From: Clare Randall <[redacted]>
Sent: Thursday, 15 December 2022 12:46 pm
To: Consult
Subject: Pharmac consultation: proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs

Thank you for the opportunity to provide feedback on this proposal. The feedback I am providing is from the perspective of a palliative care service, a pain/rehabilitation service and as a pharmacist prescriber with a scope of palliative care and chronic pain treatment.

I understand that the legislation has been passed and that this consultation relates to supporting these changes within the Pharmaceutical Schedule.

Notwithstanding this, I feel compelled to express my concerns that this significant change to legislation has been effected with little or no consultation with relevant people. While we have heard that this was consulted on widely, I am yet to meet anyone who was consulted.

The concerns I wish to raise are as follows:

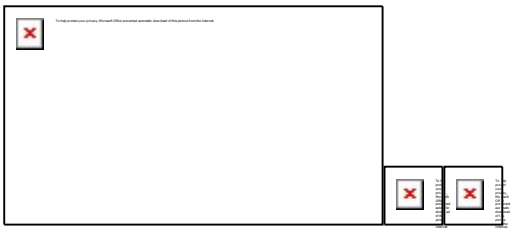
1. There is a global opioid crisis. How is the dispensing of Class B controlled drugs in monthly lots rather than 10-day lots going to help this crisis? Every week I see evidence of wastage & stockpiling of controlled drugs such as oxycodone, morphine, methadone – primarily prescribed in general practice for patients who request repeats – the "repeats" are issued for "prn" medications as well as regular medications when sometimes patients do not need more of them. This results in vast quantities going to waste and being stored in the kitchens and bathrooms in our community.
2. There is also the issue of potential diversion with essentially 3 times the quantity of opioids being dispensed into the community. Increasing the amount of controlled drugs in the community seems counter-intuitive to this problem. The risk of over-dosing must surely also increase.
3. Patients who are under palliative care or chronic pain programmes arguably need and benefit from regular review and support from their doctor or pharmacist prescriber – to be set adrift with a three month prescription seems counter-intuitive to good clinical care.
4. Wastage of controlled drugs will increase if patients are dispensed monthly lots of controlled drugs and their condition then changes – not uncommon in palliative care and in pain conditions. Wastage comes at a cost, both financial and social.
5. If patient management systems are set to default to monthly dispensing, the horse will have bolted and the likelihood of a busy general practitioner manually amending the Rx to 10-day lots will be minimal.
6. Stock shortages have been an issue of late due to the pandemic – the dispensing of controlled drugs in monthly lots potentially compounds the issue as stocks will run out faster and people may not be able to access essential pain medications. I appreciate that there are mechanisms that can be put in place to restrict supply – but this could be avoided or at least minimised by staying with 10-day dispensing in the first place.
7. Pharmacies will need to stock quantities sufficient to supply 30-day lots rather than 10-day lots. This creates storage and safety issues for pharmacists and staff.
8. Sometimes stock is short-dated – the new morphine ampoules apparently have a 12-month expiry. If pharmacies are having to stock greater quantities, the losses are greater when stock expires.
9. It seems to me that the current system is not broken – it certainly has more positive points than negative – the change to dispensing of three times the current quantity is a retrograde step that has many unintended consequences that impact on patient safety.
10. I have no issue with the likes of methylphenidate being issued as a 3-month prescription and supplied a month at a time as it currently is. This is prescribed for a chronic and ongoing condition where monthly medical review is less likely to be required.

I appreciate the difficulty faced by PHARMAC in effecting the changes to the legislation whilst lining this up with the Pharmaceutical Schedule. My concern is – who is watching over patient safety?

Please don't hesitate to contact me if you require further information.

Regards
Clare

Clare Randall
NZRegPharm, MClinPharm, FNZCP, MPallCare, PCNZ Reg Pharmacist Prescriber
Chief Executive
s 9(2)(a) | s 9(2)(a) or s 9(2)(a) ext s 9(2)(a)



1 Heretaunga Street, Palmerston North 4414

From: Kumari, Nikki <s 9(2)(a)>
Sent: Thursday, 15 December 2022 8:47 am
To: Consult
Cc: Renwick, Jane
Subject: Proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs
Attachments: 2022 12 15 LTR PHARMAC Extended Class B Controlled Drug Supply .pdf

Tēnā koe,

Please see the attached letter for Jo Chiplin Mental Health and Addiction Directorate, from Associate Professor Susanna Every-Palmer chair of New Zealand National Committee at the Royal Australian and New Zealand College of Psychiatrists (RANZCP).

Please contact Jane Renwick, RANZCP's New Zealand National Manager, at s 9(2)(a) with any pātai.

Ngā mihi,

Nikki Kumari
Administrator Officer
New Zealand National Office
Tu Te Akaaka Roa
The Royal Australian and New Zealand College of Psychiatrists
PO Box 10669 Wellington / *Te Whanganui-a-Tara* 6143
Tel/*Waea*: s 9(2)(a)
Email/*Imera*: s 9(2)(a)

The Royal Australian & New Zealand College of Psychiatrists

Our Vision: Improve the mental health of communities through high quality psychiatric care, education, leadership and advocacy.

The Royal Australian & New Zealand College of Psychiatrists
Tu Te Akaaka Roa
New Zealand National Office

Your Health in Mind
Hauora hinengaro Manatuhia

15 December 2022

Pharmac - Te Pātaka Whaioranga
The Terrace
Wellington 6143

By email to: consult@Pharmac.govt.nz

Tēnā koe

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

The Royal Australian and New Zealand College of Psychiatrists (RANZCP) welcomes the opportunity to provide comment on Pharmac's proposal to amend the Pharmaceutical Schedule General Rules (the Schedule Rules) on prescribing and dispensing of Class B controlled drugs to allow for funding provisions to align with legislative changes. Tu Te Akaaka Roa, the New Zealand National Committee, and the Aotearoa New Zealand Faculty of Addiction Psychiatry (NZ-FADDP) support Pharmac's proposal to align funding provisions with legislation, however, wish to express their concerns related to extended supplies of Class B controlled drugs.

The RANZCP is a membership organisation that prepares doctors to be medical specialists in the field of psychiatry, supports and enhances clinical practice, advocates for people affected by mental illness and advises the government and other external organisations on mental health care.

The RANZCP note that the regulatory changes to allow for extended supplies of Class B controlled drugs have been finalised, and that this proposal pertains to the funding element of these provisions in practice. Acknowledging this, the RANZCP wish to provide comment to Pharmac regarding these substantial changes to guide future funding decisions.

Aligning funding with legislative changes will improve equity of access for these patients through several potential mechanisms. Firstly, extended supplies of these medications will support access to care, and reduce barriers faced by those living rurally, with mobility issues, or in circumstances where frequent prescription renewals and collections are difficult to manage. Secondly, patients who require these medications may benefit from reduced expenses, including medical and transport costs (as repeat prescriptions may not be needed on a monthly basis, and fewer visits to the medical centre and/or pharmacy may be needed).

Although the funding of these provisions is supported, the change of practice raises serious concerns that the RANZCP wish to communicate to Pharmac. Within Aotearoa New Zealand, a significant proportion of illicit drug use originates from diverted prescription medication, highlighting the importance of tight control and oversight in this area. The upcoming legislative changes have the potential to increase the quantity of Class B controlled drugs supplied to the community by 300%. Supply frequencies are expected to leap significantly, from 30 days to 90 days (for dexamphetamine and methylphenidate) or from 10 days to 30 days (for the remaining Class B pharmaceuticals), unless the prescriber specifies a restricted dispensing frequency.

The implications of such changes are significant. With an increased supply to the community, the potential risks of diversion and harm to those with, or at risk of, addiction issues increase also.

Limited dispensing frequencies and prescription durations promote regular interactions between patients and their healthcare team (pharmacist, prescriber, and/or medical centre) and provide opportunities for informal checkpoints as part of continued and collaborative health care. Pharmac's proposal to remove the ten-day dispensing frequency threatens these regular interactions and may weaken patient-provider relationships leading to poorer outcomes and greater risk of uncontrolled and unsupported use of Class B controlled drugs.

Worthy of greater discussion is the issue that the range of medications, and their respective indications for treatment, within the Class B classification is vast and should not be considered as equivalent in terms of potentials of addiction, overdose, and other deleterious outcomes. The RANZCP suggests that the subclassifications within the Class B schedule be reviewed to reflect such variations.

We also observe that the window of time between the enactment of legislative changes on 22 December 2022 and PHARMAC's proposed changes to the General Rules (Section A) of the Pharmaceutical Schedule from 1 February 2023 presents challenges. During this gap, legislation and funding will not align, presenting a risk of inconsistent practice. We suggest, and assume planning is underway to ensure, that Pharmac provides clear and comprehensive communication regarding the approach to the prescribing and dispensing of these medicines during the period of 22 December 2022 to 1 February 2023. Stakeholders requiring this information includes prescribers, pharmacists, patients, carers, and allied support workers.

Overall, the RANCZP endorse the decision to fund these provisions, to support accessibility of appropriate medication and reduce financial barriers to care. The RANZCP does not support the removal of ten-day dispensing frequencies, unless circumstances require such as rural location or mobility issues, as this provision facilitates the safe and appropriate use of controlled medication and may reduce the risk of diversion and community harm.

We appreciate the opportunity to contribute to this consultation. If you have any queries regarding our response, please contact the RANZCP's National Manager, New Zealand, Jane Renwick. She can be contacted at s 9(2)(a) or via phone at s 9(2)(a).

Nāku iti noa, nā

Associate Professor Susanna Every-Palmer FRANZCP
Chair, Tu Te Akaaka Roa – New Zealand National Committee

From: David Hughes
Sent: Wednesday, 14 December 2022 8:15 am
To: Consult
Subject: FW: Sublocade LAIB & Controlled Drug prescribing

Another response on the Class B

Ngā mihi,
David

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

From: Alistair Dunn (NDHB) <s 9(2)(a)>
Sent: Tuesday, 13 December 2022 3:48 pm
To: David Hughes <david.hughes@pharmac.govt.nz>
Subject: RE: Sublocade LAIB & Controlled Drug prescribing

Kia Ora David ,
Yes please do forward my comments regarding controlled drug prescribing , thankyou . Suffice to say that I and my colleagues in the sector are rather alarmed at the prospect of GPs being able to prescribe opiates for 3 months at a time , and fear a Pandora's box will be opened . I acknowledge we may have a somewhat jaundiced view of GP opiate prescribing because we see the consequences of errant controlled drug prescribing by a minority of GPs regularly in our work . It would be interesting to know if the MCNZ has a similar view , based on their knowledge of cases where GP controlled drug prescribing falls below expected standards .
I have also worked as a GP for the last 30 years , and I am acutely aware of the strain GPs are under , so I am very aware of the extra workload that monthly (as opposed to 3 mthly) prescribing represents . However , this workload has been mitigated significantly with the advent or e-prescribing of opiate medications . I have also canvassed colleagues in General Practice and they actually share my concerns .
I appreciate that patients may be financially adversely affected by the monthly prescribing . Nonetheless , I think the safety benefits of monthly prescribing in the GP setting outweigh these considerations .

With regards to LAIB , there are obviously many other factors to consider in addition to those outlined my previous email . So , please forgive me if I take the liberty of outlining them here very briefly .

1. No visits to chemist (transport costs , time spent , stigma)
2. Better for client finding employment , well being , normalisation , recovery journey
3. Savings in chemist dispensing fee costs & pharmacist's time
4. NO diversion of OST possible (Methadone is NZ's most popularly injected opioid)
5. Better patient stability with better steady state serum levels
6. Simple regime of only 2 dose options (no time spent debating dose changes , reduced dose errors and dispensing errors)
7. No time spent debating takeaways with clients improves client satisfaction , focus can shift to holistic care , well being , recovery plan , engagement , psychosocial interventions
8. Better option in prisons (no supervision of doses , no stand over tactics by inmates)
9. Unexpected finding of being much easier to come off (we know Buprenorphine is easier to get off than methadone but LAIB seems easier again than sublingual Bup)
10. Provides another option / treatment choice for clients

In terms of pharmacotherapy , the Addiction sector has always had a dearth of options . For many years we basically had only two drugs to use, Disulfiram for alcohol dependence and Methadone for opiate dependence . During my

25 + year career in Addictions I have witnessed the introduction of only a handful of new medications , Naltrexone , Buprenorphine , and Varenicline. The introduction of LAIB would thus be a very significant addition to our armamentarium .

Finally , I am aware that there are two brands of LAIB available in Australia , Sublocade and Buvidal . From what I have learned from the Australian experience with these medications , there appear to be pros and cons for each medication . Ideally it would be preferable to have both available , so that the choice of medication can be determined on a case by case basis on clinical grounds , in conjunction where possible with client preference. I have previously sat on the PTAC Neurological sub-committee for several years , and have some understanding of how PHARMAC works . I wonder if one option to consider could be to reference price LAIBs to one product , thus giving the opportunity for another to still enter the market by meeting that price or adding a part charge ?

Thankyou again for this opportunity

Regards

Alistair

Regulations on Prescribing Class B Drugs

I certainly welcome the era of electronic prescribing of opiate medication , and look forward to our service progressing from its current practice , which is to print hundreds of methadone scripts every month on a dot matrix printer for our doctors to sign ! On a more serious note , this will also result in less dosing errors , better tracking and monitoring of scripts and reduce forged scripts etc .

From an administrative viewpoint the 90 day prescribing period for OST methadone is also welcomed . Given the tight regulatory framework that surrounds OST prescribing , this 90 day period does not present any increase risk in my view .

However , I do NOT think this 90 day period should be extended to opiates prescribed in the community , because I think there is a substantially greater risk for misuse and diversion of prescribed opiates in the community setting . The only rational for prescribing opiates long term in the community is for chronic non malignant pain (CNMP) . There is now good guidance for doctors which advise that opiates are not an evidence based treatment for treating CNMP , and the risks outweigh the benefits . I think any long term opiate prescribing should be reviewed regularly , and hence the monthly prescribing ensures the prescriber will undertake some sort of review every time a script is done . The length of prescription is important ; an excellent study in Boston which looked at opiates prescribed on discharge from hospital showed that the greatest correlation that predicted subsequent opiate dependence was not the type of operation , or the dose of opiate , but the number of days prescribed .

Regarding the existing ten day supply dispensed , I also have concerns regarding extending that to monthly for strong opiates in the community setting , because of risks of misuse , diversion or theft . I appreciate that those in rural areas may be impacted by this ,so perhaps some mechanism for exceptions could be devised , but as a general rule I think ten days is good . Personally I teach GPs and Registrars to in fact adopt 7 day dispensing , as it is much easier to detect when patients are picking scripts up early (an indicator of tolerance and diversion) . Another consideration is that when one month's supply is mislaid or stolen and replacements are requested , this will involve large , very lethal amounts of opiates of opiates going astray .

However I think the medications for ADHD are different and should be changed to 3 mth prescribing and allowed to be dispensed monthly dispensing. This is because (unlike with opiates) all stimulants are commenced and approved and renewed by a specialist psychiatrist , and evidence exists for its long term use . That is not to say risks do exist and these medications are still sought and abused in the community , and clear guidance needs to be given that lesser amounts should be dispensed at the prescriber's discretion where risks are identified .

Hope this is of help , thankyou gain for the opportunity to respond ,

Regards
Alistair

Dr Alistair Dunn

Lead Clinician OST
Community Mental Health & Addictions Service
Te Tai Tokerau / Northern Region

email : s 9(2)(a)
5 Three Mile Bush Road, Kamo, Whangarei
Reach us in our local channels: northlanddhb.org.nz | Facebook | LinkedIn

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FAChAM ADDICTION MEDICINE RACP

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From: David Hughes
Sent: Monday, 12 December 2022 2:57 pm
To: Consult
Subject: FW: Opioid Prescribing Regulatory Change
Attachments: Class B Drug Legislation 12-12-22.pdf

Forwarded

Ngā mihi,
David

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

From: Dr Bryan Betty <s 9(2)(a)>
Sent: Monday, 12 December 2022 2:44 pm
To: andrew.little@parliament.govt.nz
Cc: s 9(2)(a) Sarah Fitt <sarah.fitt@pharmac.govt.nz>; David Hughes <david.hughes@pharmac.govt.nz>; s 9(2)(a) Steve Maharey <steve.maharey@pharmac.govt.nz>; Lizzy Cohen <lizzy.cohen@pharmac.govt.nz>
Subject: Opioid Prescribing Regulatory Change

Tēnā koe Minister,

Please find attached a letter regarding Class B Drug Legislation changes.

Nāku noa, nā

Dr Bryan Betty
ONZM, FRNZCGP (Dist.), FACRRM, MBChB
Medical Director | Mātanga Hauora

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

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

FPM
Faculty of Pain Medicine
ANZCA

New Zealand pain society

12 December 2022

Hon Andrew Little
Minister of Health
Parliament
Private Bag 18888
Parliament Buildings
WELLINGTON 6160

By email: andrew.little@parliament.govt.nz

Tēnā koe Minister

We are writing on behalf of The Royal New Zealand College of General Practitioners, Faculty of Pain Medicine and the New Zealand Pain Society to raise concerns over the proposal that would allow class B medications to be prescribed for a three-month period instead of the current one month, with 10-day dispensing, when an electronic prescription is issued. This is about to be put through as a regulatory change and PHARMAC is now consulting to change the dispensing rules as a result of these regulatory changes.

We note that following controlled drugs have been included in the list for three-month prescriptions; Dexamfetamine sulphate, Fentanyl, Methadone hydrochloride, Methylphenidate hydrochloride, Morphine hydrochloride, Morphine sulphate, Oxycodone hydrochloride and Pethidine hydrochloride.

> Of the medications listed above, all are opioids except for Methylphenidate hydrochloride and Dexamfeatamine sulphate, which are used in treating attention deficit disorder.

Our concerns centre on the potential opioid overuse especially in the treatment of non-cancer acute or chronic pain. We believe increasing of prescription length increases the potential for opioid diversion, unintended harm and an increase in addiction issues. In fact, there is strong evidence that larger opioid prescription size substantially increases the risk of people becoming new persistent opioid users after surgery and other medical procedures.

From the early 2000s to now, opioid use has become a significant problem in OECD countries. The availability of opioid has grown by almost 110 percent. Opioid related deaths have increased 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).

In Australia, there are nearly 150 hospitalisations and 14 emergency department admissions 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 -time prescription monitoring service that enables the doctors and the pharmacist to access accurate information regarding a patient's medication history.

In New Zealand 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.

We have, 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 the 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 be given to stopping the increase in opioid script prescriptions for non-cancer pain treatment from one months to three months.

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

You can contact us via email on [redacted] s 9(2)(a)

Nāku noa, nā

Dr Samantha Murton
MNZM, MBChB, FRNZGP
(Dist.), PGDipGP, FAcadMEd
President | Te Tumu Whakarae
The Royal New Zealand College of General Practitioners

Dr Bryan Betty
ONZM, FRNZCGP (Dist.), FACRRM, MBChB
Medical Director | Mātanga Hauora
The Royal New Zealand College of General Practitioners

Dr Kieran Davis
Dean
Faculty of Pain Medicine
Australian and New Zealand College of Anaesthetists

Associate Professor David Rice
PhD BHSc NZRO
President
New Zealand Pain Society

cc: Dr Diana Sarfati, Director-General of Health, Manatū Hauora, Di.Sarfati@health.govt.nz
Sarah Fitt, Chief Executive, PHARMAC, sarah.fitt@pharmac.govt.nz
Hon Steve Maharey, Chair, PHARMAC Board, steve.maharey@pharmac.govt.nz
Dr David Hughes, Chief Medical Officer, PHARMAC, david.hughes@pharmac.govt.nz
Dr Joe Bourne, Chief Medical Officer, Manatū Hauora, Joe.Bourne@health.govt.nz

From: David Rice <s 9(2)(a)>
Sent: Friday, 9 December 2022 11:25 am
To: Consult
Cc: andrew.little@parliament.govt.nz
Subject: New Zealand Pain Society input to Pharmac consultation: proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs
Attachments: Letter to Pharmac Class B opioid dispensing changes.pdf

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Kia ora,

Please find a submission attached on behalf of the New Zealand Pain Society in relation to the above proposal (cc'd in The Minister of Health, Andrew Little).

As an organisation of more 400 clinicians involved in the management of acute and chronic pain in Aotearoa, we are very concerned about the proposed changes in dispensing and funding of Class B medications and the underlying regulatory change that is due to come into effect on December 22nd, for which there was inadequate consultation and what appears to be a lack of consideration for the considerable risks this poses to the New Zealand population.

The attached letter outlines our concerns in more detail.

Minister Little, I would welcome the opportunity to discuss this at any time. My mobile is s 9(2)(a).

Ngā mihi
David

Assoc. Prof. David Rice PhD BHSc NZRP
Associate Head of Research
School of Clinical Sciences, AUT
Waitematā Pain Service, Dept of Anaesthesiology and Perioperative Medicine, Te Whatu Ora
President of the New Zealand Pain Society

P s 9(2)(a) ext s 9(2)(a) T @David_dRice_ W https://academics.aut.ac.nz/david.rice

Recent Publications:

Kluger, M., **Rice, D.,** Borotkanics R., Lewis, G., Somogyi, A., Barratt D., Walker, M., McNair P. (2022) Factors associated with persistent opioid use 6 to 12 months after primary total knee arthroplasty. ***Anaesthesia.*** 77(8), 882-891. https://doi.org/10.1111/anae.15783
Nijs J., George S., Clauw D., Fernández-de-las-Peñas C., Kosek E., Ickmans K., Fernández Carnero, J., Polli A., Kapreli E., Huysmans E., Cuesta-Vargas A., Mani R., Lundberg M., Leysen L., **Rice, D**., Sterling M., Curatolo M. (2021). Central sensitisation in chronic pain conditions: Latest discoveries and their potential for precision medicine. ***The Lancet Rheumatology*** 3(8), e548. doi.org/10.1016/S2665-9913(21)00032-1
Lewis, G, Wartolowska, K, Parker R, Sharma S, **Rice D,** Kluger, M, McNair P. (2020). A higher grey matter density in the amygdala and midbrain is associated with persistent pain following total knee arthroplasty. ***Pain Medicine*** *21*(12), 3393-3400. doi: 10.1093/pm/pnaa227
Rice, D., Nijs, J., Kosek, E., Wideman, T., Hasenbring, M. I., Koltyn, K., . . . Polli, A. (2019). Exercise-induced hypoalgesia in pain-free and chronic pain populations: State of the art and future directions. ***Journal of Pain,*** 20(11), 1249-1266. doi:10.1016/j.jpain.2019.03.005

New Zealand pain society

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New Zealand

Email: nzpssecretary@gmail.com

Website: www.nzps.org.nz

8th December, 2022

PHARMAC consultation: proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs

To whom it may concern,

I am writing this letter on behalf of the New Zealand Pain Society, an organisation that represents more than 400 clinicians actively involved in the management of acute and chronic pain in Aotearoa. This includes 97 specialist or primary care physicians, 80 nurses and a range of allied health professionals including physiotherapists and pharmacists involved in primary care.

As a collective, we have serious concerns over the proposal that would allow class B medications to be prescribed for a three-month period instead of the current one month when an electronic prescription is issued, and PHARMAC's proposed change in the 10-day dispensing rules and funding as a result of this upcoming regulatory change.

In conjunction with the Royal New Zealand College of General Practitioners, Faculty of Pain Medicine and other organisations, we have voiced our concern directly to the Minister of Health about the impending regulatory change, for which there was inadequate consultation and what appears to be a lack of consideration for the considerable risks this poses to the New Zealand population.

We urge PHARMAC to reflect on these risks more carefully when considering the proposed change in dispensing rules and funding for Class B medications.

We note that the following controlled drugs have been included in the list for prolonged subsidisation and increase from 10 day to one-month dispensing; Dexamfetamine sulphate, Fentanyl, Methadone hydrochloride, Methylphenidate hydrochloride, Morphine hydrochloride, Morphine sulphate, Oxycodone hydrochloride and Pethidine hydrochloride.

Of the medications listed above, all are opioids except for Methylphenidate hydrochloride and Dexamfeatamine sulphate, which are stimulants used in treating attention deficit disorder.

Our concerns with the proposed changes centre on increased opioid related harms, especially in the treatment of non-cancer acute or chronic pain. Around the world, governments are working to restrict access to opioids, in direct contrast to the proposed changes. From the early 2000s to now, opioid use has become a significant problem in many OECD countries[1]. The availability of opioids has grown by almost 110 percent. Opioid related deaths have increased by 20% percent since 2011[1]. In the USA alone, the volume of opioid related deaths continues to rise and has recently reached a peak of > 100,000 people per year [2]. This is ~75% of all drug-overdose related deaths. Every day in Australia, there are nearly 150 hospitalisations, 14 emergency department admissions and three people who die from opioid-induced overdoses[3]. In New Zealand, opioid-related deaths were 1.6 per 100,000 in 2011, a 33% increase from 2001-02 [4,5]. Opioid overdose from prescription and recreational use already kills ~46 people each year and is the second leading cause of drug-related deaths in Aotearoa.[6]

Importantly, the risk of opioid related harms, including overdose and death, is substantially increased in people who are persistent opioid users[7] and there is strong evidence that in people undergoing surgery and other medical procedures, the risk of becoming a new persistent opioid user is notably increased with the size of the initial opioid prescription and the number of pills dispensed[8-11]. Increased dispensing of opioids also increases the opportunity for opioid diversion, and additional social harms[12].

Of further concern, there has been a recent trend towards opioid-stimulant co-use, which has accelerated negative social and health-related outcomes associated with the opioid epidemic[13]. We note that the other two Class B medications affected by the proposed change are both stimulants. As such, we are very concerned that the proposed changes will significantly increase opioid related harm and, potentially, opioid-stimulant co-use related harm in New Zealand.

Importantly, Māori have the highest rates of strong (prescription) opioid use, for both adults (17.7/1000 for Māori vs 14.4/1000 overall) and older adults (48.5/1000 for Māori versus 39.8/1000 overall).[14] Māori also showed the highest prevalence rate for recreational opioid and stimulant use in the New Zealand Alcohol and Drug Use Survey 2007/8 [15], suggesting a higher burden of dependency. As such, the proposed changes are likely to disproportionally affect tangata whenua, thus perpetuating current inequities in health outcomes and health related quality of life in Aotearoa.

Finally, we wish to emphasise that opioids are not recommended for the treatment of chronic non-cancer pain[16] which, despite international consensus, is the group to whom maximum numbers of opioids are prescribed. Except in rare cases, opioids should only be used for the management of severe acute pain - ***at the lowest effective dose for the shortest possible time[16]*** - or in a palliative setting, for people with cancer-related pain.

As such, we strongly urge PHARMAC to reconsider changing both the prolonged subsidisation and current 10-day dispensing rules for these Class B medications, particularly for people with non-cancer related pain.

Yours sincerely,

Associate Professor David Rice

President, New Zealand Pain Society

References

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From: Bruce Arroll <s 9(2)(a)>
Sent: Friday, 9 December 2022 9:40 pm
To: Consult
Subject: re class B drugs

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

Kia ora Pharmac

I would endorse the 3 month prescription of Ritalin at least. It is an enormous burden on patients having to collect them.

Also if the burden of needing a wet signature for some medications including Ritalin could be changed. It seems unnecessary given that prescriptions now have a number on them

The need for a specialist approval for Ritalin needs revision. This causes great inequity as it is currently impossible to get an adult patient assessed for ADHD and they are required to see a psychiatrist privately at $400+ per visit. Many of my patients cannot afford this so miss out on trament. A system of getting a patient to fill out an adult ADHD form and then a few questions answered (the form would need to be scanned in to the practice records) should suffice. The issue of diversion is a distraction given the amount of stimulants available in the community

Bruce arroll

He konei rā

Bruce Arroll MBChB, PHD, FRNZCGP (Distinguished); FRNZCUC (Honorary)
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Preferred pronouns he/him/ia

From: Anne-Marie <s 9(2)(a)>
Sent: Friday, 9 December 2022 2:10 pm
To: Consult
Subject: Class B scripts

[You don't often get email from s 9(2)(a) Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

I support the removal of barriers to the collection of scripts and therefore treatment for people affected by ADHD. 3 monthly prescribing goes a long way to help with this.
Kind regards
Anne-Marie Cullen GP
Khandallah Medical Centre

Sent from my iPad

From: Alistair Dunn <s 9(2)(a)>
Sent: Friday, 9 December 2022 12:38 pm
To: Consult
Subject: PHARMAC proposed changes to Class B drugs

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I favour the change to 3mthly Rx but **ONLY** for OST prescribing of methadone and Buprenorphine , and ADHD medications in children . These situations have safe guards in place : OSt is very regulated and ADHD m,eds , requiring Psych specialists to initiate treatment and review on a regular basis . Where presciber's have concerns they should use discretion to prescribe more tightly dispensing

However I do **not** think allowing GPs to script 3mth of strong opiates is a good idea due to frequent risk of diversion and misuse of opiates , and their resale value on the black market , an d the dangers associated with that .
For the same reason I do **not** favour extending dispensing beyond 10 days , in fact in practice I think 7 days supply is better except in special circumstances (eg distance , travel , remoteness) .
So I would favour GP prescribing still be limited to 1 mth prescriptions and max 10 days supply dispensing .
One could perhaps consider an option of GP applying for Spec Auth where GP can document

- No concerns of addiction / misuse
- Extenuating circumstances where longer prescribing is indicated (distance / access issues)
- Terminal care in conjunction with hospice
-

I also think prescribing stimulants for ADHD diagnoses de novo in adulthood is very risky due to common incidents of abuse / drug seeking

I am delighted that e prescribing of opiates is now permissible

Regards

Dr Alistair Dunn
MBChB FRNZCGP FAChAM
Bush rd Medical Centre
Whangarei
NZMC s 9(2)(a)

From: Admin <admin@mtmedical.co.nz>
Sent: Thursday, 8 December 2022 3:10 pm
To: Consult
Subject: Proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs

Good afternoon

I am a General Practitioner at Mount Medical Centre and have previously managed over 65 methadone clients here for 17 years.
I now prescribe under authority from Bay of Plenty addiction services. As I have an interest in addiction medicine I am currently prescribing to a large number of ADHD patients on methylphenidate

I am very much in support of the proposal, which would be a most welcome change for Primary care as this is going to save a lot of time and reduce potential for mistakes, or patients being left without critical treatment such as pain meds. It will allow cancer patients more time for themselves, and will reduce the cost of prescriptions to patients.

I am not concerned about safety issues with a 3 month prescription for long term conditions such as ADHD or opioid dependence. When we prescribe controlled drugs , a risk assessment is usually more focused on how often a patient must pickup in a week or month, rather than the length of time the script lasts per se. We can always choose to provide one month to ensure a patient does return for review if required. So thank you for this initiative, it makes common sense

I would also like to plea for the requirement of hard copy prescription for class B medications to be disbanded. I currently prescribe all my controlled prescriptions via e scripting which can only be done on my one computer at work. I can get remote access but this and my practice software are heavily passworded.
Currently with postal times and the lack of facsimile machines mean that hard copies can reach the pharmacy late. This causes problems for GPs , pharmacists and patients. I cannot see how these prescriptions could be forged given that they are barcoded. Essentially a patient would have to get into my surgery alone, open the software, know the password and prescribe using unfamiliar software.
(or they could hold a gun to my head at home and force me to prescribe using remote access)

The point is , that I cannot see the need for hard copies using such a process. I would appreciate if this could be taken into consideration. It will save considerable time , chagrin and money for us not to have to do this. I am open to any valid reason why they should continue of course.

Kind regards

Dr Tony Farrell

From: Nicholas Wright <s 9(2)(a)>
Sent: Thursday, 8 December 2022 9:22 am
To: Consult
Subject: Proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs

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To whom it may concern,

I am a GP Fellow. I work in several clinics including student health.

Over the last 5-10 years I have seen massive increases in the prescription rates for stimulant medications like ritalin. Despite not seeing these as always clinically necessary or the best next step for patients these are regularly initiated through psychiatrists, and most patients who seek input through private psychiatry get a diagnosis. Following these consults which occur once every two years or so (with the psychiatrist) the prescribing burden falls to us as GP clinicians. With monthly controlled drugs as an obligation this means far more unncecessary patient contact (majority of patients are stable), and for many practice more patient fees that fall on an already burdened population that (in the case of ADHD) have issues with organisation. It would seem logical and fitting that these prescriptions was moved to 3 monthly to align with other medications.

I would not generally support morphine or other opioid drugs moving to 3 monthly scripts, but the impacts of legislative change for this is lower for a general practice setting as these are far less frequently prescribed (by myself, at least). There might be logical exemptions like for those working in palliative care being allowed longer prescriptions of 3 months (but this again could be a significant source of diversion after a patient dies and there are potent drugs left lying around). The potential for harms (including harms from abuse or diversion) is in my view much greater with these medications, we cannot repeat what the US sees with their fentanyl epidemic. If 3 month prescribing is put into place there could be restrictions like a GP fellow who does these scripts or some processes in place like opioid agreements.

Regards,
Nick Wright
MCNZ s 9(2)(a)

From: Helen Temperton (ADHB) <s 9(2)(a)>
Sent: Thursday, 8 December 2022 3:20 pm
To: Consult
Subject: Amending the prescribing and dispensing of Class B controlled drugs

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Thank you for sending me through the information for these changes.
It will be very helpful for those with ADHD to have 3 monthly prescriptions as thy are often disorganised and the cost of repeat prescriptions can be hard to manage.

I am still in a paper prescription system in Private practice so it would be more helpful to get this extended to paper scripts too, but I acknowledge the risk of diversion of this as well.

I was wondering if there could be special circumstances in which a patient could collect the entire 3 months script for dexamphetamine or methylphenidate hydrochloride- for example as a practitioner if I could apply for this through pharmac for particular circumstances that would be useful. I see young adults that like to travel (especially while the borders are open) and it is incredibly difficult to access these medications overseas. I can think of 2 young adults s 9(2)(a) for which this would be very helpful. I have known these patients for several years and would trust them to care for this medication.

Many Thanks
Helen

Dr Helen Temperton (She/ Her)
Child and Adolescent Psychiatrist
Consult Liaison Team Starship Hospital | Te Toka Tumai | Auckland

waea pūkoro: s 9(2)(a) | **īmēra:** s 9(2)(a)
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Level 3, Room 3.142, Starship Children's Health, Private Bag 92024, Auckland, 1124

Please note that I work on Mondays, Tuesdays, Wednesday and Thursday

Reach us in our local channels: adhb.govt.nz | Facebook | LinkedIn

Te Whatu Ora
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From: Greg Judkins and [redacted] <[redacted]>
Sent: Thursday, 8 December 2022 10:16 am
To: Consult
Subject: Consultation feedback: ivacaftor

You don't often get email from [redacted] Learn why this is important

I am a general practitioner close to retirement.

I have a patient on opioid substitution therapy, for whom I prescribe Suboxone on behalf of CADS.
I note that Suboxone is not listed with the Class B drugs in your request for feedback to the proposed changes.
Is this an oversight? Will the proposed changes apply to *all* opioids?

From my experience in providing palliative care as well as opioid substitution therapy, I have often thought the 10-day dispensing rule was awkward, as repeats often became due in weekends.
In palliative care, dose adjustments are very common, so it is usually appropriate to prescribe for no longer than a month. Also, it is very common for the family to have unused opioids to return to the pharmacy when I patient dies, and I would not want to see these quantities increased three-fold.
Therefore, my preference would be for monthly prescribing to be retained for opioids, but with dispensing intervals of 14 days rather than 10 days.

Regarding Methylphenidate and Dexamfetamine, I support the proposal to permit three-monthly prescribing and monthly dispensing for these as the treatment is usually for long periods of time without frequent dosing adjustments.

Dr Greg Judkins FRNZCGP(Dist)
MCNZ [redacted]

From: Torrance Merkle <s 9(2)(a)>
Sent: Tuesday, 6 December 2022 7:05 pm
To: Consult
Subject: Proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs

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Great idea - much less admin for GPs - especially for Ritalin scripts!

Kind regards,

Dr Torrance Merkle
Hobsonville Family Doctors
s 9(2)(a)
124 Hobsonville Road, Hobsonville, Auckland 0618
www.hobsonvillefamilydoctors.co.nz

From: Scott Williams <[redacted]>
Sent: Tuesday, 6 December 2022 9:52 pm
To: Consult
Cc: Scott Williams PMC; rnzcgp@rnzcgp.org.nz
Subject: Pharmac - Class B drug dispensing changes

[You don't often get email from [redacted]. Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]

I support the proposal as outlined (I am a GP) EXCEPT that the 10 day dispensing rule should remain with total supply for 90 days - this will reduce the chance of having too much supply in the patients possession and reduce the risk of diverting the supply to someone else or overdose.
Often the use of opiates is very variable depending on symptom levels and too much supply should not be delivered in one lot - 30 day supply is open to abuse.

Dr S Williams NZMC [redacted]

Panmure Medical Centre

From: Jo Scott-Jones <s 9(2)(a)>
Sent: Tuesday, 6 December 2022 7:31 pm
To: Consult
Subject: Changes to class B drug use
Attachments: Pegasus_Health_Pastoral_Care_Programme.pdf

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Kia Ora,

I am writing in my capacity as medical director for Pinnacle MHN an PHO supporting 85 practice and 450,000 patients across Te Manawa Taki.

The proposed changes to class B drugs I believe will solve very few problems and cause many more.

The proposed drug list includes

- Dexamfetamine sulphate and Methylphenidate hydrochloride and Methadone hydrochloride

Which may benefit from greater than 1 month prescription provision as they are drugs for chronic conditions that are often stable in dose for long periods of time.

However including the following opioid analgesia in the changes to prescription frequency :

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

Is not likely to improve access and reduce the burden of disease. These medications are indicated for cancer related pain and palliative care. These are conditions that need close monitoring and frequently need dose changes. There is a significant danger that we will see an increase in drug imposition and drug diversion if the prescribng frequency of these medications is lenghthend.

We know from work done by Pegasus PHO that when doctors are under stress an indicator can be a spike in opioid, anxiolytic and hypnotic prescribing, as consultations are often easier and shorter when medication like this is given at patient request rather than entering into a counselling or potentially confronting consultation (see attached.)

The current 1 month prescription restriction keeps both patients and providers safer by increasing the contact they have to have for ongoing prescription of drugs of abuse.

Maintaining a 10 day dispensing frequency will reduce the amount od drug diversion into the community and help ensure good control and regular review of patients taking such medication.

My suggested changes to your proposal are as follows highlighted in yellow.

Part 1 – Prescribing and initiating Subsidies for Community Pharmaceuticals

1.2 Periods of supply for Subsidy: For Community Pharmaceuticals, periods of supply are as follows (note that legislative and regulatory requirements regarding periods of supply must also be met):

1.2.1 Only a quantity sufficient to provide treatment for a period of up to 3 Months will be Subsidised, and only if the Prescription under which the Community Pharmaceutical has been dispensed was presented to the Contractor within 3 Months of the date on which the Prescription was written, subject to the following exceptions:

~~a Class B Controlled Drugs: Only a quantity sufficient to provide treatment for a period of up to 1 Month in total (or up to 5 days when prescribed by a Dentist) will be Subsidised.~~

a Class B Controlled Drugs: Only a quantity sufficient to provide treatment for a period of up to 1 Month in total (or up to 5 days when prescribed by a Dentist) will be Subsidised with the exception of Dexamfetamine sulphate and Methylphenidate hydrochloride and Methadone hydrochloride.

Part 4 – Community Pharmaceutical Dispensing Quantities for Subsidy

4.1 Long Term Conditions (LTC) registered patients: **With the exception of prescriptions for Class B controlled drugs,** LTC patients can be dispensed to as often as the dispensing Pharmacist deems appropriate to meet that LTC patient's compliance and adherence needs.

4.4 **Community Pharmaceuticals identified in the Schedule without the ⁕ or ▲ symbols**

4.4.1 Default dispensing is Monthly Lots~~, or 10 day Lots for Class B Controlled Drugs, other than methylphenidate hydrochloride and dexamfetamine sulfate, in which case default dispensing is Monthly Lots~~.

or 10 day Lots for Class B Controlled Drugs, other than methylphenidate hydrochloride and dexamfetamine sulfate, in which case default dispensing is Monthly Lots.

4.4.2 A Community Pharmaceutical**, other than a Class B Controlled Drug,** 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.

~~b 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.~~

b 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.

4.4.3 Community Pharmaceuticals**, other than Class B Controlled Drugs,** identified in the Schedule without the ❋ symbol (where default dispensing is Monthly Lots) and prescribed in a quantity sufficient to provide treatment for more than 1 Month may be dispensed in variable dispensing periods under the following conditions:
a for stock management where the proprietary pack(s) result in dispensing greater than 30 days' supply

b to synchronise a patient's medication where multiple medicines result in uneven supply periods, or

c when the total quantity and dispensing period does not exceed the total quantity and period prescribed on the Prescription.

Part 5 – Community Pharmaceutical Modified Dispensing Quantities
5.2 Residential care: Community Pharmaceuticals**, other than Class B Controlled Drugs,** may be dispensed in modified dispensing quantities to a person whose placement in a Residential Disability Care Institution is funded by the Ministry of Health or Health NZ, or to a person residing in an Age Related Residential Care Facility, on the request of the person, their agent or caregiver provided that the following conditions are met:
5.2.1 The quantity or period of supply to be dispensed at any one time must not be less than:

~~a 7 days' supply for a Class B Controlled Drug, or~~
a 7 days' supply for a Class B Controlled Drug, or

Ngā mihi nui,

Dr Jo Scott-Jones. Pinnacle MHN Medical Director.
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Pegasus Health Pastoral Care Programme

Caroline Christie MBChB, Dip Paeds, FRNZCGP; Simon Wynn-Thomas BMedSci, BM BS, MRCP, MRCGP, FRNZCGP; Bianca McKinnon BA, BCom, BSc

Pegasus Health, Christchurch, New Zealand

ABSTRACT

INTRODUCTION: In New Zealand, 41% of general practitioners (GPs) intend to retire by 2025. Increasing workforce shortages and other stressors are putting doctors at risk of burnout, which in turn can put patients at risk of harm. Offering a range of resources can signal an organisation's commitment to physician wellness while improving patient safety and organisational stability.

AIM: To replace the current reactive approach to impaired doctors with a proactive system of monitoring performance with the goal of identifying problems early.

METHODS: This paper reports on an initiative of Pegasus Health Charitable to provide pastoral care to GPs in Canterbury experiencing increased stress, burnout or problems leading to impaired performance.

RESULTS: The pastoral care programme has been running successfully for 9 years and has helped 32 GPs. Because of the low numbers, the programme needs to be individualised and confidential.

CONCLUSION: Recent developments have seen Pegasus Health adopt a systematic approach to monitoring and supporting health practitioners. This includes the monitoring of available data on GPs at risk. Data collection is being used to manage the "psychological health" of doctors, including complaints, prescribing, referral data and attendance at education sessions.

KEYWORDS: Pastoral care; primary health care; general practitioner

Introduction

The Institute of Medicine in the United States of America has highlighted the link between patient safety, well-being of the doctor and organisational culture.[1] Doctors may be considered impaired when they are unable to practice medicine with reasonable skill and safety to their patients due to a mental or physical disability.[2]

In New Zealand, 41% of general practitioners (GPs) intend to retire by 2025.[3] Increasing workforce shortages and other stressors are putting doctors at risk of stress and burnout, which in turn can put patients at risk of harm.[1]

Assessment of the problem

There is an emerging body of evidence suggesting that health professionals may experience a range of difficulties in their practice. Estimates vary on how many doctors are working while impaired mentally or physically. One to two percent may be unsafe, while 5–12 percent may not be practising at an acceptable level.[4–7] Minor degrees of burnout can affect approximately one-third of all doctors at some stage of their career.[8] Rates of burnout are difficult to estimate due to under reporting.[9]

When a doctor is considered unsafe to work, it is generally a result of either physical[10–12] or mental health illness (including burnout and stress,[13–19] anxiety, depression and suicidal tendencies,[2,5,8,16,18] substance abuse and dependency,[14,20] or cognitive impairment).[21,22] An Australian review of complaints found that doctors with cognitive impairment started receiving complaints made against them and had inappropriately been prescribing

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WHAT GAP THIS FILLS

What is already known: There is a link between patient safety, wellbeing of the doctor and organisational culture.

What this study adds: The paper reviews ways of supporting general practitioners (GPs) who are trying to balance care and business. A study of pastoral care of GPs in Christchurch is provided to help with this. Suggestions are made as to how this care can be systematised.

drugs of abuse for ~10 years before the diagnosis of cognitive impairment is being made.[23] International evidence suggests the predictors of risk of stress and burnout include:

- Patient complaints and incidences[21,24]
- Inappropriate prescribing[14,23,25]
- Not being locally trained[26,27]
- Not involved in continuing medical education[27]
- Not from an English-speaking background[27]
- Practising in a rural area[21,27]
- In solo practice[27]
- Being single[27]
- Longer time after graduation[6,27]

Where intervention, treatment and monitoring are initiated early, outcomes for the doctor are typically positive.[13,19,27–32]

Support available through Pegasus Health

Pegasus Health is a primary care network in Canterbury, New Zealand that started 25 years ago. Pegasus Health strives for its health practitioners to practice medicine with reasonable skill and safety. Support, education and organisation improvements are available to all members.

Pastoral Care Programme

General practitioners can be supported by Pegasus Health through times of increased stress, burnout or personal problems. The Pegasus Health Pastoral Care Programme has been in existence since 2009. Pegasus Health aims to detect problems at an early stage and support doctors on an individualised basis.

The Senior Clinical Leader at Pegasus Health receives referrals, complaints or incidence reports through various means, as shown in Figure 1. The Senior Clinical Leader determines if the referral, complaint or incident deviates from best practice. Once the need for support has been identified, care needs to be individualised according to level of impairment, career stage, insight and motivation. GPs identified as needing assistance are offered individualised support and mentoring by one of five doctors in a pastoral care role. Support may involve a visit with a review of file notes. A formal practice review may be done in-house by a peer.

The pastoral care person reports back to the Senior Clinical Leader (at a high level to maintain confidentiality) and a decision is made as to whether the matter has been resolved or whether further support is needed. The current capacity for this support is ~12 new cases per annum, but will vary depending on the level of input required per doctor. The programme can offer pastoral support to GPs who are dealing with a range of issues including depression, bereavement, anxiety or organisational issues.

Where appropriate, a case may be referred to the Pegasus Health membership committee. Appropriate cases may include cases with a patient safety issue, a person not responding to individual support and mentoring or posing a risk to Pegasus Health. Issues of competency or misconduct require a referral to the Medical Council. What constitutes a competency issue is first determined on a case-by-case basis by the Membership Committee.

The purpose of the Membership Committee is to assist the Chief Executive Officer (CEO) in the management of membership support and processes for the companies, Pegasus Health Membership and Pegasus Health (Charitable), and to advise the CEO on membership matters. Members of the Membership Committee include the Senior Clinical Leader and five GP members appointed by the Senior Clinical Leader for a minimum term of 2 years. The CEO and other senior executives are in attendance. Meetings are held up to bi-monthly.

The responsibilities of the Membership Committee include: managing entry and exit processes for Pegasus Health members, advising the CEO on all areas of membership risk, making recommendations on membership issues, and providing a governance support role in member care processes.

Intervention

Pegasus Health sought to extend the pastoral care programme in a systematic way to help doctors before patient safety is affected. Until recently, the pastoral care programme has not included statistical analysis. Data collection provides a snapshot of the "psychological health" of doctors, including baseline risk factors, attendance at education sessions, complaints, prescribing, investigating and referral data. This latest development is hoped to provide much needed additional information to improve the quality of interventions and support.

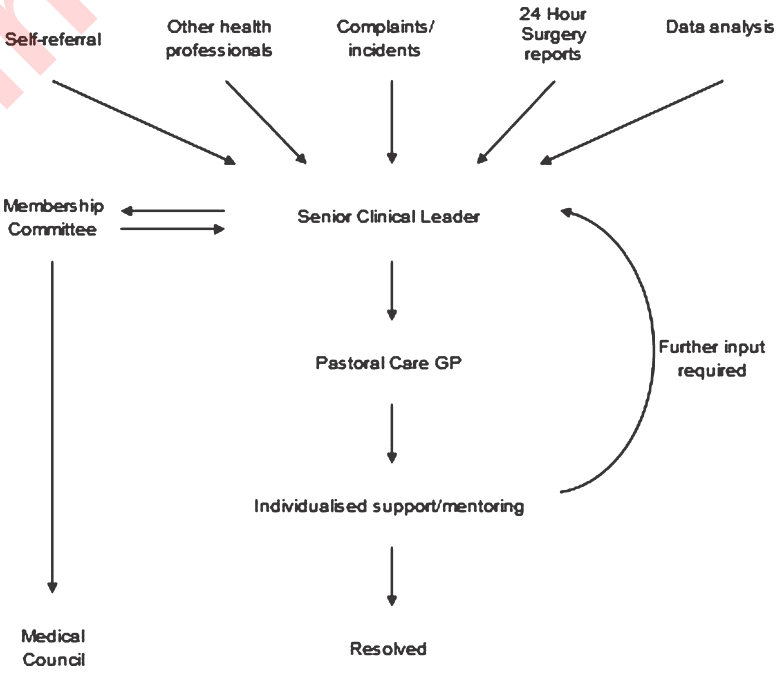
After full review of the evidence, available internal reports and databases, and consideration of the practical implications with key stakeholders, Pegasus Health elected to monitor major risk factors for stress and burnout, including patient complaints and incidents, and prescribing data. All patient complaints and incidences are reviewed. Critical incident debriefing is also undertaken at the Afterhours Surgery and is handled sensitively.

The knowledge management team in Pegasus Health were able to retrospectively review opiate and benzodiazepine data for all GP members over the preceding 10 years. A total of 20 drugs were included in the analysis from 2007 until 2016. Reporting is based on Ministry of Health Community Pharmacy Dispensing Data. Data are provided by unique head count and average milligrams per patient. These data are then drilled down by Medical Council number for Pegasus Health GPs to give an overview of individual GP prescribing over time and by each individual drug. GPs are ranked in relation to their peers by volumes dispensed. A detailed report is generated for the Senior Clinical Leader who discusses this with the GP concerned. Encrypted patient information can also be provided to the GP as there may be cases of one or two individual patients skewing data. A comparison can be made between real pastoral care cases and GPs considered to be prescribing appropriately.

Aside from these two major risk factors for stress and burnout, our internal databases can also be used to assess doctors for the other known risk factors identified in literature. Currently, there is not enough data available to develop models utilising weighted risk factors, or for model development using data analysis techniques. For example, not being locally trained was an issue because ~40% of our GPs were overseas trained, many from English-speaking backgrounds. Instead of including this as a risk factor, it was decided to take a broader approach to all GPs new to Canterbury whereby everyone receives induction information highlighting the differences in our local health system. New Pegasus members also receive a visit from a GP from the membership committee before being accepted.

Another group that appears to need more support includes GPs who are isolated either through being rural, solo practitioners or not involved in continuing medical education. All Pegasus

Figure 1. Flow diagram of Pegasus Health Pastoral Care Programme



members are monitored for attendance at small group education. Non-attenders are regularly encouraged to attend.

Risk factors outside of medicine may contribute to a doctor's functioning, such as changes in marital status and life stressors. We did not have access to this information so we were not able to include these. Males and females appear to have a different set of risks, so we decided to exclude gender. Age alone was also not a strong enough risk factor due to the variability in functioning as people age. Existing research suggests that changes in prescribing data carry more validity than increasing age alone.

Over time, the data will be monitored for its validity, and individuals considered at risk will be assessed alongside randomly selected GPs for comparison. In the future, the tool will be used to regularly monitor at-risk doctors in a systematic way. Those doctors will then receive an assessment and individualised management plan. The results will be evaluated and will further inform any developments in the area.

Results

Over the past 9 years, 32 doctors have been provided individualised support from Pegasus Health. There are currently 324 GP members. The level of need for pastoral care is consistent with national and international research. Where intervention, treatment and monitoring are initiated early, outcomes for the doctor are typically positive. Most GPs have been able to modify their practice and continue to work safely while under a mentoring programme. Where there have been concerns about cognitive impairment, a dignified retirement has been facilitated. The Medical Council has been notified of cases of involving health, competency or conduct issues.

The database has been reviewed using real cases. While the number of GPs involved in pastoral care to date is low, the data appear to be a useful tool for detecting doctors at risk. When considering prescribing data alone, the detection of at-risk doctors was strong in all but one case, which was unrelated to prescribing issues.

Limitations

The numbers in the pastoral care programme are low and not necessarily representative of other areas in New Zealand. Care has been individualised on a case by case basis. Further details cannot be evaluated as this would breach confidentiality. It is not possible to analyse trends and make recommendations for other locations or parts of the health system.

Conclusion

Pastoral care is an important aspect of a mature primary care network. Pegasus Health is now in its 25th year and has a well-developed pastoral care programme. There are several key features underpinning the success of the programme to date, as outlined below.

First, review of the evidence showed the topic to be both important and relevant, and helped to formulate a list of risk factors. This list was well researched, drawn from international and national literature and made more compelling with local data and expertise. Second, Pegasus Health has a long culture of peer support through regular peer-led education sessions and the use of free counselling and one-on-one individualised support. Finally, some cases have been successfully and delicately managed by the Senior Clinical Leader within Pegasus Health where outcomes have been positive and patient safety has been maintained. Reports from users of the pastoral care programme have been largely positive.

Pegasus Health sought to extend the Pastoral Care Programme in a systematic way to help doctors before patient safety is affected. By bringing together the evidence and various information systems available within Pegasus Health, a database has been developed. It is hoped that this tool will make a valuable contribution to the monitoring and support of at-risk doctors.

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COMPETING INTERESTS
There are no potential, perceived, or real competing interests.

FUTURE DEVELOPMENTS
The organisation is considering expanding the programme to include other health professionals such as nurse practitioners, practice nurses and community pharmacists in a systematic way.

From: Thilo Marquardt <T s 9(2)(a) >
Sent: Friday, 2 December 2022 9:01 am
To: Consult
Subject: opinion on proposal to amend pharmaceutical schedule re prescribing changes for controlled drugs

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To whom it may concern,

Thank you very much into revisiting this part of the schedule. I would like to split my opinion into TWO parts:

I do NOT agree with proposed changes (ie ability to prescribe for MORE than ONE month) for opioids and benzoediazepines. I consider this an important safety factor in my practice and having these rules to back me up, enables me to stand firm to safety principles. (I am a GP)

I do agree with the proposed changes for stimulants (MPD) for ADHD etc. as this seems to create a lot of bureaucracy without achieving much gain on the safety side. (I would still consider prescribing one month with two repeats though, as it is safer and enables better logistics especially in times of global supply turbulences).

Thank you for reading my opinion and I hope you will find it useful.
Kind regards

Dr Thilo Marquardt s 9(2)(a)
GP at Miramar Medical

From: Tracey Forward (ADHB) <s 9(2)(a)
Sent: Wednesday, 30 November 2022 11:48 am
To: Consult
Subject: Submission on proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs

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Dear Pharmac

I work in mental health and support the proposed amendments to the Pharmaceutical Schedule Rules on prescribing / dispensing Class B controlled drugs particularly in relation to ADHD medications.

As you will be aware, there is a shortage of specialised services for adults with ADHD in NZ provided by Te Whatu Ora, due to the limited number of psychiatrists or nurse practitioners with necessary ADHD assessment training. An ADHD diagnosis requires a formal extensive assessment process, and this training is not available or provided in NZ and I undertook this whilst in the UK. Many mental health authorised prescribers do not feel confident to undertake ADHD formal assessments because they have not had the relevant training. This puts an additional burden on the already small suitably qualified workforce to undertake the ADHD workload. Due to the limited number of public sector professionals, many tangata whai ora must pay to see private psychiatrists in order to be assessed/treated for ADHD.

Enabling 3-month scripts to be issued electronically will allow for tangata whai ora to receive the necessary treatment without having to return for monthly appointments in order to receive a new prescription – although regular follow up in the initiation period will obviously continue. This will free up the limited workforce to enable new assessments to be undertaken. If the tangata whai ora has paid to see a private psychiatrist, this will also be a cost saving for the patient.

I also believe that the way all services adapted prescribing methods for Class B drugs during Covid-19 lockdowns has provided evidence to support that the proposed amendments are appropriate and can be undertaken safely and effectively.

On a related topic, nurse practitioners are not permitted under the current law to apply for the special authority for methylphenidate or dexamphetamine and this can only be applied for by a psychiatrist or paediatrician. However, Nurse Practitioners can write the scripts and apply for the renewal of the special authority. It should be noted that many mental health nurse practitioners in NZ have undertaken ADHD specific training and have received more specialised ADHD education than some psychiatrists. Pease can this be changed.

Nga mihi nui

Tracey Forward
Nurse Practitioner/Mātanga Tapuhi and Honorary Professional Teaching Fellow
Liaison Psychiatry, Te Toka Tumai, Auckland City Hospital, 2 Park Road, Grafton, Auckland.
Ph: s 9(2)(a) | e: s 9(2)(a)

Te Whatu Ora
Health New Zealand

Te Whatu Ora – Health New Zealand
TeWhatuOra.govt.nz | Te Toka Tumai Auckland

From: Oliver Hainsworth (NDHB) <s 9(2)(a)
Sent: Wednesday, 30 November 2022 9:56 am
To: Consult
Subject: Consultation feedback: Proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs

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Great proposal related to Stimulants
I am concerned at the potential for harm – related to opiods – but support change to prescribing duration for methadone
Oliver Hainsworth (NDHB)

Dr Oliver T Hainsworth (he/him)
Clinical Director / Child Health Services
Rural, Family, and Community Health
Te Tai Tokerau / Northern Region

waea pūkoro: s 9(2)(a) ext s 9(2)(a) **īmēra:** s 9(2)(a)
Reach us in our local channels: northlanddhb.org.nz | Facebook | LinkedIn

Te Whatu Ora
Health New Zealand

Te Whatu Ora – Health New Zealand
TeWhatuOra.govt.nz

From: Daniel Schumann <s 9(2)(a)>
Sent: Monday, 5 December 2022 11:49 am
To: Consult
Cc: 'Malcolm Tubby'; AFT
Subject: FW: Pharmac consultation: proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs

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Dear PHARMAC,

AFT would like to provide feedback on your proposal to changes in regards to prescribing funded Class B controlled drugs. Changes will take effect from 1 February 2023. We cannot meet such a timeline as the notification period is inconsistent with current production and supply chain lead-times which are already challenged for Methylphenidate hydrochloride products and are between 6 to 8 months. The expected increased volume will have a one-time impact prior to 1 February 2023 and we cannot guarantee enough stock is available at all times as the lead-time is too short.

We would need the introduction of these changes to take effect at a later date so that we have more time to make sure sufficient stock will be available. Additionally we would need to be assured we can get the required Controlled Drug import licenses as Medsafe do seem to have some sort of quota and this may have an impact.

Many thanks in advance for your kind consideration.

Best regards,

Daniel

Daniel Schumann
Supply Manager
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www.aftpharm.com

From: Te Pātaka Whaioranga - Pharmac <consult@pharmac.govt.nz>
Sent: Monday, 28 November 2022 3:15 PM

To: s 9(2)(a)
Subject: Pharmac consultation: proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs

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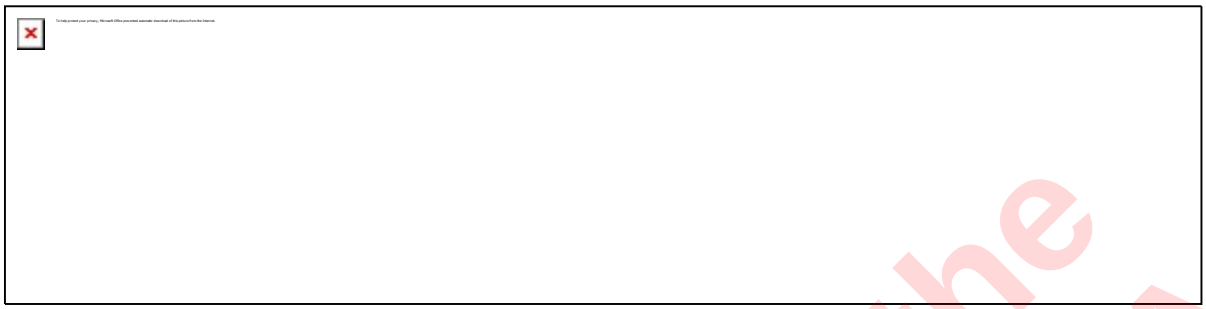


Pharmac consultation: proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs

Kia ora

Please follow this link to the Pharmac Consultation regarding proposed changes to the Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs.

Pharmac welcomes feedback on this proposal.

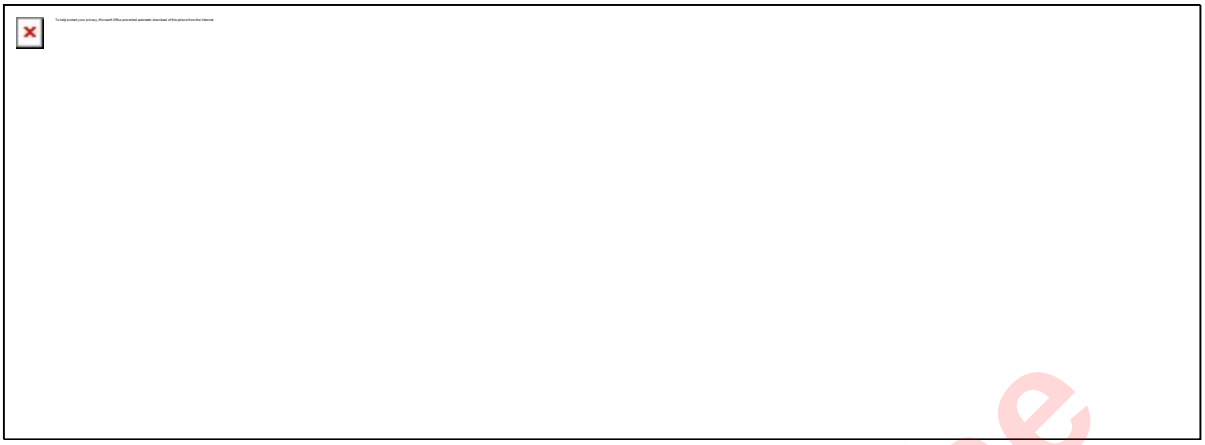
To provide feedback, please email consult@pharmac.govt.nz by **5pm on Friday 9 December 2022**.

Please circulate this email to others who may be interested.

Ngā mihi,

Belinda Ray-Johnson | Schedule Development Manager

Pharmac | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington | P: 0800 660 050 | www.pharmac.govt.nz



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From: Sutton, Andrew <s 9(2)(a)>
Sent: Friday, 9 December 2022 2:47 pm
To: Contract Management <contractmanagement@Pharmac.govt.nz>
Cc: Adam McRae <adam.mcrae@pharmac.govt.nz>; Ross Hunt <s 9(2)(a)>; James White <james.white@pharmac.govt.nz>
Subject: FW: Consultation on Class B controlled drugs

Dear Adam,

Thank you for the opportunity to feedback on the consultation. Pfizer currently supplies 3 Class B controlled drugs on Schedule B. We note that the legislative changes come into force on 22 December 2022, and Pharmac proposes to implement any changes to the Schedule Rules from 1 February 2023.

As a general point, Pfizer does not believe that this is sufficient notice to allow for an increase in initial demand to accommodate the proposed changes for funded Class B controlled drugs unless there is already sufficient inventory already in place. Further time would be required to accommodate an increase in demand from the manufacturing site and also for import and export permits. We allow 4 to 5 months for any changes in demand to flow through to wholesaler and pharmacy level which includes relevant import and export permits, however, this time of year we would allow for 6 months.

s 9(2)(b)(ii), 9(2)(ba)(i) & 9(2)(j)

s 9(2)(b)(ii), 9(2)(ba)(i) & 9(2)(j)

s 9(2)(b)(ii), 9(2)(ba)(i) & 9(2)(j)

s 9(2)(b)(ii), 9(2)(ba)(i) & 9(2)(j)

s 9(2)(b)(ii), 9(2)(ba)(i) & 9(2)(j)

s 9(2)(b)(ii), 9(2)(ba)(i) & 9(2)(j)

s 9(2)(b)(ii), 9(2)

s 9(2)(b)(ii), 9(2)(ba)(i) & 9(2)(j)

s 9(2)(b)(ii), 9(2)(ba)(i) & 9(2)(j)

Regards,
Andy

Andrew Sutton | Commercial Lead - Sterile Injectables and Tenders | Hospital Business Unit | Pfizer New Zealand | Generator Britomart, Level 10, 11 Britomart Place, Auckland 1010|☎ s 9(2)(a) |

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From: Contract Management <contractmanagement@Pharmac.govt.nz>
Sent: Tuesday, 29 November 2022 8:34 am
To: Contract Management <contractmanagement@Pharmac.govt.nz>
Subject: [EXTERNAL] FW: Consultation on Class B controlled drugs

Kia ora

There have been recent amendments to Misuse of Drugs Regulations and Medicines Regulations. These changes impact the amount of a Class B controlled drug that can be prescribed and dispensed at one time. Pharmac is proposing amendments to the Schedule rules to align with amendments to the regulations. This includes allowing for funded Class B controlled drugs to be dispensed in monthly lots (rather than the current 10-day supply). This is likely to have an impact on demand patterns for these products that you will need to consider as a supplier, while the change from 10 day dispensing to monthly will increase amount given to an individual per visit, the total amount of drug being dispensed will not change. You can view the full consultation here: Proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs - Pharmac | New Zealand Government

If you have any questions or concerns about ability to supply if these proposed changes come in to effect on 1 February 2022 please let us know by return email or reach out directly to your allocated Contract Manager prior to consultation closing on **Friday, 9 December 2022**.

Ngā mihi
Adam

Adam McRae | (he/him) | Contract Manager/Team Leader | Procurement and Contracts
Pharmac | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
P: +64 4 460 4990 | www.pharmac.govt.nz

From: Quaid, Greg <s 9(2)(a)>
Sent: Tuesday, 29 November 2022 10:50 pm
To: Consult
Subject: Consultation on Class B controlled drugs

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To whom it may concern,

In regards to the proposed amendments to the schedule goes ahead, can you please provide an indication on the projected increase in demand for class B controlled drugs from February next year? This will assist greatly in future forecasting.

Thanks
Greg
Proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs - Pharmac | New Zealand Government

Greg Quaid
AUNZ Tender Manager

Mobile s 9(2)(a)
Email s 9(2)(a)

Sandoz Pty Ltd
54 Waterloo Road
Macquarie Park, NSW 2113
AUSTRALIA