From: NZ - Policy <policy@racp.org.nz>
Sent: Tuesday, 20 December 2022 3:10 pm
To: Consult
Subject: Submission on Proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs
Attachments: FINAL_PHARMAC_ Class B Drug legislation.pdf

Kia ora,

Please find attached a submission from the Royal Australasian College of Physicians (RACP) on Pharmac's proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs.

Ngā mihi nui,

Di Cookson

Di Cookson *(she/her)*
Senior Policy and Advocacy Officer | Aotearoa New Zealand
Policy and Advocacy

NB: I work part-time Monday, Tuesday and Wednesday 8.30am - 5.00pm.

The Royal Australasian College of Physicians
Level 4, 99 The Terrace, Wellington 6011
Email: policy@racp.org.nz
Website: www.racp.edu.au

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Tino Rangatiratanga | Partnership | Active Protection | Options | Equity

RACP acknowledges Māori as tangata whenua and Te Tiriti o Waitangi partners in Aotearoa New Zealand. We acknowledge and pay respect to the Traditional Custodians and Elders past, present and emerging of the lands and waters on which RACP members and staff live, learn and work in Australia.

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The Royal Australasian College of Physicians' submission to Pharmac

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

Hakihea 2022

Introduction

The Royal Australasian College of Physicians (RACP) welcomes the opportunity to submit feedback on Pharmac's Proposal to amend Pharmaceutical Schedule Rules on the prescribing and dispensing of Class B controlled drugs.

The RACP works across 33 medical specialties to educate, innovate and advocate for excellence in health and medical care. Working with our senior members, the RACP trains the next generation of specialists, while playing a lead role in developing world best practice models of care. We also draw on the skills of our members, to develop policies that promote a healthier society. By working together, our members advance the interest of our profession, our patients and the broader community.

The RACP has drawn on consultation with our broader membership to inform this submission, including paediatricians, addiction medicine and palliative care specialists.

Background

Under the current Pharmac Schedule Rules on the prescribing and dispensing of Class B controlled drugs, people generally have Class B controlled drugs dispensed at ten-day intervals, with the exception of methylphenidate and dexamfetamine, which may be dispensed in a single monthly lot. Pharmac's proposal would enable electronic funded prescriptions for Class B controlled drugs to be written for up to 3 months instead of the current 1 month and allow the collection of controlled drugs from pharmacies in monthly lots (instead of 10 day lots) when an electronic prescription is used (or as a single monthly lot on a paper prescription), unless the prescriber directs dispensing in smaller quantities.

Note the RACP is currently developing a Drug Policy Statement to consider non-medical use of prescription medication and illicit drugs, with advice and expertise provided by the Australasian Chapter of Addiction Medicine and the Australasian Faculty of Public Health Medicine members. This work is still developing and will not be completed within the timeframe of the consultation phase.

Overall position on the proposal

There are diverse opinions among the members of the RACP who responded on Pharmac's proposal. Perspectives on the perceived risks and benefits of proposed changes to prescribing intervals differed according to speciality group and the population groups being served.

The RACP notes that there is significant concern among addiction medicine specialists that the proposed changes to prescribing intervals will carry unintended consequences and may increase the potential for disordered use. The proposal will not address the urgent priority need for consistent treatment support structures for those seeking pain relief prescriptions and professionals and others carrying the consequences of disordered use. The RACP has a position on the need to reduce availability of codeine and prescription opioids (note this in the Australian context)[1].

Palliative care specialists, however, note that the positive impacts of changing prescribing intervals and assert this would be beneficial for **both prescribers** as well as patients and their whānau. The

[1] Royal Australasian College of Physicians (RACP). Submission to the Therapeutic Goods Administration (TGA) – Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response, May 2018 [Internet]. Available from: Consultation submission: Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response (tga.gov.au) Downloaded on 13 December 2022.

College has a position on the duty of physicians and society to provide high quality end of life care to patients and their families and carers and this incudes symptom management[2].

The RACP therefore advocates that:

- caution is exercised and no relaxation of restrictions is made for Class B controlled drug availability for the majority of patients
  but
- exemptions be made for prescribers where these monitored medicines are routinely used for pain and symptom relief in palliative care settings.

Key points

Proposal may carry the unintended consequence of increased disordered use

Addiction medicine specialists have raised concerns about the unintended consequences of this proposal. Based on their observations in practice, these specialists maintain that the changes to prescribing intervals may increase the potential for disordered use of the medications listed in the proposal. This would happen in an addiction treatment sector which is already under-funded, under-recognised and not keeping pace with the extent of substance use disorders. Members note that the clients of addiction services describe serious dependence on diverted prescribed methylphenidate hydrochloride which is injected to a similar effect to methamphetamine. Members also wish to draw Pharmac's attention to the incidence of Fentanyl overdoses in the Wairarapa earlier in 2022 when 12 people were hospitalised. One RACP member noted that it is remarkable that Fentanyl is a class B drug available on prescription whereas the much safer buprenorphine is not available.

The RACP has strongly advocated for reduced availability of controlled drugs in Australia, including codeine and prescription opioids. The RACP supported changes to codeine scheduling in Australia to make codeine-based medications available only with a prescription. This came into effect on 1 February 2018 and resulted in a significant decrease in the amount of codeine supplied to Australians. Aotearoa New Zealand followed suit and all codeine-containing products were re-classified as prescription only medicines in November 2020. The Australian Government also recently made regulatory changes to the prescribing of prescription opioids to minimise the harms cause by opioid prescription medicines. These included smaller pack sizes for immediate-release opioids that provide short-term pain release and additional warning statements which came into effect from 2020. The College made a submission to inform these decisions.

Recent research in the Aotearoa New Zealand reinforces the significance of member concerns. The New Zealand Drug Foundation's 2022 State of the Nation Report found opioids are currently responsible for the deaths of around 46 people from accidental overdoses each year, a tragic situation that is potentially avoidable. The report shows the approach to drugs is leading to inequitable outcomes for Māori, including the Māori death rate from drug-related deaths which is three times the rate for non-Māori[3]. Research also shows a steady annual increase in opioid prescriptions and indicates a rise in deaths in Aotearoa NZ is largely associated with increased

[2] The Royal Australasian College of Physicians. Improving Care at the End of Life: Our Roles and Responsibilities. May 2016 [Internet]. Available from: https://www.racp.edu.au/docs/default-source/advocacy-library/pa-pos-end-of-life-position-statement.pdf. Accessed on 12 December 2022.
[3] New Zealand Drug Foundation. Te Tūāpapa Tarukino o Aotearoa. State of the Nation 2022. [Internet]. Wellington: NZ Drug Foundation, February 2022. Available from: State-of-the-Nation-2022-web.pdf (drugfoundation.org.nz) Downloaded on 12 December 2022.

prescribing[4]. The Drug Foundation reports that Aotearoa New Zealand is "grossly underprepared" should we follow in the footsteps of North America where opioid misuse has resulted in a public health crisis and tens of thousands of deaths[5].

Prioritise improved treatment support structures

Addiction medicine specialists contend that rather than improving access to medications, improvements to ensure consistent treatment support structures for both clients seeking prescriptions and those carrying the unintended consequences of disordered use should be prioritised . Key areas for improvement include robust clinical care, quality assurance, support and guidance. Members advocate for structured, consistent monitoring, deprescribing and adequate access to non-pharmacological management. Clients are typically disadvantaged and report being angry that prescription medicines are being obtained and sold without apparent monitoring by the prescriber, sometimes despite complaints to the prescriber.

Disordered use of controlled medications is carried inequitably into the community. Addiction support is often only available for those who enter the criminal justice system. For those clients dependent on diverted pharmaceuticals, there is harmful criminalisation and inadequate access to addiction treatment. Māori are vastly over-represented in these treatment services[6].

The RACP has previously called on the New Zealand Government to support health-centred drug policy that focuses on increasing the resources available to the addiction treatment and services sector[7]. The extent to which services are struggling to meet the unmet need in this sector can be seen in the findings of the Government Inquiry into Mental Health and Addiction, which called for investment in addiction services and emphasised the importance of providing interventions earlier, before an individual starts to experience serious problems[6].

RACP members call for actions to address the social determinants of drug use/misuse as well as actions to improve healthy communities including:

- equitable and improved access to primary care for all New Zealanders and
- an electronic prescribing system which is fully integrated across the entire health system, accessible by all prescribers and pharmacists, with automated flags and reminders for review processes.

In Australia, where real-time prescription monitoring (RTPM) systems are being rolled out, RACP has flagged that this needs to happen alongside wider service planning. Recommendations are made for plans to ensure:

- nurse prescribers are well informed on RTPM and how to support patients identified through the system, including the development of clinical guidelines

[4] Shipton E, Shipton A, Williman J, Shipton E. Deaths from opioid overdosing: implications of coroners' inquest reports 2008–2012 and annual rise in opioid prescription rates: a population-based cohort study. Pain Ther. [Internet]. 2017; 6: 203-215. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5693811/pdf/40122_2017_Article_80.pdf Downloaded on 12 December 2022.

[5] New Zealand Drug Foundation. Grossly underprepared – NZ'S naloxone mess, 30 August 2021 [Internet]. Available from: 'Grossly underprepared' - NZ's naloxone mess | NZ Drug Foundation - At the heart of the matter Donwloaded on 13 December 2022.

[6] Government Inquiry into Mental Health and Addiction. He Ara Oranga: Report of the Government Inquiry into Mental Health and Addiction. Wellington: Government Inquiry into Mental Health and Addiction; 2018. Available from https://mentalhealth.inquiry.govt.nz/inquiry-report/he-ara-oranga/..

[7] Royal Australasian College of Physicians (RACP). Submission to Health Select Committee on Misuse of Drugs Amendment Bill [Internet].. Available from: https://www.racp.edu.au/docs/default-source/advocacy-library/racp-submission-to-health-quality-and-safety-commission-misuse-of-drugs-amendment.pdf?sfvrsn=e5a1181a_6 Downloaded on 13 December 2022.

- nurse prescribers are well informed on RTPM and how to support patients identified through the system, including the development of clinical guidelines
- invest in research, evaluation and service models that combine pain and addiction medicine to build the evidence-base on how best to treat concurrent chronic pain and substance use disorders
- implement ongoing monitoring and evaluation of RTPM to ensure the system can be improved to best serve the health needs of patients and the broader community.

Exemptions recommended for palliative care

The medications specified in this proposal are essential for a range of symptom management, including pain relief in palliative care. The RACP suggests that Pharmac make exemptions to allow the proposed new regulatory settings for prescribing where these monitored medicines are routinely used for pain and symptom relief in palliative care.

Palliative care medicine specialists advocate that the changes proposed would be hugely beneficial for both patients and prescribers. Provisions to allow a two-week holiday for patients reduces the stress of getting GPs to email prescriptions to pharmacies in their destination of choice and the worry that this process might not work out. The proposal also reduces the number of visits to pharmacies and the significant time, travel and financial costs involved in reaching a pharmacy. From the point of view of the prescriber, this proposal reduces the need to write repeated controlled drug scripts.

The stance of RACP palliative care medicine specialists is reflected in the RACP position statement Improving Care at the End of Life: Our Roles and Responsibilities[2] which recognises that physicians and society have a duty to provide high quality end of life care to patients and their families and carers and this incudes symptom management. Palliative Care Australia's position statement Sustainable access to prescription opioids for use in palliative care outlines it is essential to ensure the sustainable access to prescription opioids for use in palliative care and emphasises that "regulations regarding the availability or accessibility of opioids that may inadvertently lead to limitations on palliative care must be carefully considered" and was endorsed by RACP. The statement recognises that "research demonstrates opioids as a safe, effective medication for patients with distressing symptoms related to life-limiting illness, when prescribed in conjunction with clinical practice guidelines".

The RACP thanks Pharmac for the opportunity to provide feedback on this consultation. To discuss this submission further, please contact the NZ Policy and Advocacy Unit at policy@racp.org.nz.

Nāku noa nā

Dr Stephen Inns FRACP
President, Aotearoa New Zealand
The Royal Australasian College of Physicians

From: David Hughes
Sent: Monday, 19 December 2022 7:53 am
To: Consult
Subject: FW: FYI re opioids

Ngā mihi,
David

Te Pātaka Whaioranga – Pharmac will be closed from Saturday 24 December 2022 to Tuesday 3 January 2023 inclusive.

From: Matthew Doogue <s 9(2)(a)>
Sent: Friday, 16 December 2022 5:36 pm
To: David Hughes <david.hughes@pharmac.govt.nz>
Subject: FYI re opioids

> You don't often get email from s 9(2)(a) Learn why this is important

And FYI

I'm on MARC but this came to a meeting I wasn't at. https://www.medsafe.govt.nz/committees/marc/reports/186-3.2.3-Opioid.pdf
Note the part of the review related to prescribing restrictions suggests small effect. I'm not aware of studies of loosening prescribing restrictions but there may be some. Changes in any single control measure usually have little effect but collectively can be substantive.
Whatever change we make it would be helpful to prospectively measure.

NB. My personal suggestion is an opt out of 10 days rather than opt in (e.g. by special authority for longer interval dispensing) and keep prescribing limited to 1 month.
Dose requirements change and it is not possible to validly predict requirements more than one month ahead.
If there are good arguments for further loosening it could be a step by step change. Regulations are blunt tools and Pharmac can be more nuanced than MedSafe.

Have a good weekend

Matt

From: Judy Dalrymple <[redacted]>
Sent: Monday, 19 December 2022 9:16 am
To: Consult
Cc: Medicines; Mary Young (Pharmacist)
Subject: Class B Controlled drugs rule amendments_Te Whatu Ora Waitaha submission
Attachments: Class B Controlled drugs rule amendments_Te Whatu Ora Waitaha submission.pdf

Kia ora,

Please find attached the response from Te Whatu Ora Waitaha to the Pharmac proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs.

Kind regards,

Judy Dalrymple (she/her) | **Medicine Utilisation Pharmacist**
Matt Doogue (he/him) | **Clinical Pharmacologist**

Waitaha Canterbury
waea pūkoro: +64 3364 1858 | **īmēra:** medicines@cdhb.health.nz
Christchurch Hospital | 2 Riccarton Avenue, Christchurch 8011 | Private Bag 4710, Christchurch 8140

Te Whatu Ora
Health New Zealand

MEDICINES UTILISATION SERVICE
Department of Clinical Pharmacology,
Christchurch Hospital
PO Box 4710, Christchurch
e: medicines@cdhb.health.nz
t: 03 364 1858

19 December 2022

PHARMAC
PO Box 10 254
Wellington 6143
e: consult@pharmac.govt.nz

RE: Pharmac proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs **Due 21 December 2022**

Summary of proposal
PHARMAC are seeking proposal to amend the Pharmaceutical Schedule General Rules to bring funding in line with legislative changes to the prescribing and dispensing of controlled drugs (the Medicines Amendment Regulations 2022 and the Misuse of Drugs Amendment Regulations 2022 changes are confirmed and will come into force 22 December 2022).
It is noted that although the requirement to prescribe and dispense Class B controlled drugs every ten days is removed that prescribers may request this as appropriate.

Te Whatu Ora Waitaha response:

It is noted this is implementation of a regulatory decision rather than initiated by PHARMAC.

Benefit: Reduced patient visits (to prescribers and pharmacies) and therefore reduced patient treatment burden and cost for patients receiving treatment with Class B controlled drugs.

Harm: Over prescribing of opioids and increased risk of opioid-related harm and diversion from increased opioids in the community is a major concern. In many situations this outweigh the benefit of convenience offered to patients by this proposal. Clinical advice from our analgesic stewardship group is that the increased risk of opioid-related harm outweighs the benefit of this proposal. They note:

- opioid dose requirements change rapidly and often
- opioid prescribing for non-cancer pain should be of short duration
- diversion of prescribed opioids is a substantial public health problem
- the quantity of opioids in a long-term prescription has high street value

Opioid prescriptions should be presented for dispensing within seven days of prescribing when the dose and quantity are clinically appropriate. Valid doses cannot be determined weeks or months before dispensing. This proposal may lead patients to pressure GPs for prescriptions 3-monthly for their convenience, when shorter time periods are warranted to ensure medication safety.

Cost: Possibly this change will modestly reduce health sector costs (reduced GP appointments, reduced community Pharmacy dispensing). However, there may be direct (increased wastage with dosage changes, reduced visibility of drug seeking behaviour and diversion) and indirect health sector impact due to the proposed amendments.

We submit:

- that dispensing every ten days should be opt out rather than opt in
- an alternate mechanism for prescribing a longer duration of opioids (such as Special Authority) be used
- that wider consultation be undertaken before this proposal is progressed

We submit that increased duration of prescribing should be restricted to specific situations where the risks may be justified, for example cancer pain. These patients still require clinical support and supervision of dosing, however, may benefit from having a longer duration of supply. Please consider a Special Authority for dispensing of longer durations in specified circumstances.

Response from: Analgesic Stewardship Committee, Pharmacy Services and Clinical Pharmacology Department.

Regards,

Judy Dalrymple | Medicine Utilisation Pharmacist
Matthew Doogue | Clinical Pharmacologist

From: David Hughes
Sent: Monday, 19 December 2022 10:39 am
To: Consult
Subject: FW: Opioid schedule changes

More feedback

Ngā mihi,
David

Te Pātaka Whaioranga – Pharmac will be closed from Saturday 24 December 2022 to Tuesday 3 January 2023 inclusive.

From: John Barnard <s 9(2)(a)>
Sent: Monday, 19 December 2022 10:15 am
To: Matt Doogue <s 9(2)(a)>; David Hughes <david.hughes@pharmac.govt.nz>
Cc: Shaheeda Othman <s 9(2)(a)>; Chris Cameron <s 9(2)(a)>; CMO Office <s 9(2)(a)>
Subject: RE: Opioid schedule changes

> You don't often get email from s 9(2)(a) Learn why this is important

Hi Matt
Thank you for writing to David. I would support your concerns.

For some reason the change to allow prescribing controlled drugs without a hardcopy prescription seemed to overshadow this concurrent change to allow the prescription to be for a 3 month period and to allow the whole prescribed quantity to be dispensed at one time. Yet from a safety perspective these latter two changes are the more significant. Maybe we looked as far as seeing that a signed hardcopy prescriptions would no longer be required for controlled drugs and missed the added detail about quantities. Much larger quantities of opioids or other controlled drugs will be able to be dispensed as a single transaction and I am not certain that due diligence has been done on this.

As you note there are some patient groups where this change would be sensible and welcome,, but I suspect this would be the minority of people receiving prescriptions for opioids.

This will put a greater responsibility on prescribers to think about and manage, dispensing intervals and quantities of opioids, to limit the risks of having larger quantities of opioids in people's homes. In my view changes to the length of controlled drug prescription and dispensing interval should be accompanied by an education campaign and with the addition of restrictions to the daily oral morphine equivalent dose that can be prescribed without specialist review and supervision (as per the Australian model).

I suspect that part of the reason that NZ has not gone down the same pathway of opioid excess as the USA, is simply that the amount of opioid sitting in bathroom cabinets in people's homes is less.

I don't think the desire for consistency and simplicity for prescribing and dispensing rules should completely outweigh concerns around safety.

The change to allow e-prescribing across the full range of our national formulary is a much more straightforward step to take. From a safety perspective I believe this will be an improvement, and I look forward to the day when we won't have any of those triplicate prescription pads in our wards and clinics.

No doubt there has been a lot of consultation that I am aware of, but the extent of this was not made very obvious in the proposal.

Dr John Barnard
Chair M&T Committee Te Whatu Ora Waikato District
and member HQSC NMSEAG

From: Matt Doogue <s 9(2)(a)>
Sent: Friday, 16 December 2022 5:maximum 25 PM
To: David Hughes <david.hughes@pharmac.govt.nz>
Cc: Shaheeda Othman <s 9(2)(a)>; Chris Cameron [CCDHB] <s 9(2)(a)>; John Barnard <s 9(2)(a)>; CMO Office <s 9(2)(a)>
Subject: Opioid schedule changes

Morena David

I'm contacting you in your capacity as the Pharmac contact for NMSAG.
I note the upcoming changes in regulations related to Class B opioids and the associated changes the pharmaceutical schedule. I would like to raise concerns about the proposed change to the pharmaceutical schedule for class B opioids.
I've cc'd Chris Cameron as MARC chair.

May I request PHARMAC consider a longer consultation to allow wider discussion. Changes in opioid supply has potential risks to patients and other members of the public. How the changes in prescribing and dispensing may affect opioid supply has not been worked through. There are issues for quality use of medicines and public health with changes in opioid prescribing and dispensing. The change in regulations is an opportunity for a more nuanced approach to both manage risk and ensure equity of access.
There are two key points, my bolding below, prescribing going from 1 month to 3 months and the removal of the 10 day dispensing rule.
There are also other stakeholders not identified in the consultation, for example public health and the police, who may wish to contribute.

There are some patients who may benefit from improved access, e.g. cancer pain, severe COPD. However there are significant public health risks of making strong opioids more available. Opioids are the most common cause of drug related death in New Zealand https://www.tandfonline.com/doi/full/10.1080/15563650.2019.1582777 New Zealand currently performs well compared to other jurisdictions https://link.springer.com/article/10.1007/s40122-020-00229-6
I haven't listed particular issues as a considered response would need wider input from the committee. There is a body of guidelines and primary literature that can inform discussions.
My apologies I wasn't aware of this until today. The regulation changes did not come to my attention and the Pharmac consultation reached my desk today via the Canterbury Medicines Utilisation processes. The Te Whatu Ora Canterbury analgesic stewardship group has considered the proposed changes and expressed concerns.

BPAC have just published an education piece, which helpfully includes a summary of the pharmaceutical collection data figure 1B. https://bpac.org.nz/2022/opioids.aspx

Further, If or when changes are implemented, may I request consideration of a monitoring plan? Or would this be via MedSafe?

Nga mihi

Matt

Matt Doogue | Clinical Pharmacologist.
Department of Medicine
University of Otago, Christchurch
Departments of Clinical Pharmacology and General Medicine
Waitaha | Canterbury & Te Tai o Poutini | West Coast
Te Whatu Ora – Health New Zealand
waea: s 9(2)(a) **īmēra:** s 9(2)(a)

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/

About this proposal

On 22 December 2022 the Medicines Amendment Regulations 2022(external link) and the Misuse of Drugs Amendment Regulations 2022(external link) will come into force. This amends the law to enable controlled drugs to be prescribed electronically and, for some controlled drugs, the amount of drug that can be on a single prescription will be increased when using the New Zealand Electronic Prescription Service(external link)(NZePS).
Before 22 December 2022, the Misuse of Drugs Act 1975 and Misuse of Drugs Regulations 1977(external link) mean that prescriptions for Class B controlled drugs can legally only be written for a supply of **up to one month**. The Schedule Rules allow supply for up to one month on a prescription, with dispensing in ten day lots (with the exception of methylphenidate and dexamfetamine, which may be dispensed in a single monthly lot).
This proposal is intended to align funding rules more completely with the updated legislation, by allowing funded prescriptions for Class B controlled drugs to be written for **up to three months**. In addition, we would be **removing the requirement for dispensing in ten day lots**, as this is inconsistent with the Regulations.

From: Stephanie Clare <s 9(2)(a)>
Sent: Monday, 19 December 2022 2:44 pm
To: Consult
Subject: Consultation: proposal to amend Class B Controlled Drugs
Attachments: ANZCA FPM PHARMAC Class B Legislation Response.pdf

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Kia ora koutou

Attached is the response from NZNC FPM. FPM is supportive of further discission on the subject.

Ngā mihi
Stephanie

Stephanie Clare
Executive Director New Zealand

Te Whare Tohu o Te Hau Whakaora

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

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Te Whare Tohu o
Te Hau Whakaora

December 19, 2022

Thank you for the opportunity to provide feedback on Pharmac's proposed amendment to Pharmaceutical Schedule Rules on prescribing and dispensing Class B controlled drugs.

The Faculty of Pain Medicine has considered the proposed amendment and wishes to strongly advise on the impact of these potential changes.

In particular, the Faculty of Pain Medicine notes that the following controlled drugs could be prescribed for three months instead of one month, and dispensed for 30 days instead of 10 days, when an electronic prescription is issued:

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

Globally, opioid availability grew by almost 110 per cent in the first decade of the 2000s. Alongside this, since the early 2000s, problematic opioid use has become a significant issue in OECD countries.

Opioid-related deaths have increased by 20 per cent since 2011. In the United States alone, 400,000 people died from an opiate overdose between 1999 and 2017, while opioids were involved in 68,630 United States overdose deaths in 2020 – making up 74.8 per cent of all drug overdose deaths in that country.

Every day in Australia, almost 150 hospitalisations and 14 emergency department admissions involve opioid harm, and three people die from drug-induced deaths involving opioid use. The Therapeutic Goods Administration has recommended opioids be used only for short-term management of severe pain.

State governments in Australia have previously taken action to ensure better oversight to reduce unintended harm from opioids.

The Victorian government has initiated opioid stewardship and Safe Script programs. The Safe Script program is real-time prescription monitoring which enables the doctors and the pharmacist to access accurate information about a patient's prescription history for high-risk medicines, to enable safer clinical decisions.

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FPM
ANZCA

Te Whare Tohu o
Te Hau Whakaora

Similarly, the Queensland government has also instigated an opioid stewardship program.

In New Zealand the rate of prescribed opiates is 112.5/1000 compared to 37.5/1000 between the ages of 65 to 79 years, 13.5/1000 between the ages of 25 and 64 years and 1.9/1000 from zero to 24 years.

The Faculty of Pain Medicine is concerned that increasing the electronic prescription duration for Class B controlled drugs to three months presents a significant risk of developing opioid problems in New Zealand and could lead to significant harm.

We look forward to continuing to engage on this important issue and would welcome the opportunity to make further submissions as needed.

Sincerely,

Dr Duncan Wood
New Zealand Chair
NZNC FPM

From: Louise Abolins <s 9(2)(a)>
Sent: Friday, 16 December 2022 11:38 am
To: Consult
Cc: Maureen Gillon
Subject: Proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs
Attachments: 2022.12.16 Pharmac pharmaceutical schedule rules.pdf

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Tēnā koe

Please find attached a submission from The Royal New Zealand College of General Practitioners on the Pharmac proposal to amend Pharmaceutical schedule rules on prescribing and dispensing of Class B controlled drugs.

Nāku noa, nā

Louise Abolins
Secretariat and Administrator – Membership Services

The Royal New Zealand College of General Practitioners
Te Whare Tohu Rata o Aotearoa

The Royal New Zealand College of General Practitioners
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The Royal New Zealand
College of General Practitioners
Te Whare Tohu Rata o Aotearoa

16 December 2022

Pharmac | Te Pātaka Whaioranga
40 Mercer Street
PO Box 10 254
WELLINGTON

via email: consultation@pharmac.govt.nz

Tēnā koe

Submission – Pharmac Proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs

Thank you for the opportunity to provide comment on the proposal to amend Pharmaceutical Schedule Rules on the prescribing of Class B controlled drugs, *Fentanyl, Methadone hydrochloride, Morphine hydrochloride, Morphine sulphate, Oxycodone hydrochloride and Pethidine hydrochloride (10-day dispensing) and*, *Methylphenidate hydrochloride and Dexamfetamine sulphate* (*dispensed monthly)*. We note except for *Methylphenidate hydrochloride and Dexamfetamine sulphate* which are used in the treatment primarily of ADHD, the other medications are opioids.

The Royal New Zealand College of General Practitioners (the College) is the largest medical college in New Zealand. Our membership of 5,748 general practitioners comprises almost 40 percent of New Zealand's specialist medical workforce. The Division of Rural Hospital Medicine also sits within the College's academic remit of vocational training of doctors working in rural hospitals. Our members cover both urban and rural settings, and work in a variety of business structures. The College kāupapa is to set and maintain education and quality standards for general practice, and to support our members to provide competent and equitable patient care.

Background

Changes to the Misuse of Drugs Regulations 1977 relate to the prescribing of controlled drug medicines through the New Zealand ePrescription Service (NZePS) announced in August 2022 by Hon Andrew Little, Minister of Health, which will come into effect on 22 December 2022 now that the amendment regulations have been finalised.

We note that this consultation does not seek feedback on the changes in the Medicines Amendment Regulations 2022 and the Misuse of Drugs Amendment Regulations 2022 . Pharmac's proposal introduces a regulatory change to the dispensing rules. Decisions on these regulatory changes have been confirmed, and the Pharmac proposal relates to supporting that change within the Pharmaceutical Schedule.

We note that these regulatory changes were considered and approved without adequate consultation with medical experts or peak medical bodies, which is highly unusual for such a sensitive area. We have no indication that there was an adequate risk assessment done of the potential for increasing opiates addiction, diversion or other opioid related harms in New Zealand, or adequate examination of ways to mitigate the risk of this happening.

Under the current Schedule Rules, Class B controlled drugs are prescribed monthly. Our submission focuses on Pharmac's proposal to allow opiates , *Fentanyl, Methadone hydrochloride, Morphine hydrochloride, Morphine sulphate, Oxycodone hydrochloride and Pethidine hydrochloride* to be prescribed for a three-month period with one month dispensing, instead of the current one month, with 10-day dispensing as specified by Pharmac. We note that non-opioids, *Methylphenidate hydrochloride and Dexamfetamine sulphate,* are presently prescribed monthly and dispensed monthly.

Our submission

While the College is supportive of a move to e-prescribing of Class B drugs, we are strongly opposed to the proposed move away from monthly prescribing of opiates and opioids with 10-day dispensing especially in the clinical situation of non-caner pain. We believe this proposal demonstrates a lack of understanding of what opiates and opioids are, how they work and don't work, and the risks to patients in particular, and society in general.

Context

The potential for opioid overuse especially in the treatment of non-cancer acute or chronic pain is significant and misuse of these medications is on the rise. Increasing the length of a prescription creates greater potential for opioid diversion, unintended harm and addiction. Although it is more common in primary care settings for a person using a medicine to take it for the purpose it was prescribed, misuse mostly occurs when medication is taken at a higher dose, increased frequency, or for a longer duration than indicated.[1] There is strong evidence that larger opioid prescription size substantially increases the risk of people becoming new and persistent opioid users after surgery and other medical procedures. [2 3 4 5 6 7]

- From the early 2000s to now, opiate and opioid use has become a significant problem in OECD countries. Their availability has grown by almost 110 percent, coinciding with opioid related deaths increasing by 20 percent since 2011. In the USA alone, 400,000 people died from an opioid overdose between 1999 and 2017, and opioids were involved in 68,630 overdose deaths in 2020 (74.8 percent of all drug overdose deaths). [8]

- In Australia, there are nearly 150 hospitalisations and 14 emergency department admissions per day involving opioid harm and three people dying from drug-induced deaths involving opioid use per day. The Australian TGA has recommended that opioids be used only for short-term management of severe pain.

- Around the world, governments are working to restrict access to opioids, in direct contrast to the proposed regulatory change. For example, the Victorian government in Australia has initiated an opioid stewardship programme and Safe Script Programme. The Safe Script Programme is a real-time prescription monitoring service that enables the doctors and the pharmacist to access accurate information regarding a patient's medication history.

- New Zealand health professionals are concerned about the increased use of opioids for back pain and other chronic musculoskeletal pain accompanied by increases in prescription opioid addiction and fatal overdoses. The rate of prescribed opiates is 37.5/1000 between the ages of 65 to 79 years, 13.5/1000 between the ages of 25 and 64 years, and 1.9/1000 up to 24 years of age.

Key points:

1. **Opioids for the patient – questionable effectiveness and rising risks**

   Opioids are increasingly being prescribed to manage chronic pain. Recent Cochrane evidence-based research challenges whether opioids are indeed effective at all against long-term pain.[9] There are also patient safety concerns due to the risks associated with long-term use of opioids such as fractures and falls, endocrine abnormalities, immunomodulation, opioid-induced hyperalgesia, and dependence. Based on the clinical evidence, Public Health England and the Faculty of Pain Medicine (UK) have advised that opioids: Opioids are very good analgesics for acute pain and pain at the end of life but there is little evidence that they are helpful for long-term pain.[10]

   - "The rate of opioid-related deaths in New Zealand has increased by 33 percent from 2001 to 2012. More than half of the opioid-related deaths between 2008 and 2012 were unintentional opioid overdoses. Opioid analgesic deaths were most likely due to methadone, morphine and codeine prescribed by healthcare professionals. 179 of these opioid-related deaths between 2008 and 2012 were unintentional opioid overdoses, and thus could have been avoided. This study shows that there was a steady annual increase in opioid prescriptions in New Zealand from 2001 to 2012. This

rise in opioid analgesic deaths was associated with the increases in the numbers of opioid prescriptions."[11] A recent study of the 325 deaths found 179 deaths were from unintentional overdose and may have been preventable. There was also a significant disparity in outcomes for Māori and a higher relative risk for an adverse event due to persistent opioid use and subsequent opioid harm.[12]

- We have learned from other countries, e.g., "In the USA, there is a rapidly emerging public health epidemic of prescription opioid-related mortality in patients with chronic non-cancer pain; more than 100,000 people have died from an unintentional overdose since policies changed in the late 1990s, and more than 16,000 people are dying from opioid-related causes annually. Opioid prescription drug overdose has surpassed motor vehicle collision as the leading cause of unintentional injury-related death in the USA."[13] [14] [15]

2. Diversion into the community

The introduction of three-monthly scripts for opiates will increase the already significant risk of diversion by users and potential harm to patients. International evidence suggests misuse of AOT(an increase in the required opioid dose to maintain adequate analgesia), ranging from 18 to 81 percent diversion occurs in 23 to 39 percent of all cases.[16] Opiates have a high potential for addiction and any change to prescribing rules must be viewed with extreme caution. If opioids and Class B drugs were classified as special authority and audited, it would alert inappropriate prescribing or potential suppling of black-market opioids.[17]

New Zealand has traditionally lower rates of diversion than other western countries and we consider that the proposal to extend timeframes for opiate prescribing would compromise best practice guidelines and or clinical governance gains made in this area. Interventions to reduce inappropriate opioid prescribing should be focused on improving patient care, managing patients with complex pain, and reducing comorbidities rather than seeking to enforce a threshold for prescribing. We suggest that opioids should not be started without a clear plan for stopping them.[18]

3. Even the status quo is not safe enough

There is growing concern among New Zealand health professionals that addiction and death from prescription opioids is already rising. Increased opioid use for indications with a weak evidence-base, such as back pain and other chronic musculoskeletal pain conditions, has been accompanied by increases in prescription opioid addiction and fatal overdoses.

Between 1992 and 2012, opioid-dispensing episodes have increased by 15-fold (500,000 to 7.5 million) in Australia.[19] There is a parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes.[20]

4. Assessing risk – What can be done

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.

The maximum of one month prescribing and dispensing already in place is not robust enough.

5. **The proposed process is against international best practice guidelines, undermines professionalism, clinical judgement, and equity**

Prescribers are required to uphold the MCNZ principle: being satisfied that the ongoing prescribing of medicines with the potential for addiction or misuse remains clinically indicated and based on evidence and good prescribing practice. The focus of care should be focused on periodically reviewing the effect (benefits and harms) of the treatment and any new information about the patient's condition and health if the treatment is being prescribed for an extended period. Continuation or modification of treatment should depend on an evaluation of progress towards the objectives outlined in a treatment plan.

The British National Formulary (BNF) advises that the prescriber has three main responsibilities:

- To avoid creating dependence by introducing drugs to patients without sufficient reason.
- To see that the patient does not gradually increase the dose of a drug, given for good medical reasons, to the point where dependence becomes more likely.
- To avoid being used as an unwitting source of supply for addicts and being vigilant to methods for obtaining medicines.[21]

For all the above, a maximum of four weeks is workable, often much less. Three months is inappropriate, and dangerous. The Faculty of Pain Medicine of the Royal College of Anaesthetists, United Kingdom advises regarding repeat prescribing, "if an opioid has a demonstrable positive benefit for an individual patient and there is a robust system for monitoring use, then consideration may be given for short-term authorisation of repeat prescriptions. Prescribe enough to meet the person's clinical needs up to a maximum of 30 days for all opioids, including those in Schedules 4 and 5. Do not prescribe with the instructions to be taken 'as directed'. State the dose frequency or the minimum dose interval suitable for 'when required' opioids, along with the maximum dose in 24 hours." [22]

6. **e-prescribing supports continuity of care**

We support continued investment and use of electronic medication management systems with built-in decision support tools to reduce the chance of errors when prescribing, dispensing and administering strong opioids. Electronic medical records are an essential clinical tool for supporting and monitoring continuity of care and improving safety. Practice management systems have enabled activities, such as repeat prescribing to be automated, so recorded information can be analysed to understand outcomes. The ability to create computer-generated prescriptions for Controlled Drugs within the electronic realm has made the process of prescribing and understanding opioid use much easier.

However, we do not consider e-prescribing a rational for lifting the system time limits on opioid use for pain management.

In answer to your consultation questions:

1. **Is the list of drugs considered adequate? Does it need to be expanded, or refined?**

We believe opiates need to be considered separately to *Methylphenidate hydrochloride and Dexamfetamine sulphate*. The completely different clinical uses are not clearly outlined in the consultation and is a potential flaw in the consultation as it stands. We do not believe the list should be expanded.

2. **In your view, is the shift from 10-day dispensing to one-month dispensing appropriate?**

There are four very distinct clinical situations in which the Class B Drugs are used, and this is not differentiated in the consultation document. We consider this an obvious flaw in the consultation.

Each has a different set of clinical imperatives:

1. *Methylphenidate and dexamfetamine* are used in longer term treatment of diagnosed ADHD

2. *Methadone* used primarily in addiction substitution programs.
3. *Fentanyl, Methadone hydrochloride, Morphine hydrochloride, Morphine sulphate, Oxycodone hydrochloride and Pethidine hydrochloride* for cancer pain.
4. *Fentanyl, Methadone hydrochloride, Morphine hydrochloride, Morphine sulphate, Oxycodone hydrochloride and Pethidine hydrochloride* for non-cancer pain.

We note a patient who is diagnosed with ADHD and is stable with continuous follow up, methadone in an addiction substitution program and opioids for the treatment of cancer pain are very different clinical scenarios to prescribing opiates for non-cancer pain. These differing clinical scenarios have not been outlined in the consultation and we believe this leads the wording of the consultation to be open to misinterpretation.

Where medications such as *Methylphenidate* and *Dexamfetamine* are used in a stable long term treatment regime with continuity of prescriber, there may be a benefit to three-monthly prescription with monthly dispensing. For *methadone* in an opiate substitution programme where the patient is in a regular pharmacy dispensing situation likewise there may be a benefit for three monthly scripts. However non-cancer pain is where the main risk lies for diversion and increased potential for addiction and this scenario should not move away from monthly scripts with 10-day dispensing.

As we have stated it is a shortcoming in the consultation document that these distinct clinical situations have not been considered or outlined for separate feedback

3. In your view, is the shift from one month prescribing to three-month prescribing when that prescription is issued through the NZePS appropriate?

Considering the points raised in the previous question, the College raises serious concerns about increasing the prescription duration to three months as it presents a significant risk of increasing opioid problems in New Zealand, leading to significant harm for patients. We believe this is an equity issue, which will likely disproportionally affect those with high needs, and in Māori and Pasifika populations.

We do not support the proposed changes because it has significant implications and will compromise efforts made to ensure patient safety.

We seek reassurance that there will not be a change to three-monthly prescribing of opiates.

Continuity of care is supported by e-prescribing to support review potential harms

We agree that continued investment and use of electronic medication management systems with built-in decision support tools will reduce the chance of errors when prescribing, dispensing and administering medication.

4. If we are to make this change, what would be appropriate safeguards? Are they in place?

As stated above, the College strongly opposes the increase in opiate scripts to three months and moving away from 10-day dispensing. We question whether there has been any risk assessment done in relation to the proposed changes for opiate prescribing with the potential for diversion, serious harm, and death.

Regardless of these we believe more focus should be placed on opioid prescribing and supporting the integration of the National Medication Safety Programme[1]. It has a key leadership role in improving overall medication safety, harm from medication errors and addressing unwarranted variation and inequities, developing best practice and clinical leadership.

[1] National Medication Safety Programme. Health Quality and Safety Commission. https://www.hqsc.govt.nz/our-work/system-safety/reducing-harm/medicines/

Developing indicators of appropriate opioid prescribing practices are known to help reduce harm where there are areas of known risk, e.g., when prescribing high daily doses of opioids, where there are significant effects impacting on people taking hypnotics, opioids and other pain medicines due to long-term use, and no plan to discontinue use.[23]

Standards, best practice prescribing, medication reconciliation

Given the significant contribution of inappropriate opioid prescribing to opioid-related harms, we support improving safety of opioid prescribing practices at system level to support prescribers with evidence, best practice and establish systems to include:[24]

- 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.

The College integrates prescribing practices within its quality framework[2] [25] [26], and aligns with legal and safety requirements for prescribing and medicine reconciliation,[27] [28] [29] [30] and other relevant standards or best practice.

5. How or when would we know if this was increasing the harmful use of Class B drugs in the community?

In relation to increasingly harmful use of Class B drugs in the community we point out that there does not seem to have been an adequate risk assessment of potential harm with this change and is not in-line with international evidence referred to in our submission. We do not expect that New Zealand would be different to other countries. We consider that unintended consequences of the proposed approach would cause additional pain and suffering and put patients at further risk of harm. Because the evidence shows there will be harm, the proposal goes against best practice and waiting to see what will happen has further legal, ethical and moral implications for the health system as whole and specifically for Specialist GPs in prescribing Class B drugs in the community. We consider this question is not answerable without the detailed work being completed.

Summary

The College is not in favour of the changes proposed by Pharmac to a change which would enable Class B control drugs, in particular the opiates, to be prescribed in three monthly lots. There has been inadequate risk assessment of the potential harm that could result. Some Specialist GPs are under extraordinary pressure by some patients to prescribe and feel threatened, loosening the rules may result in confusion and greater acquiesce to patient demand. Even a well-controlled opioid recipient may have changes in circumstances which mean that their control degrades - this is a much bigger problem if they have ready access to larger amounts of opioids. In these situations, the inconvenience of monthly prescriptions for those small number of opioid recipients that could benefit from a three-monthly script is very slight in comparison to the risks of providing more.

System level limitations in the amount of opiates that can be prescribed are an important safety step in limiting the potential harm that can or will be caused by this change.

[2] The RNZCGP integrates prescribing practices within its Foundation Standard and Cornerstone quality programme.[2] Practices must develop a repeat prescribing policy[2] and develop their practice systems against, evidence, best practice and legislative requirements, which are assessed in an external audit[2] to measure their effectiveness against The College Foundation Standard [2]. The standard aligns with legal and safety requirements for prescribing and medicine reconciliation practices of the: Ministry of Health, MCNZ, BPAC, and HQSC.

- We are supportive of e-prescribing and can see the benefit of potential of three-monthly scripts and monthly dispensing for *Methylphenidate and Dexamfetamine* where the patient has been definitively diagnosed and there is a stable relationship with a long-term specialist general practitioner.
- *Fentanyl, Methadone hydrochloride, Morphine hydrochloride, Morphine sulphate, Oxycodone hydrochloride and Pethidine hydrochloride* should continue to be prescribed monthly and dispensed at ten-day intervals.

We do not consider that the decision has been based on best practice, nor has the expected level of consultation on a matter of considerable risk to patients, been given due consideration. We would request before any change to the prescribing amounts for opiates be made a thorough risk assessment be taken of the potential direct harm to patients that could occur from these highly addictive medications.

Our submission draws attention to potential unintended consequences of extending the one month dispensing system being replaced by a three-monthly prescription period for non-cancer pain opiates. We note New Zealand has, up until this point, been relatively spared from significant opiate diversion issues, although it is an issue which needs active monitoring. We would note opioids are not recommended for treatment of chronic non-cancer pain which is a group to whom maximum numbers of opioids are prescribed over the world.

Our concerns are that increasing the prescription duration to three months presents a significantly increased risk of patients developing opioid addiction problems in New Zealand, which could lead to significant harm. This will likely disproportionally affect those with high needs, Māori and Pasifika populations.

We are in favour of rationalising prescribing through use of electronic prescribing; however, this should not be used as a rationale for increasing the script duration of opioids for the treatment of non-cancer pain.

We are also concerned that there was no consultation with medical experts or peak medical bodies when the proposal for the regulatory changes were considered, which was highly unusual for such a sensitive area. We have had no indication that there was an adequate risk assessment done of the potential for increasing opioid addiction, diversion or other opioid related harms in New Zealand, or adequate examination of ways to mitigate the risk of this happening.

We ask that urgent consideration is given to stopping the increase in opioid script prescriptions for non-cancer pain treatment from one month to three months.

We urgently request a meeting with you to discuss the proposed changes further.

For further clarification please contact Maureen Gillon, Manager Policy, Advocacy, Insights - s 9(2)(a)

Nāku noa, nā

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