From: Sean Dougherty
Sent: Tuesday, 17 January 2023 9:49 am
To: Trevor Lloyd
Subject: RE: BSO and CDBSO forms

Hi Trevor,

Out of scope

Out of scope

I expect that we'll be sharing an overview of the feedback with the CD working group. As you can appreciate, consultation feedback is provided in confidence and we don't have permission to share it far and wide.

Regards,

Sean

Sean Dougherty | Manager, Schedule Strategy and Development

Te Pātaka Whaioranga | Pharmac
PO Box 10-254, Wellington 6140 | Level 9, 40 Mercer Street, Wellington 6011
DDI: s 9(2)(a) | P: 0800 660 050 | www.pharmac.govt.nz

From: Trevor Lloyd <Trevor.Lloyd@health.govt.nz>
Sent: Tuesday, 17 January 2023 9:41 am
To: Sean Dougherty <sean.dougherty@pharmac.govt.nz>
Cc: Peter Sergent <s 9(2)(a)>; Lisa Williams <s 9(2)(a)>
Subject: FW: BSO and CDBSO forms

Hi Sean

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As always I appreciate your insight and look forward to your reply.

PS If you have and feedback on the CD Consultation that you can share that would be useful so that I can understand the direction of travel and consider any changes we may need in advance of the outcome of the consulation.

Ngā mihi

Trevor Lloyd B.Pharm
NZePS Change Manager
Data and Digital

waea pūkoro: s 9(2)(a) | **īmēra:** Trevor.Lloyd@health.govt.nz
133 Molesworth Street, Wellington

Te Whatu Ora
Health New Zealand

Te Whatu Ora – Health New Zealand

From: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>
Sent: Tuesday, 17 January 2023 2:33 pm
To: Belinda Ray-Johnson; Eddy Sommers
Cc: Sean Dougherty
Subject: RE: Media query: controlled drugs rules

Thanks Belinda

From: Belinda Ray-Johnson <belinda.ray-johnson@pharmac.govt.nz>
Sent: Tuesday, 17 January 2023 2:26 pm
To: Eddy Sommers <Eddy.Sommers@health.govt.nz>
Cc: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>; Sean Dougherty <sean.dougherty@pharmac.govt.nz>
Subject: RE: Media query: controlled drugs rules

Kia ora Eddy and Suzanne

Happy new year to you.

Thanks for seeking our input on question 5. Suggestion as below based on our review of the feedback.

A large amount of feedback was received and this feedback was mixed, with both support for and concerns about changes to the prescribing and dispensing of Class B controlled drugs.

Ngā mihi

Belinda

From: Eddy Sommers <Eddy.Sommers@health.govt.nz>
Sent: Tuesday, 17 January 2023 1:05 pm
To: Sean Dougherty <sean.dougherty@pharmac.govt.nz>; Belinda Ray-Johnson <belinda.ray-johnson@pharmac.govt.nz>
Cc: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>
Subject: FW: Media query: controlled drugs rules

Kia ora Sean and Belinda

Happy new year, hope you both had a good break.

We have received a media query regarding the delay to changes to the Pharmac Schedule for Class B controlled drugs (see below for original request). We wanted to run this past you before we go through sign-out on the responses (in red), also to get your input on question 5 as thought you would be better placed to answer. Note that the request has been made to get a response by 330pm today, so if you could get back to ASAP that would be much appreciated.

Ngā mihi

From: Eddy Sommers <Eddy.Sommers@health.govt.nz>
Sent: Tuesday, 17 January 2023 12:15 pm
To: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>
Subject: RE: Media query: controlled drugs rules

Hi here are some draft responses. Probably more input needed on question 5 which Pharmac could answer.

1. Why has the ministry decided to revisit the regulatory arrangements for opioids?

Pharmac was consulting on proposed changes to the Schedule Rules that would impact the prescribing and dispensing of opioids. Through this consultation concerns were raised as to whether existing system settings that impact opioid prescribing are sufficient to both ensure access to these important medicines while mitigating the risk of harm if misused. Pharmac and Manatū Hauora have both agreed to suspend the proposed changes to the Schedule Rules until an assessment of these controls has been carried out.

2. What does revisiting the arrangements involve?

A cross-agency working group has been established to examine the existing system settings. These include, but are not limited to, oversight of prescribing behaviour, appropriate regulation, and training and clinical guidance for prescribers and dispensers of opioids.

3. When will this work be completed?

The working group has already been established and will have their first meeting in January 2023. It is expected that this work will be completed in the first half of 2023. If any changes are recommended by the working group then they may take longer to implement.

4. Last year, health minister Andrew Little announced that prescribers would be able to send prescriptions for controlled drugs through the NZePS system? Will this still go ahead or is this also being reviewed?

This change is not impacted. The Misuse of Drugs Amendment Regulations 2022 removed the regulatory barriers to controlled drugs being prescribed through the NZePS, this change took effect 22 December 2022.

5. Was the feedback received mostly against increasing the supply period for controlled drugs or in support of it?

Strong concerns were expressed any increase to the supply period for Class B opioid medicines.

From: Jonathan Chilton-Towle <jct@pharmacytoday.co.nz>
Sent: Tuesday, January 17, 2023 10:55 AM
To: media@moh.govt.nz <media@moh.govt.nz>
Subject: controlled drugs rules

Hi MOH media team

Hope you had a good Christmas and New Year.

I have a query for you related to this consultation on changes to the supply period for controlled drugs https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/2022-11-28-proposal-to-amend-pharmaceutical-schedule-rules-on-prescribing-and-dispensing-of-class-b-controlled-drugs/

It is a Pharmac consult but the update says 'in light of this feedback, Manatū Hauora, the Ministry of Health, has indicated that it would like to revisit the regulatory arrangements for opioids. They have asked Pharmac to delay making a decision on the proposed changes to the Schedule Rules to support this work.

My questions are:

1. Why has the ministry decided to revisit the regulatory arrangements for opioids?
2. What does revisting the arrangements involve?
3. When will this work be completed?

4. Last year, health minister Andrew Little announced that prescribers would be able to send prescriptions for controlled drugs through the NZePS system? Will this still go ahead or is this also being reviewed?
5. Was the feedback received mostly against increasing the supply period for controlled drugs or in support of it?

I am hoping to run an article on this on our website today so if you could get me a response by 3.30pm this afternoon that would be much appreciated

Kind regards,

Jonathan Chilton-Towle
Senior Journalist | **Pharmacy Today** | **Kaitiaki Rongoā o te Wā**
Healthcare Handbook
The Health Media Limited
P s 9(2)(a) | **E** jct@pharmacytoday.co.nz
11 Omana Road, Milford, Auckland
PO Box 31 905, Milford, Auckland 0741

From: Media
Sent: Wednesday, 18 January 2023 2:07 pm
To: Sanjana George
Subject: RE: Media response on revisiting proposed changes to Class B drug prescription

Hey Sanjana, I saw an article this morning so thought it had been sent sorry! Yes all accurate from our end.

Ngā mihi,
Rosa

Rosa Bach | Communications Advisor, media and social media | s 9(2)(a)

Te Pātaka Whaioranga - Pharmac | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

From: Sanjana George <Sanjana.George@health.govt.nz>
Sent: Wednesday, 18 January 2023 1:29 pm
To: Media <media@pharmac.govt.nz>
Subject: RE: Media response on revisiting proposed changes to Class B drug prescription

Kia ora Rosa,

Just thought I'd check if you'd heard anything back from your team?

Sanjana George (she/her)
Media Advisor, s 9(2)(a)
media@health.govt.nz
info for media: https://www.health.govt.nz/news-media/media-centre

Manatū Hauora, 133 Molesworth Street Wellington 6011

From: Sanjana George
Sent: Tuesday, 17 January 2023 4:38 pm
To: Media <media@pharmac.govt.nz>
Subject: RE: Media response on revisiting proposed changes to Class B drug prescription

Thanks Rosa,

He asked for 3:30pm today but it only came in a few hours ago so I don't think that was ever going to be achievable anyway.

Sanjana George (she/her)

Media Advisor, s 9(2)(a)
media@health.govt.nz
info for media: https://www.health.govt.nz/news-media/media-centre

Manatū Hauora, 133 Molesworth Street Wellington 6011

From: Media <media@pharmac.govt.nz>
Sent: Tuesday, 17 January 2023 4:36 pm
To: Sanjana George <Sanjana.George@health.govt.nz>
Subject: RE: Media response on revisiting proposed changes to Class B drug prescription

Hey Sanjana, thanks for the heads up – I'm checking with our team. When did Johnathan ask for the response to go back to him?

Ngā mihi,
Rosa

Rosa Bach | Communications Advisor, media and social media | s 9(2)(a)

Te Pātaka Whaioranga - Pharmac | Level 9, 40 Mercer Street, Wellington
www.pharmac.govt.nz

From: Sanjana George <Sanjana.George@health.govt.nz>
Sent: Tuesday, 17 January 2023 4:31 pm
To: Media <media@pharmac.govt.nz>
Subject: Media response on revisiting proposed changes to Class B drug prescription

Kia ora Pharmac team,

I wanted to give you a heads up about this media response we are hoping to send. I believe our policy team have already run this past the team undertaking this review at Pharmac, but let me know if you have any concerns.

Query and Response - Jonathan Chilton-Towle, Pharmacy Today

I have a query for you related to this consultation on changes to the supply period for controlled drugs https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/2022-11-28-proposal-to-amend-pharmaceutical-schedule-rules-on-prescribing-and-dispensing-of-class-b-controlled-drugs/

It is a Pharmac consult but the update says 'in light of this feedback, Manatū Hauora, the Ministry of Health, has indicated that it would like to revisit the regulatory arrangements for opioids. They have asked Pharmac to delay making a decision on the proposed changes to the Schedule Rules to support this work.

My questions are:

1. **Why has the ministry decided to revisit the regulatory arrangements for opioids?**

Following Pharmac's consultation, we received both support for, and concerns about changes to the prescribing and dispensing of Class B controlled drugs. Consultation is an important part of the process, and in light of the feedback, Pharmac and Manatū Hauora have agreed to suspend the proposed changes until an assessment can be done into whether there are sufficient controls in place to ensure these drugs are prescribed safely. This is part of the work being done to improve access to these important medicines while mitigating the risk of harm if misused.

2. **What does revisiting the arrangements involve?**

A cross-agency working group has been established to look at access to opioids. This will include reviewing the current oversight of prescribing behaviour, appropriate regulation, and training and clinical guidance for prescribers and dispensers of opioids.

3. **When will this work be completed?**

The working group has already been established and will have their first meeting in January 2023. It is expected that this work will be completed in the first half of 2023.

4. **Last year, health minister Andrew Little announced that prescribers would be able to send prescriptions for controlled drugs through the NZePS system? Will this still go ahead or is this also being reviewed?**

This change is not impacted. The Misuse of Drugs Amendment Regulations 2022 removed the regulatory barriers to controlled drugs being prescribed through the NZePS, this change took effect 22 December 2022.

5. **Was the feedback received mostly against increasing the supply period for controlled drugs or in support of it?**

A large amount of feedback was received and this feedback was mixed, with both support for and concerns about changes to the prescribing and dispensing of Class B controlled drugs.

Sanjana George (she/her)
Media Advisor, s 9(2)(a)
media@health.govt.nz
info for media: https://www.health.govt.nz/news-media/media-centre

Manatū Hauora, 133 Molesworth Street Wellington 6011

From: Eddy Sommers <Eddy.Sommers@health.govt.nz>
Sent: Thursday, 19 January 2023 1:46 pm
To: Anna Skinner; Michael Haynes; Billy Allan; David Hughes; Teei Kaiaruna; Anna-Lee Annett; Andi Shirtcliffe; John Crawshaw; [redacted] s 9(2)(a) Trevor Lloyd
Cc: Allison Bennett; Suzanne Townsend; Meg Larken; Geethma Weliwatta
Subject: Safe Access to Opioids Working Group
Attachments: Meeting Agenda - 25th Jan 2023.docx; Safe Access to Opioids - Initial Report - 25 Jan 2023.docx; Safe Access to Opioids - Terms of Reference.docx

Kia ora koutou

Thank you all for agreeing to be part of the Safe Access to Opioids Working Group. The first meeting will be on 25 January 2023 (please advise if you have not yet received an invite).

Attached are the following documents to be read before the first meeting:

1. **Initial report to the Safe Access to Opioids Working Group** – this report provides a high level overview of the current opioid prescribing controls. This report is intended to assist discussion at the first meeting of the Working Group.
2. **Draft Terms of Reference** – this will be confirmed by the Working Group at the first meeting
3. **Agenda for meeting on 25 January.**

A meeting room at 133 Molesworth Street has been booked however if you are unable to attend in person please let us know and we'll provide a teams link.

Ngā mihi nui

Eddy Sommers (he/him)
Policy Analyst
Health System Settings
Strategy Policy and Legislation | Te Pou Rautaki
eddy.sommers@health.govt.nz
Manatū Hauora, 133 Molesworth Street Thorndon, Wellington 6011

MANATŪ HAUORA
MINISTRY OF HEALTH

Agenda

Safe Access to Opioids Working Group

Date: 25 January 2023

Time: 9.30-11.30

Location: 3S.1 133 Molesworth Street

Chair: Anna Skinner

Attendees: Michael Haynes, Billy Allan, David Hughes, Teei Kaiaruna, Anna-Lee Annett, Andi Shirtcliffe, John Crawshaw, Shaheeda Othman, Suzanne Townsend, Trevor Lloyd

Secretariat: Regulatory Policy Team (Eddy Sommers, Meg Larken)

Apologies:

	Time	Agenda Item	Presenter	Paper
1	9.30-9.40	Welcome, introductions and apologies	All	N/A
2	9.40-10.00	Agree Terms of Reference	Chair	Yes
3	10.00-10.15	Discuss overview paper: - What are the risks? - Deliverables of the working group	Suzanne	Yes
4	10.15-10.30	Overview of monitoring and compliance	Michael	N/A
5	10.30-10.45	Opportunities provided by electronic prescribing	Trevor	N/A
6	10.45-11.00	Are there immediate concerns that we need to manage?	Chair	N/A
7	11.00-11.15	Identify issues / data that the working group wants more information on	Chair and Secretariat	N/A
8	11.15-11.30	Next steps	Chair	N/A

MINISTRY OF HEALTH
MANATŪ HAUORA

Initial report to the Safe Access to Opioids Working Group

25 January 2023

Contents

1 INTRODUCTION

1.1 Context

Opioids are important or essential pain medicines for many; however, they can also be addictive and cause significant harm when misused. Caution is therefore needed when prescribing opioids. They should only 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.

There has been international concern over increases in opioid prescribing which has led to sharp increases in prescription opioid-related deaths and overdoses. Regulators have implemented various legislative changes and regulatory actions with the aim of limiting opioid harm in their jurisdictions. New Zealand has so far avoided the same level of harm experienced in other countries caused by access to and misuse of prescription opioids. However, there are concerns among some New Zealand health professionals about the potential risk of an increase in misuse of prescription opioids.

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.

There is a question as to whether these current controls are fit for purpose, in both managing the risk of inappropriate prescribing and ensuring adequate patient access to these medicines. Manatū Hauora has established a Safe Access to Opioids Working Group to assess the potential risk of opioids in New Zealand and identify options to improve the regulatory system. The analysis done through the working group will support the development of options to ensure appropriate access to opioids.

1.2 Purpose

This initial report provides some background on opioid prescribing in New Zealand, including an overview of:

- existing controls used to regulate access to opioids
- international regulation of opioids and recent actions taken
- current data on the prescribing and use of opioids in New Zealand

The information contained in this document is not exhaustive. This report has been drafted by the Health System Settings, Regulatory Policy Group and is intended as background to inform discussion at the first meeting of the Safe Access to Opioids Working Group on 25 January 2023. Further reports on specific aspects of the regulatory system will be drafted as needed to assist the working group.

Much of the information in this initial report has come from the 2020 report "Opioids and abuse, misuse and dependence" prepared by the Pharmacovigilance team (within Medsafe) and provided to the Medicines Adverse Reactions Committee.

2 OVERVIEW OF EXISTING CONTROLS

There are several legislative controls that can influence access to opioids. The Medicines Act 1981 and the Misuse of Drugs Act 1975 provide specific limits and restrictions on prescribing, supply and possession of drugs. The Health Practitioners Competence Assurance Act 2003 establishes the structure for the regulation of health practitioners.

2.1 Legislation

2.1.1 Medicines Act 1981

The Medicines Act 1981 sets out the legislative framework for prescribing medicines and establishes the prescribing authority for each profession. All opioids are classified as prescription medicines under the Medicines Regulations 1984.

The Therapeutic Products Bill was introduced to the House in late 2022 and is intended to replace the Medicines Act 1981. In its current state the TPB will move the for setting prescribing authority to the responsible authorities under the Health Practitioners Competence Assurance Act 2003.

This does provide an opportunity to address legislative issues that may influence access to opioids.

2.1.2 Health Practitioners Competence Assurance Act 2003

New Zealand health practitioners are regulated primarily under the Health Practitioners Competence Assurance Act 2003 (the HPCA Act). Under the HPCA Act, responsible authorities (RAs) oversee registration of practitioners, set scopes of practice, accredit education and training providers, and define professional standards, including standards for prescribing.

All prescribers are regulated under the HPCA Act. As a regulator an RA is responsible for the disciplinary process when a health professional is suspected of inappropriate prescribing. Each RA may define standards and determine the disciplinary process in their own way. However, the RAs that oversee prescribing are currently working together to develop shared prescribing standards and guidelines.

Work is currently underway to better understand the disciplinary processes of each RA and how they impact prescribing behaviour.

2.1.3 Misuse of Drugs Act 1975

The Misuse of Drugs Act 1975 places further restrictions on those medicines that are also classified as controlled drugs. Controlled drugs listed in the Schedules of the Misuse of Drugs Act 1975 are classified as A (very high), B (high) or C (moderate) according to their risk profile.

Substances are classified as controlled drugs through a process that begins with a recommendation from the Expert Advisory Committee on Drugs (EACD). The EACD, supported by Medsafe, provides regular advice to the Minister of Health on drug classification matters. Decisions to classify or reclassify a drug are made by Cabinet, on the Ministers recommendation, and then confirmed by the House of Representatives. To assist the Minister in making a recommendation to classify a drug the EACD must provide advice on the following:

- the likelihood or evidence of drug abuse, including such matters as the prevalence of the drug, levels of consumption, drug seizure trends, and the potential appeal to vulnerable populations
- the specific effects of the drug, including pharmacological, psychoactive, and toxicological effects
- the risks, if any, to public health
- the therapeutic value of the drug, if any

- the potential for use of the drug to cause death
- the ability of the drug to create physical or psychological dependence
- the international classification and experience of the drug in other jurisdictions
- any other matters that the Minister considers relevant.

Misuse of Drugs Regulations 1977

The Misuse of Drugs Regulations 1977 provide specific prescribing controls for each class of drug. The prescribing regulations in the Misuse of Drugs Regulations were created to provide extra protections for medicines which are considered to have a high risk of causing harm, including dependence and abuse. As shown in **Table 1** below, most opioids in New Zealand are scheduled as Class B (high risk) or Class C (moderate risk).

Under the Misuse of Drugs Regulations there are restrictions by professional group on the maximum period of supply for controlled drug prescriptions, prescription form requirements and requirements for dispensing within a certain time. As most opioids prescribed in NZ are controlled drugs these regulations are currently the primary mechanism used to determine how opioids can be prescribed. The regulations dictate which type of health professional can prescribe each class of controlled drug. For some professions (designated nurse prescriber, designated pharmacist prescriber and midwife) specific controlled drugs need to be added to their relevant schedule within the regulations to be given the authority to prescribe.

Each type of prescriber has specific limits under the regulations for the amount of opioid they can usually prescribe. This maximum amount can vary from 3 days (designated pharmacist prescribers) to 3 months for medical practitioners.

Recent changes to the Misuse of Drugs Regulations enabled Class B opioids to 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). However, these changes are currently only applicable to non-funded medicines as such prescriptions are not eligible for subsidy under the Pharmac Schedule rules (see **Table 2**).

Table 1: Summary of opioids approved in New Zealand by active ingredient - classification and funding status (community and hospital)

Opioid	Classification		Funded	
	Medicines Regulations 1984	Misuse of Drugs Act 1975	Community[a]	Hospital[b]
Alfentanil	Prescription	Class B3 Controlled Drug	No	Yes
Buprenorphine	Prescription	Class C4 Controlled Drug	No	No
Buprenorphine with naloxone	Prescription	Class C4 Controlled Drug	Yes	Yes
Codeine	Prescription	Class C2 Controlled Drug Class C6 Controlled Drug[c]	Yes	Yes
Codeine combination products	Prescription[d]	-	Yes[e]	Yes[e]
Dihydrocodeine	Prescription	Class C2 Controlled Drug Class C6 Controlled Drug[c]	Yes	Yes
Fentanyl	Prescription	Class B3 Controlled Drug	Yes	Yes
Methadone	Prescription	Class B3 Controlled Drug	Yes	Yes
Morphine	Prescription Pharmacy only[f]	Class B1 Controlled drug	Yes	Yes
Oxycodone	Prescription	Class B3 Controlled Drug	Yes	Yes
Pethidine	Prescription	Class B3 Controlled Drug	Yes	Yes
Remifentanil	Prescription	Class B3 Controlled Drug	No	Yes
Tramadol	Prescription	-	Yes	Yes

a. PHARMAC. 2020. Online Pharmaceutical Schedule – November 2020. URL: https://pharmac.govt.nz/pharmaceutical-schedule/community-section-b/ (accessed 3 November 2020).

b. PHARMAC. 2020. Online HML – November 2020. URL: https://schedule.pharmac.govt.nz/HMLOnline.php (accessed 3 November 2020).

c. A Class C6 Controlled drug when: (i) Compounded with one or more other pharmacologically active ingredients in such a way that the substance cannot be recovered by readily applicable means or in a yield which would constitute a risk to health; and (ii) Containing not more than 100 milligrams of the substance in each dosage unit and with a concentration of not more than 2.5 percent in undivided preparations.

d. All codeine combination products were reclassified from pharmacy only or restricted medicines to prescription medicines on 5 November 2020.

e. Paracetamol with codeine is the only funded codeine combination product.

f. Morphine is pharmacy only in medicines for oral use containing not more than 0.2% of morphine, when combined with 1 or more active ingredients in such a way that the substance cannot be recovered by readily applicable means or in a yield that would constitute a risk to health, when sold in a pack approved by the Minister or the Director-General for distribution as a pharmacy-only medicine.

Important note: Two of these opioids will be reclassified when the Misuse of Drugs (Classification and Presumption of Supply) Order 2022 comes into effect in 2023. Tramadol will become a Class C3 Controlled Drug and Fentanyl will become a Class B1 Controlled Drug. This will lead to increased restrictions on the maximum period of supply for tramadol, prescription form requirements and tramadol would also be subject to drug abuse containment activities., under the Misuse of Drugs Regulations.

2.2 Funding restrictions

2.2.1 Pharmaceutical Schedule rules for prescribing and dispensing

In addition to the regulatory restrictions there are also controls on the prescribing and dispensing of controlled drugs in the Pharmaceutical Schedule (the schedule). Pharmac is required to maintain and manage this schedule under section 69 of the Pae Ora (Healthy Futures) Act 2022. The schedule includes prescribing and dispensing criteria that must be met for Community Pharmaceuticals (including controlled drugs) to be eligible for subsidy.

The schedule specifies that a prescription for a subsidised Class B controlled drug can only cover a period of

up to one month.

The schedule also controls the amount of Class B controlled drug that may be dispensed at one time. For Class B opioids the default dispensing limit is 10-day lots.

Subsidised Class B opioids can be dispensed in monthly lots if the patient certifies that they meet certain requirements such as having limited physical mobility, or they live more than 30 minutes from a pharmacy by their usual means of travel.

Unsubsidised Class B opioids do not have to meet the Pharmac Schedule criteria and therefore can be dispensed in monthly lots if the patient is willing to pay full price.

The following are the Class B opioids impacted by this part of the Pharmac Schedule:

- Fentanyl
- Methadone hydrochloride
- Morphine hydrochloride
- Morphine sulphate
- Oxycodone hydrochloride
- Pethidine hydrochloride

Table 2: Current dispensing controls for Class B controlled drug

<table>
<tr><th colspan="2">Misuse of Drugs Regulations</th><th colspan="2">Pharmac Schedule Rules</th><th>Resulting supply</th></tr>
<tr><td rowspan="4">r31 Restrictions on supply on prescription
(1) A person may not supply a controlled drug on a prescription—
…
(d) in a quantity that, having regard to the dose and frequency of dose or the directions given by the controlled drug prescriber, is greater than a quantity sufficient for use for a period of 1 month

Note: r31A enables a prescriber to specify the intervals of dispensing (eg, daily, weekly, etc.)</td><td rowspan="4">Up to 1 month</td><td>Non-subsidised drugs</td><td>Not applicable</td><td>Up to 30 days</td></tr>
<tr><td>for Class B Controlled Drugs (except methylphenidate hydrochloride and dexamfetamine sulfate)</td><td>10-day Lots</td><td>10 days</td></tr>
<tr><td>for Class B Controlled Drugs (except methylphenidate hydrochloride and dexamfetamine sulfate) where a patient meets specified criteria*</td><td>Monthly Lots</td><td>Up to 30 days</td></tr>
<tr><td>Methylphenidate hydrochloride and dexamfetamine sulfate)</td><td>Default dispensing is Monthly Lots</td><td>Up to 30 days</td></tr>
</table>

A Class B Controlled Drug may be dispensed in Monthly Lots if the patient meets the requirements of the criteria in 4.4.2.a.

4.4.2 *A Community Pharmaceutical may be dispensed in one Lot in the following circumstances:*
a *a patient or their representative signs the Prescription to qualify for single Lot dispensing. In signing the Prescription, the patient or their nominated representative must certify which of the following criteria the patient meets:*
i *they have limited physical mobility*
ii *they live and work more than 30 minutes from the nearest pharmacy by their normal form of transport*
iii *they are relocating to another area, or*
iv *they are travelling and will be away when the repeat Prescriptions are due.*

2.2.2 Removal of additional Pharmac restrictions

As a result of the recent changes to the Misuse of Drugs Regulations, Pharmac has proposed that the Schedule should be amended to align with the new regulations. It is Pharmac's view that the Schedule is not the appropriate mechanism to determine prescribing and dispensing rules. Consultation on this change began late 2022 and any changes were intended to be implemented from February 2023.

After discussions with Manatū Hauora, Pharmac agreed to delay any changes to the Schedule until a system review of opioid controls could be completed. This is important as the Schedule currently provides important controls over the prescribing and dispensing of Class B opioids.

A central task for the Safe Access to Opioids Working Group will be to determine what the required limits should be for prescribing and dispensing opioids and what the appropriate mechanism for setting these limits should be.

2.3 Professional guidance/standards

There are many guidelines for prescribing opioids, and there is a growing consensus on best practice when considering or initiating opioids. This includes:

- recognising and dealing with psychosocial aspects of pain
- managing patient expectations about the degree of pain relief likely to be achievable
- starting with a therapeutic trial and an agreement to stop or reduce opioids when they do not work
- recording care plans agreed with patients to guide all subsequent prescribers in maintaining the plan.

Clinical guidance can be an important mechanism to influence prescriber behaviour. However, it can be challenging to ensure that the guidance reaches all relevant prescribers, especially when that guidance changes frequently. Some recent New Zealand and Australian clinical guidelines on opioid use are summarised below.

2.3.1 Acute pain

Australian and New Zealand College of Anaesthetists and Faculty of Pain Medicine

ANZCA | College publications

Acute Pain Management: Scientific Evidence aims to combine a review of the best available evidence for acute pain management with current clinical and expert practice, rather than to formulate specific clinical practice guidelines.

Best Practice Advisory Centre (bpac^{NZ})

Revisiting opioid use in New Zealand: how does your prescribing compare? - bpacnz - 2022

This resource allows prescribers to compare their opioid prescribing with New Zealand prescribers 2017-2021. It notes that a key focus in recent years has been to reduce the prescribing of opioids in the community, particularly in the context of chronic illness where there are few appropriate indications.

The principles of managing acute pain in primary care – 2018

This article provides guidelines for NZ primary care providers for managing acute pain. It states that after treating the cause of the pain, the primary aim of acute pain management is to provide treatment that reduces the patient's pain, with minimal adverse effects, while allowing them to maintain function. A secondary aim is to prevent acute pain from progressing to chronic pain.

2.3.2 Chronic non-cancer pain

Australian and New Zealand College of Anaesthetists and Faculty of Pain Medicine

Statement regarding the use of opioid analgesics in patients with chronic non-cancer pain – PS01(PM) 2021

This position statement was published by ANZCA's Faculty of Pain Medicine in 2020, in acknowledgment of the lack of definitive evidence to support the long-term effectiveness of opioid analgesics in people experiencing chronic non-cancer pain (CNCP) and the substantial evidence for harm. It also recognises the changed regulatory environment introduced in Australia by the Therapeutic Goods Administration (TGA), where modified release products are not indicated for use in CNCP other than in exceptional circumstances. This position statement is an interpretation of "exceptional circumstances" and describes the current position of the FPM regarding the prescription of opioids in CNCP, presented as a series of principles, including (but not limited to) the following:

- First line therapy for CNCP involves engaging the person to develop pain self-management skills.
- Second line therapies in CNCP include drug treatment which, while not a core component of a management plan, may play a role in facilitating functional goals and maintaining social roles including employment.
- Opioid treatment (in the context of exceptional circumstances) in CNCP is always an ongoing individual trial of therapy, and is contingent on demonstration of benefit, active surveillance for harms, and periodic attempts at dose minimisation.
- Opioid treatment requires regular, documented assessment that addresses the "5As": analgesia, activity, adverse effects, affect, aberrant behaviour.

2.3.3 Misuse, addiction, opioid substitution therapy

Best Practice Advisory Centre (bpac^{NZ})

Codeine: all formulations prescription only – 2020

This article provides advice following the reclassification of codeine to prescription-only in November 2020. It summarises the reasoning behind the reclassification, provides guidance for managing requests for pain treatment in general practice and in pharmacies, and gives information for how to prescribe codeine safely.

Codeine reclassified as a prescription-only medicine: a community pharmacist perspective – 2020

Information for pharmacists to support the reclassification of codeine (described above). Pharmacists will need to recommend other methods to manage pain and people who are accustomed to buying codeine-containing products from pharmacies will need to be informed about the change. People with severe, persistent or recurrent pain should be encouraged to consult with their general practitioner to investigate and treat any underlying cause.

Unintentional misuse of prescription medicines – 2018

Guiding principles for prescribing medicines that have a higher potential for misuse. It includes strategies to mitigate risk of prescription medicine misuse, including trialling the medicine for a short period, contacting the dispensing pharmacist to share information about the treatment protocol and any early requests for repeats, ensuring that there is a clinical need for any ongoing prescriptions. The article also includes information about identifying medicine misuse.

Identifying and managing addiction to opioids – 2014

This article describes the international experience with oxycodone misuse, defines terms related to opioid misuse, summarises the New Zealand situation (as at 2014). Clinicians need to be aware of the misuse and abuse issues associated with prescription opioids, and how to identify and manage patients with inappropriate opioid use. All patients with non-malignant pain who have been taking opioids for longer than a few weeks should be reviewed, to consider whether treatment is still appropriate and how adequate controls can be ensured. The article provides clinical guidance for withdrawing patients from opioid treatment, including managing symptoms. Opioid substitution treatment in New Zealand is also discussed.

Ministry of Health

Prescribing Controlled Drugs in Addiction Treatment 2018: Guidance for nurse practitioners, designated prescriber nurses and designated prescriber pharmacists

Guidance to help addiction treatment services comply with section 24A of the Misuse of Drugs Act 1975 as it relates to nurse practitioners, designated prescriber nurses and designated prescriber pharmacists who are authorised to prescribe controlled drugs as a treatment for people dependent on controlled drugs.

New Zealand Practice Guidelines for Opioid Substitution Treatment – 2014

This document contains advice for clinicians on best practice for the clinical assessment and treatment of clients with opioid dependence. These guidelines endorse a path that moves away from a maintenance-treatment model and towards client-led, recovery-focused treatment. The guidelines highlight the importance of early transition planning, with an emphasis on transitioning stable clients to primary level care.

2.4 Oversight and Accountability

Medicines Control is a regulatory team within Manatū Hauora that oversees the local distribution chain of medicines and controlled drugs within New Zealand. Drug abuse containment activities are carried out by Medicines Control staff in conjunction with two Medical Officers of Health who have wide powers under both the Misuse of Drugs Act 1975 and the Medicines Act 1981.

These activities include:

- liaising with doctors, pharmacists and addiction services in relation to drug abuse and misuse issues
- monitoring controlled drug prescribing
- working with the Medical Officers of Health in the preparation of Restriction Notices for drug seekers and writing to practitioners if there are any concerns regarding possible aberrant prescribing of controlled drugs or medicines
- advising health professionals of current drug misuse issues
- liaising with Police and other agencies locally and nationally on drug misuse
- preparing reports for the disciplinary processes of the Medical Council, Dental Council and Pharmacy Council
- providing advice on the requirements of the Misuse of Drugs Act and Medicines Act.

2.4.1 Monitoring

The prescribing and dispensing data held in the NZePS provides better visibility of prescribing patterns for regulators. This service has been in place since 2013, with an initial focus on community dispensing and GP prescribing. Uptake of the service has increased dramatically as a result of the COVID-19 lockdowns. There is ongoing investment to improve the functionality of the service and after electronic prescribing of controlled drugs was enabled in 2022 it is expected that more health providers will make use of the service.

Currently the Medicines Control branch of Medsafe primarily relies upon specific reports of inappropriate prescribing before investigating individual prescribing practices. Inappropriate prescribing can go on for some time before it is reported. The capability to easily monitor and identify inappropriate prescribing in real time does not yet exist. Aligning with the decommissioning of the current Lotus Notes Electronic Prescription Monitoring database, work is in progress to implement tools, including the new Medicines Data Repository (MDR) that will enable Medicines Control to enhance monitoring capabilities. Implementation of these tools is expected to be completed by June 2023.

The MDR will provide significantly improved monitoring capability, such as the ability to quickly request a patient's medication history, view medications prescribed by a specific provider for a patient, and request records of specific prescribed and dispensed medications. Medicines Control is still scoping how they will use the information held in MDR more proactively using alerts and business rules, but it is anticipated that

the system will enable proactive analytics which could provide earlier notification when prescribing behaviour falls out of defined parameters. It is also expected that the system will enable real-time access to controlled drug prescribing history.

It should be noted that using the improved monitoring capability of the MDR to its full potential will be dependent on continued investment in IT infrastructure and sufficient resourcing being available to conduct the required monitoring activities.

2.4.2 Enforcement/compliance

Medicines Control investigation

There are mechanisms to address inappropriate prescribing by an individual. Medicines Control will investigate incidents. Prescribers and dispensers are required under regulation 44B of the Medicines Regulations 1984 and regulation 35 of the Misuse of Drugs Regulations 1977 to supply information relating to the prescribing, administering or supply of medicines to support these with investigations.

If Medicines Control is notified of suspected inappropriate prescribing the first step is to send a letter to the prescriber requesting further information relating to the prescribing. Under these regulations the prescriber has 30 days to supply the information. If there is still a cause for concern once this information is received Medicines Control may refer the case to the relevant regulatory authority, or in rare cases the Police.

Restriction notices

If required, Manatū Hauora can limit the supply of medicines for a specific patient in high-risk circumstances. Under section 25 of the Misuse of Drugs Act 1975 and section 49 of the Medicines Act 1981 a Medical Officer of Health can place restrictions on any person that is obtaining controlled drugs or a prescription medicine.

A restriction notice is a legal document issued by the Medical Officer of Health. The effect of a restriction notice is ultimately to protect the patient and can be issued for prescription medicines (section 49(2) of the Medicines Act 1981) and/or controlled drugs (section 25(3) of the Misuse of Drugs Act 1975).

This can be used to restrict an individual to only receiving controlled drugs from a single prescriber and dispenser.

2.5 Recent regulatory actions

In 2020 and 2021 Medsafe prepared two reports to the Medicines Adverse Reactions Committee (MARC) on minimising opioid misuse, abuse and dependence. As a result of this the following changes have been actioned:

- A risk benefit review of dihydrocodeine (DHC) was completed and changes to the indications were recommended. In this review MARC agreed that there was insufficient evidence to recommend revoking consent of the approved DHC products in New Zealand, however they recommended that regulatory action was needed to improve information about DHC for prescribers and patients. MARC also recommended that the sponsors of DHC products in New Zealand supply a Consumer Medicines Information sheet for publication on the Medsafe website.
- Addition of warning and advisory statements for all opioids through the Label Statements Database. This warning will indicate the risk of overdose and dependence and sponsors will have until 1 March 2024 to comply with new requirements. This label change would only impact the original manufacture's packaging so unlikely to be seen by patients.
- Risk Management Plans are to be submitted as part of new medicine applications for opioids.
- Opioid data sheet updates to align with Australian safety information. These have been requested and will be actioned at the discretion of each sponsor. Medsafe does not have regulatory powers to mandate this change.
- Medsafe has developed a consumer leaflet on opioids:

https://www.medsafe.govt.nz/Consumers/educational-material/Risks-of-opioid-medicines.pdf

- Medsafe has met with the Pharmaceutical Society of New Zealand (PSNZ) to discuss the addition of Cautionary and Advisory Labels (CALs) to medicine containers at the time of dispensing. These are intended to prompt further discussion between patients and health providers. PSNZ expressed that they would like further information about the implementation of CALs in Australia and will discuss with their counterparts before making any decisions for New Zealand.
- MARC also requested that Medsafe explore the possibility of using the NZePS as a platform for a prescription drug monitoring programme for opioids. This work programme is ongoing (see above).

3 INTERNATIONAL REGULATION OF OPIOIDS

This section provides a brief summary of the regulatory frameworks and recent developments in Australia, Canada and the United Kingdom. All three countries have experienced an "opioid crisis" in the past decade and have responded with public policy measures. A more detailed analysis of these jurisdictions' regulatory structure is underway and specific aspects can be explored if requested by the Working Group.

Australia

In Australia, the classification of drugs and poisons is set out in the Schedules of the Poisons Standard. The Poisons Standard also includes model provisions about containers and labels, a list of products recommended to be exempt from these provisions, and recommendations about other controls on drugs and poisons. Opioids are classified as Schedule 4 (prescription) or 8 (controlled drugs).

Codeine was up-scheduled from over the counter to prescription-only in 2018. An evaluation of evidence 12 months after the change concluded that codeine reclassification successfully reduced harm from codeine, and the amount of codeine used.[1]

Each state in Australia is responsible for the regulation of Schedule 8 drugs under the general principles established by the Therapeutic Goods Administration (TGA).[2] In general each state requires a special authority from a senior health official (Chief Health Officer or Director-General) to prescribe a Schedule 8 drug for an extended period of time.

Manatū Hauora will be reaching out to officials from the TGA to discuss the existing regulatory settings for opioid access and to seek key learnings from their recent reform work.

Recent developments in Australia

The usage of and harm from prescription opioids has been increasing in Australia since 2007. The Australian Government asked the Therapeutic Goods Administration (TGA) to play a role in tackling the prescription opioid problem. The TGA conducted a public consultation in 2018, seeking comments on options for a regulatory response to misuse of prescribed opioids in Australia. The consultation was framed around the level of prescription opioid overdose, and concern over indication creep towards use in chronic non cancer pain, despite limited evidence for efficacy or safety in these patients.

As a result of the consultation, four options were proposed:

- Consider the pack sizes for strong opioids
- Consider a review of the indications for strong opioids
- Review of label warnings and revision to Consumer Medicines Information (CMI)
- Increase health professional awareness of alternatives to opioids in the management of chronic pain.

The TGA established the Opioid Regulatory Advisory Group (ORAG) to provide independent, expert advice. ORAG strongly supported the proposed options and provided advice on how best to implement them.

[1] BPAC NZ. 2020. *Codeine: all formulations prescription only* 9 October 2020. URL: https://bpac.org.nz/2020/codeine.aspx
[2] Andy C Hua, Finna Shen and Xiaoting Ge. State-based legal requirements for Schedule 8 prescriptions: why so complicated? Med J Aust 2015; 203 (2): 64-66. || doi: 10.5694/mja14.01587.

These measures align with broader Australian Government initiatives to improve appropriate pain management, particularly the National Strategic Action Plan for Pain Management.

In June 2020, changes to the Australian Pharmaceutical Benefits Scheme (PBS) came into effect to support the TGA's regulatory changes, including funding for smaller quantities, changes to the indications that are funded, and changes to the authority process required for opioids to be subsidised. Before prescribing high-strength opioids such as morphine and fentanyl under the PBS, prescribers must ensure that patients with chronic non-cancer pain are unresponsive or intolerant or have not achieved adequate pain relief from lower strength opioids. There are no repeat dispensings for the treatment of non-cancer pain. Additional changes to the PBS came into effect from 1 October 2020 to ensure continued and unimpeded access for palliative care patients receiving opioid analgesic medications.

Australia is also implementing a National Real Time Prescription Monitoring (RTPM) system to monitor the prescribing and dispensing of controlled medicines. The RTPM provides information to prescribers and dispensers about a patient's history and use of controlled medicines.[3] Real time alerts and information is accessible to both health professionals and state regulators.

Canada

In Canada at the federal level, the legal framework for controlling opioids is established by the Controlled Drugs and Substances Act (CDSA) and the Narcotic Control Regulations (NCR). The NCR outline the which activities with drugs scheduled in the regulations are permitted. Drugs regulated under the NCR can still be obtained by patients via a written prescription however verbal prescriptions and refills are not permitted. This includes the possession, sale, distribution, importation and production of scheduled drugs.

British Colombia was at the forefront of Canada's opioid crisis and declared a public health emergency in April 2016. Canadians are second highest users per capita of prescription opioids in the world, after the USA.[4] Between 2005 and 2011, there was a strong and significant correlation between prescription oxycodone dispensing levels and opioid-related mortality in Ontario.

In 2016, the government announced the Canadian Drugs and Substances Strategy (CDSS), and allocated $100 million over five years and $22.7 million ongoing to address drugs and opioids. Actions from this include changes to Customs officers' powers, expedited approvals for nasal spray Naloxone, mandatory hand-outs and stickers for opioid medicines, and restricted advertising.

In March 2022 Canada added tramadol to Schedule I of the CDSA and to the NCR. It had previously been regulated under the Food and Drugs Act and available under prescription only. However recent evidence had demonstrated that it should be more tightly regulated along with other opioids.

United Kingdom

Under the UK Human Medicines Regulations (2012), most opioids are classified as prescription medicines. However, some opioids are available for purchase without prescription as pharmacy only or general sales medicines: low-dose codeine and dihydrocodeine (in combination with paracetamol; co-codamol and codydramol) and low-dose morphine.

The Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001 set out the rules and regulations for opioids use in United Kingdom. The Misuse of Drugs Regulations 2001 set out specific requirements for the prescription, dispensing, and distribution of controlled drugs, the requirements for the labelling and packaging of controlled drugs. Drugs are classified within one of five different schedules based on their risk of harm and therapeutic usefulness.

Exceptional circumstances are defined similarly to New Zealand in above instances. exceptional cases include patient's condition (terminal, debilitating or seriously disabling and there is no satisfactory alternative), a patient (who require ongoing treatment) is unable to obtain a new prescription due to difficulties in accessing a healthcare professional and have an established patient-practitioner relationship.

[3] https://www.health.gov.au/our-work/national-real-time-prescription-monitoring-rtpm
[4] Health Canada. 2017. Government of Canada: Actions on Opioids. URL: https://www.canada.ca/en/health-canada/services/publications/healthy-living/actions-opioids-2016-2017.html

Recent developments in the UK

In 2019, an expert working group of the UK's Commission on Human Medicines, a committee within the Medicines and Healthcare products Regulatory Agency (MHRA), began a review of dependence and addiction to the opioids as a class.[5] This was initiated in response to the growing concern, both in the UK and internationally, of the increased prescribing and the growing numbers of reports of addiction, dependence and fatalities in association with the use of the opioids in the USA.

The review made recommendations for regulatory action to better support appropriate use of prescription opioids, including changes to the Summary of Product Characteristics and Patient Information Leaflet and product labelling and packaging.

4 DATA ON OPIOID PRESCRIBING AND USE

4.1 Data collection and reporting

This section discusses opioid data collection in New Zealand, followed by an overview of the current available data on opioid prescribing and harms.

It is difficult to draw conclusions from the available data on issues caused by the prescribing of opioids. There are limitations to the currently collected data on both prescribing and the impact of these substances.

The newly established Medicines Data Repository (MDR) provides a more functional tool than the current Pharmaceutical Collection for reporting on prescribing and dispensing. The MDR will provide the ability to monitor, in real time, the dispensing of all medicines in NZ. This could enable far greater oversight of prescribing behaviours and potentially allow inappropriate prescribing to be dealt with more quickly. Using this improved functionality will be dependent on adequate investment in IT infrastructure and resourcing of Medicines Control.

Current data

The information below covers:

- prescribing
- harms - hospitalisations, adverse reactions, poisonings, deaths and fatal overdoses
- illicit opioid use
- opioid substitution treatment

This information draws heavily on a report provided by the Medsafe Pharmacovigilance Team to the Medicines Adverse Reactions Committee, titled "Options for minimising opioid abuse, misuse and dependence" (10 June 2021). Other sources include the NZ Health Survey, and recent research by the NZ Drug Foundation. This data does not by itself demonstrate issues with the prescribing of opioids; It is intended to provide some background information, more specific data can be requested by the Working Group if needed.

4.1.1 Prescribing data

Data extracted from the Pharmaceutical Data Web tool are summarised below.

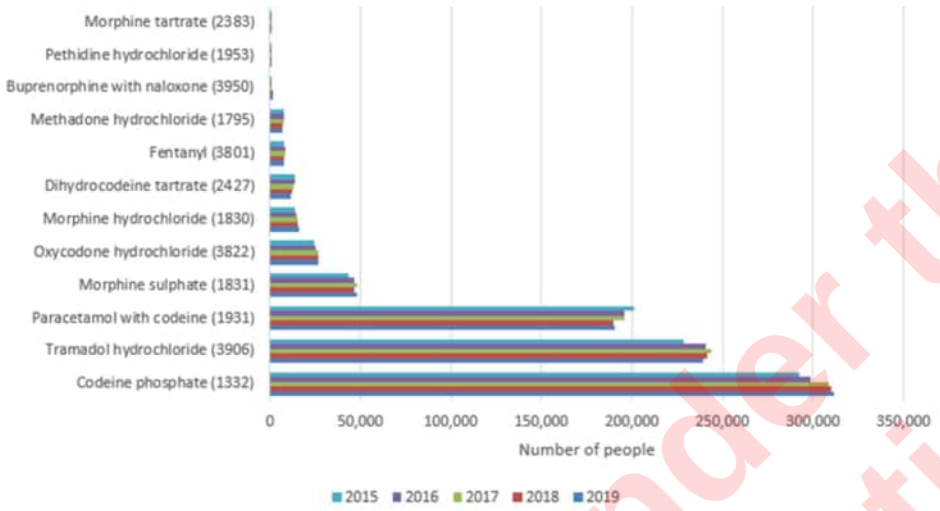
This tool provides summary data from the Pharmaceutical Collection about opioids that were dispensed in the community and funded by the New Zealand Government. It does not provide the indication for use, nor whether the patient took their dispensed medicine as prescribed.

Figure 1 below shows the number of number people dispensed an opioid (by chemical) for 2015 to 2019.

[5] Medicines and Healthcare products Regulatory Agency. 2019. *Opioid Expert Working Group meets at MHRA* 13 February 2019. URL: https://www.gov.uk/government/news/opioid-expert-working-group-meets-at-mhra

Codeine phosphate, tramadol hydrochloride and paracetamol with codeine were dispensed to the greatest number of people. The number of people dispensed codeine phosphate has increased each year, whereas tramadol peaked in 2017 but decreased in 2018 and 2019.

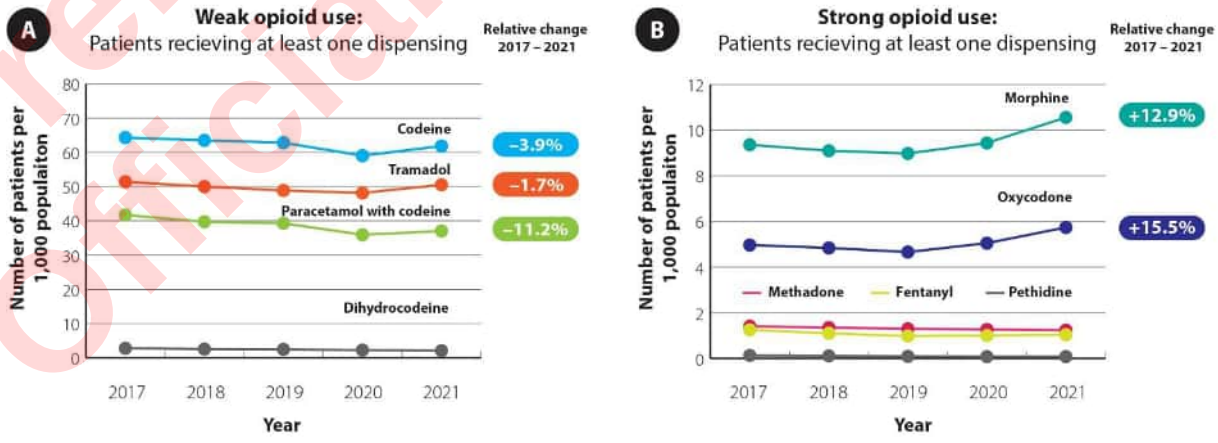
Figure 1: Number of people dispensed a particular opioid (by chemical ID), 2015 to 2019



Notes:
The number of people dispensed an opioid is the number of people who received a dispensing of the pharmaceutical product as a named person from a pharmacy at least once during the year, as an initial dispensing or all at once (excludes people who only received a repeat dispensing during the year).
The approval for morphine tartrate lapsed in January 2020; there are now no approved morphine tartrate products available in New Zealand.
Source: Ministry of Health's Pharmaceutical Collection, extracted on 05 March 2020. URL:
https://minhealthnz.shinyapps.io/pharmaceutical_data_web_tool/ (accessed 11 November 2020).

Figure 2 below shows dispensing of (A) weak and (B) strong opioid analgesics (number of patients with at least one dispensing/1,000 population) in New Zealand between 2017 – 2021. Note the different scales on the y-axis between panels A and B. The panels show there has been a decrease in weak opioid prescribing and an increase in morphine and oxycodone prescribing.

Figure 2: Weak opioid use and strong opioid use (per 1,000 population)[6]



[6] Revisiting opioid use in New Zealand: how does your prescribing compare? - bpacnz

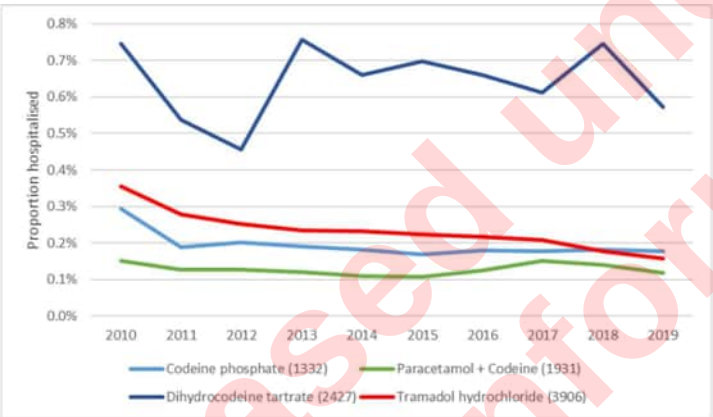
4.1.2 Opioid harms

The data below is a linked administrative data set from the Pharmaceutical Collection, the National Minimum Dataset (hospital discharges) and the Mortality Collection of patients who were prescribed a particular opioid between 2010 and 2019. The data set includes unidentifiable information on the first and last date of opioid dispensing, along with hospital discharges and mortality information for ICD-10/ICD-10-AM clinical codes associated with mental and behavioural disorders due to psychoactive substance use (F11 and F19) and poisoning due to narcotics and dysleptics (T40, X42, X62, Y12).

Figure 3 shows the proportion of people who were dispensed weak opioids and then hospitalised for substance abuse or poisoning in the same year. **Figure 4** shows the strong opioids, excluding the opioid substitution treatments (OST), methadone and buprenorphine with naloxone.

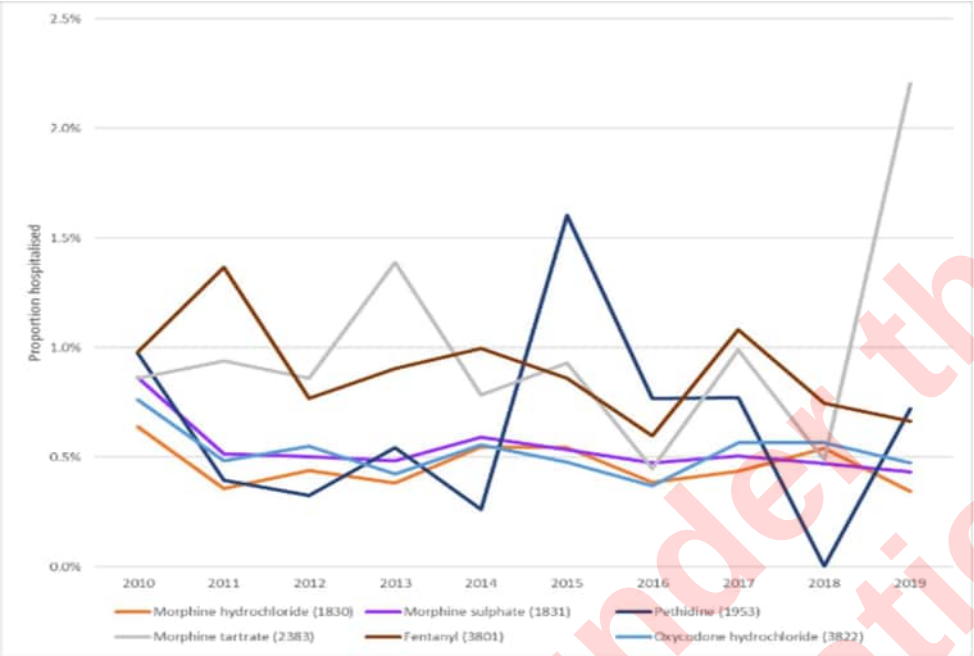
Of the weak opioids, a greater proportion of people were hospitalised with a poisoning or substance abuse code following a dispensing of dihydrocodeine compared to the other opioids. Compared to the weak opioids, the proportions fluctuate more and are higher for the strong opioids. This may be in part due to the lower numbers of people who received strong opioids. Due to their increased potency, strong opioids may also be more likely to contribute to a hospitalisation event within 12 months of dispensing compared to a weak opioid.

Figure 3: Proportion of people dispensed a weak opioid who were hospitalised with a substance abuse or poisoning clinical code in the same year as the initial dispensing, 2010 to 2019



a. Numerator: number of people hospitalised who had an initial opioid dispensing in that year; Denominator: all people who had an initial opioid dispensing in that year
b. Clinical codes: F11 Mental and behavioural disorders due to use of opioids; F19 Mental and behavioural disorders due to multiple drug use & use of psychoactive substances; T40 code (Poisoning by narcotics and psychodysleptics [hallucinogens] (T40.2, T40.3, T40.4 and T40.6 only); X42 Accidental poisoning by and exposure to narcotics and psychodysleptics, not elsewhere classified; X62 Intentional self-poisoning by and exposure to narcotics and psychodysleptics, not elsewhere classified; Y12 Poisoning by and exposure to narcotics and psychodysleptics, not elsewhere classified.
c. Excludes repeat discharges in the same calendar year.

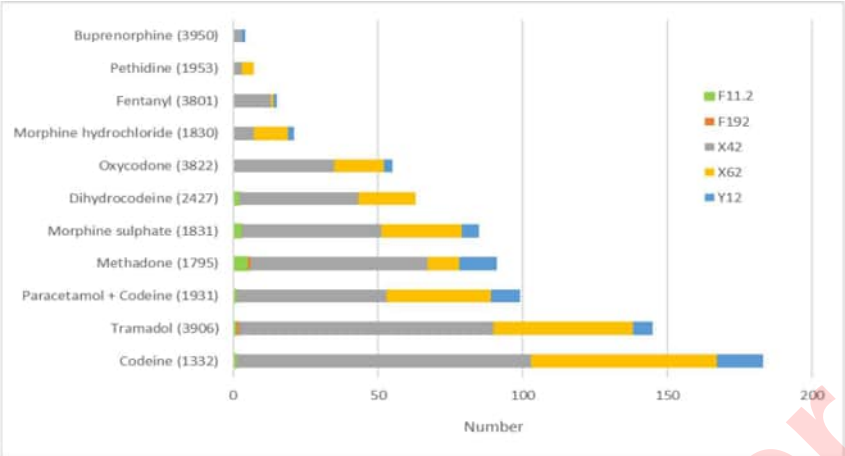
Figure 4: Proportion of people dispensed a strong opioid who were hospitalised with a substance abuse or poisoning code in the same year as the initial dispensing, 2010 to 2019



a. Numerator: number of people hospitalised who had an initial opioid dispensing in that year; Denominator: all people who had an initial opioid dispensing in that year
b. Excludes the strong opioids methadone and buprenorphine with naloxone that are used for opioid substitution treatment.
c. As at January 2020, morphine tartrate was no longer approved in New Zealand.
d. Clinical codes: F11 Mental and behavioural disorders due to use of opioids; F19 Mental and behavioural disorders due to multiple drug use & use of psychoactive substances; T40 code (Poisoning by narcotics and psychodysleptics [hallucinogens] (T40.2, T40.3, T40.4 and T40.6 only); X42 Accidental poisoning by and exposure to narcotics and psychodysleptics, not elsewhere classified; X62 Intentional self-poisoning by and exposure to narcotics and psychodysleptics, not elsewhere classified; Y12 Poisoning by and exposure to narcotics and psychodysleptics, not elsewhere classified.
e. Excludes repeat discharges in the same calendar year.

Codeine, tramadol, paracetamol + codeine, and methadone were the dispensed opioids associated with the greatest number of deaths per year (**Figure 5**). With the exception of morphine hydrochloride, accidental poisoning (X42) was most frequently recorded as the primary cause of death for the dispensed opioids, followed by intentional self-poisoning.

Figure 5: Total deaths between 2010 and 2016 due to substance abuse or poisoning clinical codes, by dispensed opioid



a. Clinical codes: F11.2: Mental and behavioural disorders due to use of opioids: dependence syndrome; F19.2 Mental and behavioural disorders due to multiple drug use & use of psychoactive substances: dependence syndrome; X42 Accidental poisoning by and exposure to narcotics and psychodysleptics, not elsewhere classified; X62 Intentional self-poisoning by and exposure to narcotics and psychodysleptics, not elsewhere classified; Y12 Poisoning by and exposure to narcotics and psychodysleptics, not elsewhere classified.

National Poisons Centre data

There were 1,889 calls to the National Poisons Centre for opioid exposures between 1 January 2017 and 30 June 2020 (**Table 3**). Codeine and tramadol were the most prevalent opioid exposures reported to the NPC, accounting for 828 (1,137 when including codeine + paracetamol) and 601 exposures, respectively.

Table 3: Overall prevalence of opioid substances in contacts to the National Poisons Centre, 1 January 2017 to 30 June 2020

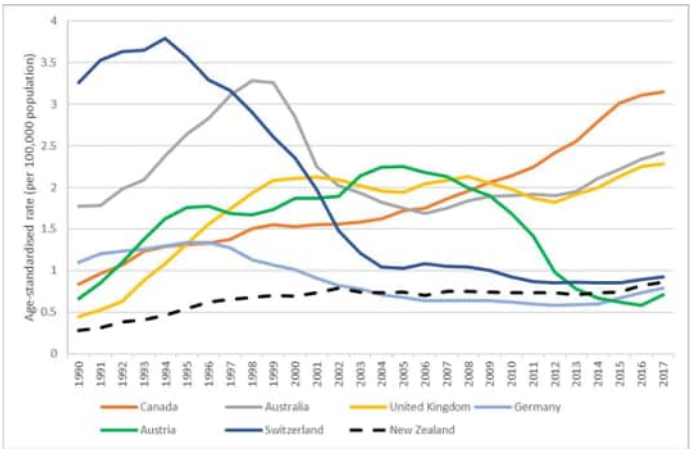
	2017	2018	2019	2020*	Grand Total
Total patients with one or more of the opioids of interest indicated	530	547	542	270	1,889
% of all human exposure patients	2.5%	2.6%	2.4%	2.3%	2.5%
Total human exposure patients	21,066	21,311	22,925	11,798	77,100
Patients "positive" for specific substance of interest (substance present)**					
Buprenorphine + naloxone	0	1	4	1	6
Codeine	233	242	219	134	828
Codeine + paracetamol	81	91	107	30	309
Dihydrocodeine	6	7	8	4	25
Fentanyl	3	3	6	7	19
Methadone	2	11	9	1	23
Morphine	66	56	68	31	221
Oxycodone	20	17	17	11	65
Pethidine	0	2	0	3	5
Tramadol	177	185	163	76	601

*To 30 June 2020. **NOTE: a single patient may have multiple opioids involved in their exposure; therefore total numbers of substance cases do not necessarily match total opioid-positive patients.

International comparisons - mortality

Rates of death from opioid-use disorders in New Zealand are low compared to many other Western countries (**Figure 6**), and much lower than in the USA. The rate of death has also been reasonably stable in NZ, compared to other countries.

Figure 6: Age-standardised rates of death due to opioid-use disorders (cause B7.2.1), selected countries (excluding USA), 1990 to 2017

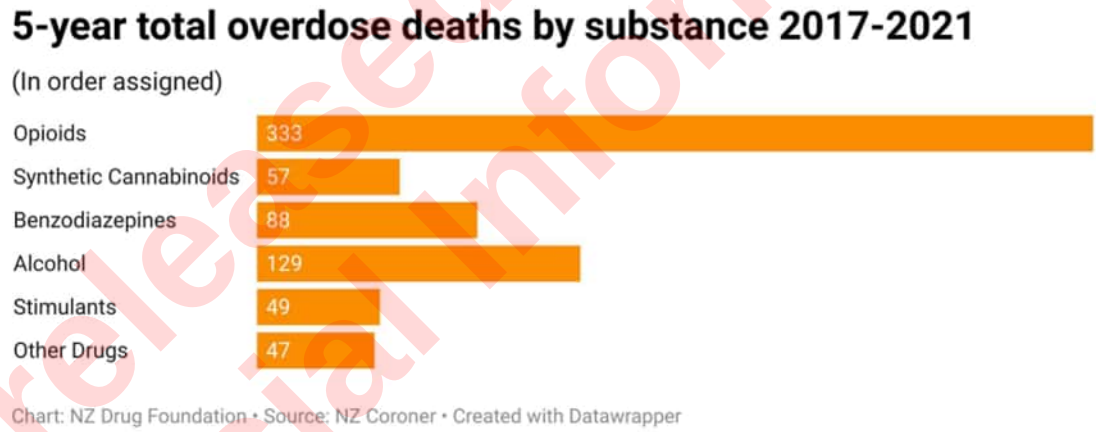


Source: Global Health Data Exchange. *GBD Results Tool*. URL: http://ghdx.healthdata.org/gbd-results-tool?params=gbd-api-2017-permalink/569cfab3777a4c822ca0ec07c4a578f9 (accessed 30 September 2020).

Fatal overdoses

In November 2022, the NZ Drug Foundation published the report Fatal Overdoses in Aotearoa 2017-2021, based on coroner data on 702 overdose deaths. **Figures 7** and **8** show overdose deaths in New Zealand between 2017 and 2021. Across the five-year period from 2017 – 2021, cases rose by 54 percent, whereas the population increased by only 6 percent.

Figure 7: 5-year total overdose deaths by substance 2017-21



In most cases multiple substances were identified in the toxicology report, thus it is not possible to definitively identify which substance or combination was responsible for death.

The report showed Māori are disproportionately affected by drug harm and fatal drug overdose in New Zealand. While making up approximately only 15% of the population, Māori made up 27% of the total closed overdose cases between 2017-2021 and 25% of all cases (closed and open). Māori were overrepresented in synthetic cannabinoid overdoses, making up 67% of cases.

In the majority of closed overdose cases, people had a number of drugs in their system when they died; this includes illicit drugs, alcohol and medicines (over the counter and prescription).

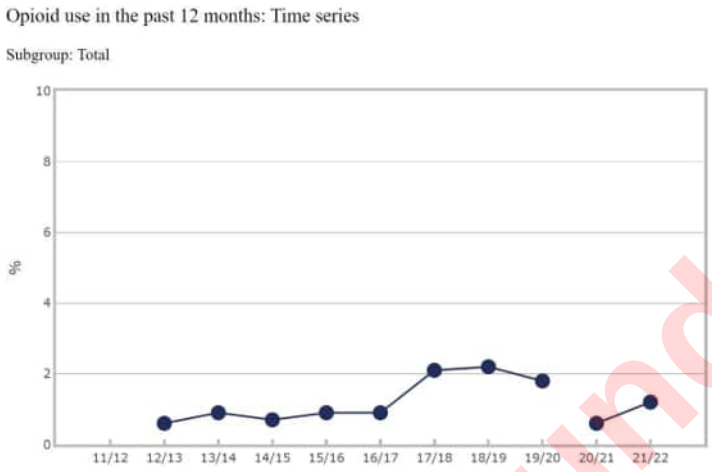
- Over the last 5 years, 42% of closed cases listed 5 or more substances on the toxicology report. 91% of cases listed 2 or more substances.
- Only 9% of closed cases listed just one substance on the toxicology report

This data shows a clear relationship between the number of substances in a person's system and the likelihood of dying of an overdose.

Illicit opioid use

The New Zealand Health Survey 2021/2022 found that 49,000 adults (1.2 percent of the population) had used opioids, other than as a prescribed medicine, in the past 12 months. **Figure 9** shows an increase from 2017/18. The dip in 2020/21 coincided with a change in the question, which may have affected the result.

Figure 8: Opioid use in the past 12 months



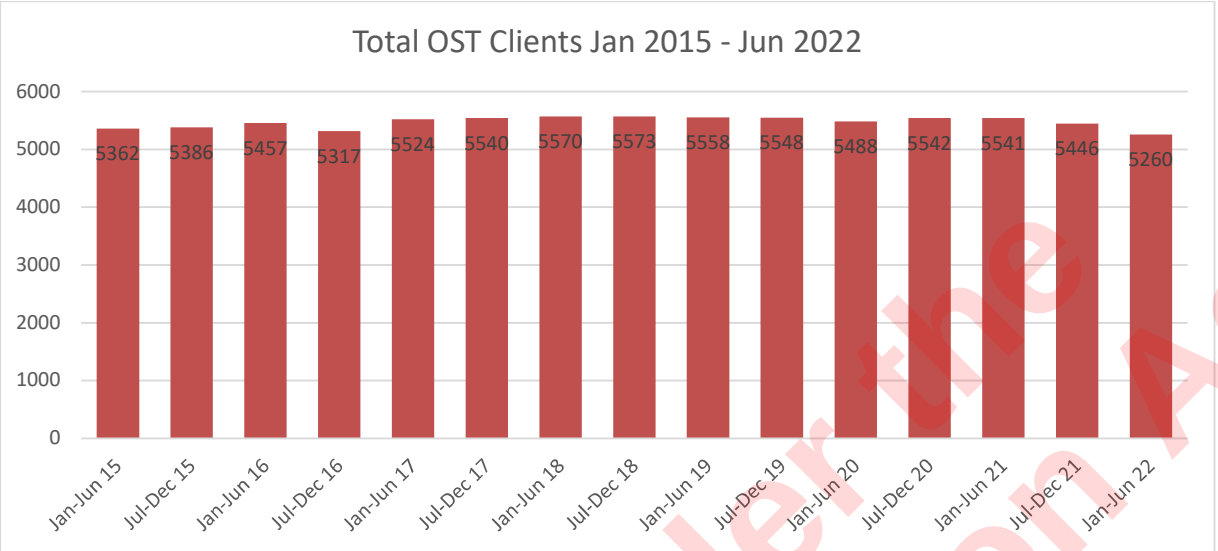
Opioid Substitution Treatment

The Mental Health and Addictions team have supplied data on the numbers of people in New Zealand accessing opioid substitution treatment (OST). In 2022 there were 5,260 clients. There has been no real change since 2015, with numbers over 5,000 clients at any one time (**Figure 9**).

Client numbers are influenced by a range of factors:

- funding/resourcing of the services – which has in the main not gone up in any real terms. We do not know how much unmet demand there is, but programmes do get full and anecdotally word gets around quickly so potential clients may not even apply.
- access to GP shared care, which essentially distributes stable clients to GP care, so that new or unstable ones have access to specialist care. This is a challenge with GPs retiring.
- those coming off the programme: deaths, voluntary withdrawal or involuntary withdrawal.

Figure 9: Total OST Clients 2015 to 2022



Assessment of opioid access

Safe Access to Opioids Working Group Terms of Reference

Sign off	
This document requires the following approvals:	
Safe Access to Opioids Working Group	**Date:**

Author	Allison Bennett, Group Manager Health System Settings, Strategy, Policy and Legislation, Manatū Hauora
Status	DRAFT for discussion

1. Context

New Zealand has so far avoided the same level of harm experienced in other countries caused by overprescribing and misuse of prescription opioids. However, there is growing concern among New Zealand health professionals about the increase in misuse of prescription opioids.

Opioids are important and essential pain medicines for many, however, they can also be addictive and cause significant harm when misused. Caution is therefore needed when prescribing opioids, they should only be prescribed in-line with best practice clinical guidelines to ensure appropriate access for patients to manage their pain.

A number of controls and safeguards exist to manage the risk of prescribing opioids. 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.

There is a question as to whether these current controls are fit for purpose, in both managing the risk of inappropriate prescribing and ensuring equitable patient access to these medicines.

2. Role/Purpose

To address the concerns raised about access to opioids, the Ministry is commissioning an inter-agency Working Group to

1. Assess the current risk associated with opioid access in New Zealand
2. Review current system controls for managing access to opioids, and
3. Identify priority areas for improvement to mitigate the risk of harm posed by opioids and to ensure they are accessible to the patients that need them.

The Safe Access to Opioids Working Group is intended to inform the Ministry's activities to manage risks associated with opioid access.

3. Policy support

The Health System Settings, strategy and policy team will be responsible for two functions to support the Working Group:

- Policy support – including preparing materials that describe the existing prescribing controls, comparative analysis of controls in other jurisdictions, gathering data/evidence as needed by the Working Group, advising the Working Group
- Secretariat – Administrative support.

The Working Group's recommendations will be captured in a report to be prepared by the Health System Settings policy group in Manatū Hauora. This report will be provided to the Director-General of Health, along with further advice on what would be required to implement the Working Group's recommendations.

4. Scope

The assessment will consider all system settings that influence the access to prescription opioids, including the identification of potential changes to legislation, regulations, resourcing, investment or other arrangements.

5. Membership

Agencies will be responsible for choosing an appropriate representative for the Working Group.

The Working Group may choose to co-opt members if it considers that it requires access to expertise that it is not readily available or invite experts to attend in order to support a particular discussion.

Group Chair	Anna Skinner, Clinical Chief Advisor, OCCO, Manatū Hauora
Member	Michael Haynes, Manager Medicines Control, Manatū Hauora
Member	Billy Allan, Manager Pharmacy, Te Whatu Ora
Member	Trevor Lloyd, NZePS Change Manager, Te Whatu Ora
Member	David Hughes, Chief Medical Officer, Pharmac
Member	Andi Shirtcliffe, Chief Clinical Advisor, Manatū Hauora
Member	John Crawshaw, Mental Health and Addictions, Manatū Hauora
Member	Teei Kaiaruna, Te Aka Whai Ora
Member	Anna-Lee Annett, Te Aka Whai Ora
Member	Shaheeda Othman, Health Quality and Safety Commission New Zealand
Member	Suzanne Townsend, Manager, Regulatory Policy, Manatū Hauora

6. Responsibilities

Members are responsible for maintaining appropriate confidentiality, communications and accountabilities within their respective organisations.

Members are responsible for reviewing any provided materials prior to scheduled meetings to be able to participate in discussions.

7. Role of Chair

The Chair will provide overall leadership of the working group, and ensure agreed positions are reached wherever possible.

8. Operation

Term & Frequency	The Working Group is expected to meet weekly from January 2022 to March 2022. The initial meeting will be about 2 hours, and subsequent meetings 30 minutes (or as agreed by the chair and the group).
Quorum	The quorum for meetings to proceed will be XXX
Secretariat	Manatū Hauora will provide a Secretariat for administrative and policy support. It is the Secretariat's responsibility to: • Ensure meeting packs are created and promulgated to the committee within an appropriate timeframe. • Liaise with the Chair and key stakeholders regarding materials being submitted to the Working Group • Ensure meeting rooms, teleconference, or video conference units are booked. • Provide draft minutes to the Chair as soon as possible after a Working Group meeting and ensure that actions are being followed up in accordance with the agreed due dates.

From: David Hughes
Sent: Tuesday, 24 January 2023 1:46 pm
To: Meg Larken
Cc: Suzanne Townsend
Subject: RE: Safe access to opioids working group first meeting

Kia ora Meg and Suzanne,

The regulation changes included the stimulants and given the interest and concerns about access to these treatments, I had hoped the group would be able to provide guidance on the issues.
The issues as I see them are:

- Regulations requiring written recommendation by Psychiatrist / Paediatrician for other prescribers
- Special authority renewal criteria linked to the regulatory requirement leading to a recommendation to have occurred in writing within two years
- Limit to 1 month scripts

Pharmac views this time as an opportunity to clarify the role of and interaction between regulations and funding criteria across all Class B medicines. Our strong preference is to reach consensus on both opioids and stimulants so that regulation and pharmaceutical schedule changes can be aligned in one wave rather than in piecemeal.

Ngā mihi,
David

David Hughes (he/him)
Tumu Whakarae Haumanu | Chief Medical Officer

Te Pātaka Whaioranga | Pharmac | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
P: s 9(2)(a) | M: s 9(2)(a) | F: +64 4 460 4995 | www.pharmac.govt.nz

---

From: Meg Larken <Meg.Larken@health.govt.nz>
Sent: Tuesday, 24 January 2023 12:06 pm
To: David Hughes <david.hughes@pharmac.govt.nz>
Cc: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>
Subject: RE: Safe access to opioids working group first meeting

Kia ora David,

Yes my understanding is the opioids prescribing is seen as a policy issue needing attention, whereas the stimulants is not. But you're welcome to bring it up in the meeting if you would like to clarify the scope.

Meg

From: David Hughes <david.hughes@pharmac.govt.nz>
Sent: Tuesday, 24 January 2023 9:37 am
To: Meg Larken <Meg.Larken@health.govt.nz>
Subject: RE: Safe access to opioids working group first meeting

Kia ora Meg,
Thanks for adding the teams invite.

I had a look at the agenda, I can't see much on the stimulants. Is that because we believe there is consensus to move to 3 month prescribing for this sub group of the Class Bs ?
It would be good to confirm that so we can move forward.

Ngā mihi,
David

From: Meg Larken <Meg.Larken@health.govt.nz>
Sent: Tuesday, 24 January 2023 9:26 am
To: David Hughes <david.hughes@pharmac.govt.nz>
Subject: RE: Safe access to opioids working group first meeting

Kia ora David,

I've put a Teams link in the calendar invite. See you on-line tomorrow.

Meg

From: David Hughes <david.hughes@pharmac.govt.nz>
Sent: Monday, 16 January 2023 4:35 pm
To: Meg Larken <Meg.Larken@health.govt.nz>
Subject: RE: Safe access to opioids working group first meeting

Just to note I will be in AKL on the day and I am keen to attend remotely.

Ngā mihi,
David

-----Original Appointment-----
From: Meg Larken <Meg.Larken@health.govt.nz>
Sent: Friday, 23 December 2022 9:06 am
To: Meg Larken; Suzanne Townsend; Anna Skinner; John Crawshaw; Annie Hindle; Rawiri McKree Jansen; Andi Shirtcliffe; Michael Haynes; Billy Allan; David Hughes; Eddy Sommers; Allison Bennett; [redacted]
Subject: Safe access to opioids working group first meeting
When: Wednesday, 25 January 2023 9:30 am-11:30 am (UTC+12:00) Auckland, Wellington.
Where: Molesworth 3S.1

Thank you for being available for this meeting. Agenda and papers to come.

Meg Larken (she/her)
Senior Policy Analyst
Regulatory Policy, Te Pou Rautaki
[redacted]
meg.larken@health.govt.nz
[redacted]
Manatū Hauora, 133 Molesworth Street, Wellington

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From: David Hughes
Sent: Wednesday, 25 January 2023 3:57 pm
To: Meg Larken
Cc: Suzanne Townsend
Subject: RE: Safe access to opioids working group first meeting
Attachments: 2023-01 Themed feedback Pharmac CD consultation - for working group.pdf

Kia ora korua,
Please find attached a few items of interest.
The first is an analysis of the feedback we received on the consultation. I would summarise this as mixed with a degree of separation of issues into stimulants, opioid substitution (mostly positive about extending prescribing) and opioids for cancer / palliative care and opioids for non-cancer pain. Movement to ePS was generally positive.
The second is a link to the review of opioids by MARC looking at some of the same issues (I see a number of the charts in the report prepared for the meeting). There is a useful discussion on other jurisdictions and an evidence review. 186-3.2.3-Opioid.pdf (medsafe.govt.nz)
The third is a link to the atlas of variation on opioids by the commission – this might be useful stater for a opioids prescribing and dispensing dashboard that could be accessed at a national, regional, practice and prescriber level. Opioids | Health Quality & Safety Commission (hqsc.govt.nz)

With regard to the stimulants, as you will see in the feedback, there is support for the extended prescribing period. In parallel to this, as you know, there are calls for relaxing the regulations and special authority criteria for the stimulants. Pharmac's view is that changes to the special authority criteria will require review of legal, clinical and health economic advice. I am very keen for the group (or a parallel sub group) to consider the ongoing need for regulations requiring a paediatrician / psychiatrist to recommend stimulant treatment in writing. This regulation has led to the current funding renewal criteria requiring that recommendation to have a 2 year currency. Previous feedback from paediatricians and psychiatrists raised concern that a written recommendation from childhood was being relied on for continued funding many years later.
If we were thinking of a smaller group to consider this, it would be good for John Crawshaw and Michael Haynes to be part of this.

Ngā mihi,
David

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Meg Larken (she/her)
Senior Policy Analyst
Regulatory Policy, Te Pou Rautaki
[redacted]
meg.larken@health.govt.nz
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Manatū Hauora, 133 Molesworth Street, Wellington

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Themed feedback from Pharmac Proposal to amend the Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs

Contents

1: Introduction

Legislative changes to the prescribing and dispensing of controlled drugs were Gazetted on 24 Nov 2022, and came into effect on 22 December 2022. Pharmac consulted in late November 2022 on changes to amend the Pharmaceutical Schedule General Rules (the Schedule Rules) to bring funding in line with these legislative changes, with funding changes proposed to take effect from 1 February 2022.

Pharmac note that the Misuse of Drugs Amendment Regulations 2022 are restrictive and that funding rules are required to fit within these regulations.

Pharmac received a large amount of feedback[1] from consumers and their advocates, prescribers, pharmacists and their professional organisations, and from suppliers. This feedback showed both support for and concerns about changes to the prescribing and dispensing of Class B controlled drugs.

[1] This feedback is subject to the Official Information Act 1982.

In light of this feedback, Manatū Hauora, the Ministry of Health, has:

- indicated it would like to revisit the regulatory arrangements for opioids and have convened a working group to support this work.
- asked Pharmac to delay making a decision on the proposed changes to the Schedule Rules (which Pharmac has agreed to) until this work is completed.

We are grateful for the time people have taken to share their feedback. Sharing this feedback is intended to support the work of this working group only. This feedback was received in the specific context of a Pharmac funding consultation and, as such we ask that this information remains within the group and is not circulated further.

This document captures the feedback Pharmac received and attaches it to themes. The size of this document reflects the large volume of feedback.

2: Consumer voice

We received supportive feedback from consumers regarding E-prescriptions being provided for a 3 month period, with monthly dispensings:

i) For opioids, consumers noted this proposal would:

- Reduce stress for patients and whanāu associated with arranging regular prescriptions and dispensings (in palliative care use)

  "My father is totally reliant on this morphine to control the misery of end-stage heart failure and the resultant shortness of breath. He worries that the morphine delivery will be late or will not come. It is an added stress he does not need." (caregiver)

ii) Stimulant specific feedback from consumers noted:

- Reduced costs (both GP and prescription fees) for patients on ADHD medicines

  "as someone who's prescribed methylphenidate, shifting to 3 monthly scripts with monthly dispensing will save a lot of money for many patients." (consumer)

  "from the perspective of decreasing the costs and complexities of obtaining access to methylphenidate, the changes proposed by Pharmac are welcome and bring the (Schedule) Rules into line with the Regulations.
  This represents a small but useful reduction in the excessive bureaucratic overhead associated with being neurodiverse in Aotearoa" (ADHD community)

- The ADHD community acknowledged the opportunity to provide feedback to this consultation and the importance of the consumer voice.

3: Legislation changes

Much of the feedback we received was on the legislative changes that necessitated changes to the Schedule General Rules to give effect to the legislation[2].

Overall medical and pharmacy stakeholders and their affiliated professional organisations were in favour of:

- Electronic prescribing and E-prescriptions resulting in reduced dosing errors, better tracking and monitoring of prescriptions, reduced forged prescriptions

- Improving equity of access to these medications by
  a) supporting access to care
  b) reducing barriers faced by those living rurally/ those with mobility issues/ in circumstances where frequent prescription renewals and collections are difficult to manage, including medical (GP visit, pharmacy co-payment) and transport costs.
  c) ensuring patients don't miss out on repeat prescriptions (when 10-day dispensing falls on a weekend)

- Reduced GP and pharmacy administration and workload in relation to stimulants and methadone prescribing

We observed differing views on the range of issues in many cases between professional organisations and the individuals they represent.

Some stakeholder feedback fully supported the proposed changes to the General Rules (Section A) of the Pharmaceutical Schedule noting the changes would make patient's lives easier – especially for those on longstanding opioid or methamphetamine prescriptions, reduce the burden on GPs and other prescribers and free up GP appointment times.

These stakeholders noted that under this proposal and within the legislation, prescribers can restrict prescription and dispensing volumes as required.

Stakeholders noted the following concerns:

- Potential to increase the quantity of controlled drugs (in the community) by 300%
- Risk of reduced interactions with patients, review opportunities and informal checkpoints between patients and their healthcare team
- Some professional medical organisations noted the inconvenience of monthly prescriptions for those small number of opioid recipients that could benefit from a three-monthly prescription is very slight in comparison to the risks of providing more.

i) General feedback included:

- Inadequate legislation consultation process (multiple stakeholders)

[2] The legislation changes were Gazetted on 24 Nov 2022, to come into effect 22 December. Pharmac proposed funding changes would take effect from 1 February 2022.

- Regulatory changes were considered and approved without adequate consultation with medical experts of peak medical bodies which is highly unusual for such a sensitive area (medical professional organisation)
- Concerns about consultation timing and feedback window (Pharmacy stakeholders)

ii) Opioid specific feedback:

- Concerns no adequate risk assessment has been done of the potential for increasing opioid addiction, diversion or other opioid related harms in NZ, or adequate examination of ways to mitigate the risk of this happening
- Do not consider E-prescribing a rationale for lifting the system time limits on opioid use for pain management
- The regulatory changes go against international best practice guidelines, undermines professionalism and clinical judgement (for Class B opioids outside of methadone)

4: Prescribing periods and dispensing frequency

While the legislative changes are concerned with prescribing periods (prescription length), the Pharmac consultation also proposed a change to the default dispensing frequency for Class B opioids from 10 days at a time to monthly.[3]

Some stakeholders provided feedback on both prescribing and dispensing periods, while others provided feedback only on one of these aspects.

Where feedback was provided on the proposed change from 10 day dispensing, there was both support for and concerns about this.

The views expressed and relative emphasis on prescribing periods versus dispensing periods varied with the type of Class B controlled drug and clinical use situations (see also sections 6-9).

5: Timing of proposed funding change

We received a range of feedback from stakeholders about the timing of the proposed funding. Pharmac proposed subsequent funding changes would take effect from 1 February 2023.

Some pharmacy stakeholders endorsed this proposed time frame for implementing the funding changes.

Feedback relating to timeframe concerns included:

- Concern about the gap and inconsistency in practice, in between legislation in force and proposed implementation of funding change (medical and pharmacy professional organisations)
- Insufficient time to plan and address (CD) storage requirements (pharmacists)

[3] The initial decision to dispense in 10 day lots was made by the Department of Health therapeutics section (Pharmac's predecessor) in 1991. This started as 7 day dispensing in February 1991 and was further amended to 10 day dispensing in August 1991.
Methylphenidate and dexamfetamine may be dispensed as a single monthly lot under the current Schedule rules.

- Implementation date (for funding) too soon to ensure sufficient stock of Class B CDs (Suppliers)
- Insufficient time to make software changes (Software vendors)
- The negative impact on patients (taking stimulants) of implementation date later than 22 Dec was seen as non-justifiable (ADHD community)

  "The reasons Pharmac offers for the delay (Implementation of proposed Pharmac rule changes) do not justify the impacts on the ADHD community" (ADHD community)

6: Call for legislation review – not all Class B controlled drugs or clinical use situations are the same

We received feedback from professional medical bodies and the ADHD community calling for a review of subclassifications within class B controlled drugs schedule.

The ADHD community told us that:

- Already stigmatized people living with ADHD are further stigmatized in being treated differently by being required to collect medicines monthly (because of the Class B controlled drug legislation), rather than 3 monthly as with medicines used for other conditions (ADHD community)

  "The front-line medications for ADHD are Class B drugs. There is no objective reason for this classification, as is widely acknowledged. The Ministry's unwillingness to address this system failure plays a very substantial financial and logistical burden on the ADHD community" (ADHD community)

Other professional medical stakeholder groups had diverse opinions amongst their members on E-prescriptions being provided for a 3-month period with monthly dispensings because of the heterogenicity of Class B controlled drugs.

They noted:

- The range of medicines within Class B is vast, varied and should not be considered equivalent in terms of overdose, addiction and other deleterious outcomes[4]

Some clinicians noted prescribing opioids (methadone) for opioid dependence, or stimulants for ADHD uses a risk assessment approach and were not concerned about increased prescription length.

Medical stakeholders noted the use of Class B controlled drugs in distinct clinical situations had not been considered or outlined for separate feedback.

Given this varied consultation feedback across the Class B controlled drug group, we have themed this feedback as it has been given to us by respondents in the following sections.

[4] Class B controlled drugs include Fentanyl, Methadone hydrochloride, Morphine hydrochloride, Morphine sulphate, Oxycodone hydrochloride and Pethidine hydrochloride (opioids)
and Methylphenidate hydrochloride and Dexamfetamine sulphate (stimulants used primarily for ADHD)

- Stimulants
- Methadone
- Other Class B opioids

7: Stimulants (Methylphenidate and Dexamfetamine)

i) Supportive feedback

We received supportive feedback from consumers, clinicians, medical professional bodies and pharmacists regarding:

- E-prescriptions for methylphenidate and dexamphetamine being provided for a 3 month period
- Methylphenidate and dexamfetamine monthly dispensings

Specific supportive feedback included:

- Good evidence for long term use of stimulants
- Reduced costs (GP visits and prescription costs) for patients on ADHD medicines
- Patients with ADHD should have prescription length the same as for other conditions
- Support for reduced barriers to collection of prescriptions and therefore reduced treatment burden for people with ADHD
- Dose stability of patients on methylphenidate allows for 3 monthly prescriptions
- Safety mechanisms in place include stimulants being commenced and approved by a specialist psychiatrist
- Supports efficient use of small ADHD workforce by reduced administration

ii) Patient safety

We received the following feedback from clinicians treating people with ADHD regarding patient safety with stimulants under our proposal:

- Guidance should support lesser amounts of stimulants being dispensed at prescribers' discretion where risks are identified
- Considers concerns about abuse and misappropriation (from stimulants) won't be any different under proposed new funding framework

8: Methadone

i) Supportive feedback

We received the following supportive feedback from multiple medical and pharmacy stakeholders and their professional organisations regarding:

- E-prescriptions for methadone being provided for a 3 month period
- Methadone monthly dispensings

Specific supportive feedback included:

- Support for proposed prescribing duration and electronic prescribing for methadone
- Noted safeguards and standards and regulatory framework in place with the Opioid substitution treatment (OST) which support 90 day methadone prescriptions

9: Other Class B opioids (Fentanyl, Morphine, Oxycodone and Pethidine)

Professional organisations noted the change in regulations with regard to Class B opioids is an opportunity for a more nuanced approach to both manage risk (from Class B opioids) and ensure equity of access for patients.

i) Supportive feedback

We received supportive feedback from multiple stakeholders) regarding

- E-prescriptions for these opioids being provided for a 3 month period
- Monthly dispensings of these opioids

Some stakeholders noted that it would be difficult to manage if the funded duration was not in line with the Regulations.

Specific supportive feedback included:

- Some patients may hugely benefit from improved access to opioids (cancer, palliative care, COPD)
- Patients not picking up repeats frequently enough are being denied repeats under 10 day dispensing rules
- Reducing stress for patients and whanāu experienced with more regular prescriptions and dispensings
- Monthly dispensing has worked well for ADHD medicines and monthly dispensing should be expanded for all chronic use Class B controlled drugs
- Noting the ability of the prescriber to endorse an electronic prescription for more frequent dispensing if there were concerns re: abuse/diversion

ii) Patient safety, Inappropriate prescribing and abuse potential

Other professional medical stakeholder groups were strongly opposed to the proposed move away from monthly prescribing of opiates and moving away from 10-day dispensing of opiates, especially in clinical situations of non-cancer pain. They proposed longer periods of supply being available in specific circumstances such as people living rurally or in specific clinical situations, for example cancer pain.

They, in addition to many clinicians, pharmacists and other professional organisations noted the increased risk of opioid related harm outweighs the benefit of this proposal.

Some of these stakeholders considered the controls to date on opioid dispensing in NZ has (in part) led to NZ's avoidance to date of opioid excess and harm (as seen in for example the USA).

These stakeholders supported wider consultation before this proposal is progressed.

Specific patient safety feedback included:

- Non-cancer pain is where the main risk lies for diversion and increased potential for addiction (with Class B opioids) and this clinical scenario should not move away from monthly prescriptions with 10-day dispensing.
- Noting there is little evidence for the use of opioids in the treatment of long-term non-cancer, acute or chronic pain.
- Risk of misuse, overdose/ diversion, unintended harm and increase in addiction issues will likely disproportionately affect those with high needs, Māori and Pacific peoples
- Increasing the length of prescription creates greater potential for opioid diversion, unintended harm and addiction
- Misuse mostly occurs when medication is taken at a higher dose, increased frequency or for a longer duration than indicated
- Risk of increased stockpiling of opioids (prn meds often given on repeat prescriptions in addition to regular medicine)
- Concern that patients with supplies of opioids may be targeted
- Noting the quantity of opioids in a long-term prescription has high street value
- Reduced visibility of drug seeking behaviour (by prescribers)
- Greater responsibility for prescribers to think about and manage dispensing intervals and qualities of opioids
- Risk of prescriber not over-riding default monthly dispensing in patient management system to smaller dispensing amount
- Concern GPs will be pressured to prescribe 3 monthly opioid prescriptions where there are not clinically indicated
- Prescribing opioids for longer periods of time reduces the opportunity for the prescriber to review
- Rather than improving access to Class B opioid medications, improvements to addiction medicine treatment support structures should be prioritised

iii) Patient stability

There were different viewpoints from clinicians regarding stability of dosing with patients taking Class B opioids

Specific feedback included:

- Opioid prescribing for non-cancer pain should be of short duration
- Many patients are on stable doses of chronic use opioids (and proposed funding changes are supported)

- Opioid dose requirements change rapidly and often (and proposed funding changes are unsupported)

10: Operational process considerations

We received feedback from pharmacy stakeholders on operational considerations for E-prescriptions being provided for a 3 month period, with most of this feedback focused on monthly dispensings.

i) Safe storage of CDs in a community pharmacy

Specific feedback included:

- Storing increased volume of CDs, noting dispensed CDs need to be stored in safe until patient collects
- Lack of CD safes available for purchase within New Zealand (where larger safes are required)
- Pharmacist professional organisations noted that there is no additional funding from Te Whatu Ora to help manage any future controlled drug safe storage requirements.
- Pharmacy and staff safety – concerns about pharmacies being "targeted"

ii) Wastage and disposal/destruction of CDs

Specific feedback included:

- Financial and social cost of increased wastage (opioid dose changes, prn meds often given on repeats in addition to regular medicine, when not required)
- Environmental hazard with increased wastage of CDs
- Increased workload for safe disposal of CDs

iii) Financial and workload impact on pharmacies

Specific feedback included:

- Cost of CD safes
- Greater financial losses if holding short-dated stock (because of greater volume)
- Reduction in dispensing fees
- An adjustment to the class B Controlled Drugs fee multiplier in the ICPSA would mitigate the disincentives associated with reduced dispensing revenue
- Increasing pharmacy workload
- Pharmac should provide financial support
- Early implementation of the electronic Controlled Drugs register would reduce administrative time input in the Controlled Drugs service

iv) Impact on the supply chain

Specific feedback included:

- Increased “owings” to patients where the full quantity of a prescription cannot be met.
- Risk of “out of stocks”

11: Implementation

We received feedback from medical stakeholder groups on activities that may assist with implementing regulatory changes relating to Class B opioids (excluding methadone) and managing the risks of opioid related harms.

Specific feedback included:

- Consideration of a monitoring plan
- Suggest need for accompanying education campaign and addition of restrictions to daily oral morphine equivalent dose that can be prescribed without specialist review and supervision (as per Australian model)
- We suggest that opioids should not be started without a clear exit plan for stopping these medications.
- Interventions to reduce inappropriate opioid prescribing should be focused on improving patient care, management of patients with complex pain, and reducing comorbidities rather than seeking to enforce a threshold for prescribing.
- Given current data, we want to see safeguards put in place such as a special authority, and auditing to highlight inappropriate prescribing against best practice guidelines and give the ability to provide governance over the supply of opioids
- More focus should be placed on opioid prescribing and supporting the integration of the National Medication Safety Programme
- Support improving safety of opioid prescribing practices at system level to support prescribers with evidence, best practice and establish systems to include
  - standards for best practice prescribing and dispensing
  - auditing and reconciliation of medicines that have a known potential for misuse
  - setting boundaries for prescribing
  - dispensing pharmacists should reiterate information to patients

We received multiple suggestions requesting pharmacist discretion and annotation in limiting supply periods for Class B controlled drugs for certain patient groups.

Specific feedback included:

- Pharmacists should be able to adjust supply periods to provide smaller quantities when deemed in the best interest of the patient and community e.g., patient doesn’t have safe storage at home or is worried about stealing, or for long term conditions patients.

11: Other feedback

Other feedback received included

i) Prescription co-payments

- Co-payments should be applied to all Class B controlled drugs, noting currently opioids are exempt from co-payments and stimulants attract a co-payment

ii) Specialist applicant type for Special Authorities

We received feedback from multiple stakeholders including clinicians and consumer advocates regarding the SA applicant type for stimulants

Specific feedback included:

- Specialist approval/ SA applicant type for methylphenidate and dexamfetamine is a barrier to access
- Requesting nurse practitioners be able to initiate a special authority for methylphenidate hydrochloride
- Calls for changes to additional requirements under regulations for written recommendation from a psychiatrist or paediatrician and Pharmac's requirement for renewal of that recommendation to have a 2 year currency
- Difficulty of getting adult patients with ADHD assessed in the public system and the cost of seeing a psychiatrist privately