled drugs (opioids and non-opioids) will remain at 6 months. However, it should be noted that the period of validity for subsidy will remain at 3 months as set out in the Pharmaceutical Schedule.

How do these changes apply to tramadol?

Tramadol will be classified as a Class C controlled drug from **1 October 2023**.

As an opioid, tramadol will be subject to the new limits on opioid prescribing from **5 October 2023**. This means prescriptions for tramadol will only be authorised for a quantity not greater than is reasonably required for the treatment of the patient for one month.

Prior to the amendments taking effect on 5 October, prescriptions for tramadol for a total quantity up to a 3 months' use will still be valid.

Will existing prescriptions still be valid from 5 October 2023?

Prescriptions issued prior to the new limits taking effect will still be valid for dispensing after 5 October 2023. Any remaining repeats on these prescriptions can be dispensed.

This is also the case for prescriptions written for tramadol prior to it being classified as a controlled drug on 1 October.

Any prescriptions issued from 5 October must comply with the new limits.

Summary of the upcoming changes (from October 5) to controlled drug prescribing regulations

Criterion	Example	Change to maximum period of supply
Class B opioids	Fentanyl Methadone Morphine Oxycodone	Maximum one month supply per prescription (NZePS electronic prescription or paper prescription) The Pharmaceutical Schedule default dispensing amount will remain at 10 days' supply
Class C opioids	Codeine Dihydrocodeine Tramadol (from 1 October 2023)	Maximum one month supply per prescription (NZePS electronic prescription or paper prescription)
Class B and C opioids through Opioid Substitution Therapy (OST) services	Methadone under Opioid Substitution Therapy (OST) services	There will be an exemption for OST services who will be able to prescribe for up to 3 months

Criterion	Example	Change to maximum period of supply
Class B non-opioids (this category includes controlled stimulants used to treat ADHD)	Class B medicinal cannabis products Dexamfetamine sulfate Methylphenidate hydrochloride Lisdexamfetamine	Maximum 3 months' supply (NZePS electronic prescription or paper prescription) Note that one month maximum dispensing also remains
Class C non-opioids	Benzodiazepines (e.g. Lorazepam) Zopiclone Class C medicinal cannabis products	Maximum 3 months' supply (NZePS electronic prescription or paper prescription) Note that one month maximum dispensing remains
Prescribers	Medical practitioners Nurse practitioners Dentists Midwives Designated nurse prescribers Designated pharmacist prescribers	The changes above have been aligned for all prescribers of controlled drugs. This does not change the specific controlled drugs that certain prescribers are authorised to prescribe.