From: Sean Dougherty
Sent: Monday, 5 December 2022 11:35 am
To: Eddy Sommers; Belinda Ray-Johnson
Cc: Suzanne Townsend
Subject: RE: Comms on prescribing changes

Thanks Eddy.

I should note that the statement that *"Pharmac is currently consulting on proposed amendments to the Pharmaceutical Schedule to determine what appropriate controls should be placed on specific Class B controlled drug medicines."* is not accurate.

The controls, as we've noted before, are a regulatory issue. The Schedule will just be adopting the approach used in the regs.

Regards,

Sean

Sean Dougherty | Manager, Schedule Strategy and Development

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

From: Eddy Sommers <Eddy.Sommers@health.govt.nz>
Sent: Monday, 5 December 2022 11:26 am
To: Sean Dougherty <sean.dougherty@pharmac.govt.nz>; Belinda Ray-Johnson <belinda.ray-johnson@pharmac.govt.nz>
Cc: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>
Subject: Comms on prescribing changes

Hi both

A link to a news update on the MOH website about the changes. An email also sent out to stakeholders with similar wording.

https://www.health.govt.nz/news-media/news-items/expansion-new-zealand-eprescription-service-include-controlled-drug-medicines

Cheers

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Eddy Sommers (he/him)
Policy Analyst
Health System Settings
s 9(2)(a)
eddy.sommers@health.govt.nz
Manatū Hauora, 133 Molesworth Street
Thorndon, Wellington 6011

****
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From: Sarah Fitt
Sent: Thursday, 8 December 2022 8:50 am
To: Di Sarfati
Subject: FW: Class B Drug Legislation issues - Follow-up email from Dr Jane Thomas, Chair of PTAC
Attachments: Kolodny 2020.pdf

Di
As mentioned on Sunday. Jane has asked us to raise with Minister so giving you the heads up

Ngā mihi,

Sarah

Sarah Fitt | Chief Executive
PHARMAC | Te Pātaka Whaioranga | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
DDI: s 9(2)(a) | P: s 9(2)(a) | M: s 9(2)(a) |www.pharmac.govt.nz

From: Jane Thomas <s 9(2)(a)>
Date: 7 December 2022 at 11:54:33 PM NZDT
To: Steve Maharey <s 9(2)(a)>
Subject: Class B Drug Legislation issues - Follow-up email from Dr Jane Thomas, Chair of PTAC

Kia Ora Steve
I am writing to you as a follow-up to the discussion we had at the Pharmac Board Meeting last Friday in regard to the Class B Drug legislation changes. You are no doubt aware of my absolute horror and discomfort around the change to the legislation and the potential effect this will have on the people of Aotearoa. I have worked as a Pain Medicine Specialist and Anaesthetist for over 20 years in Auckland and have followed the opioid epidemic in the US, Canada, and Australia closely since the problem began in the US in the mid 1990's. When Oxycontin was approved by the FDA and subsequently vigorously and deceitfully promoted as 'less addictive and better for neuropathic pain' by Purdue Pharma the first wave of deaths linked to use of prescription opioids began. I'm attaching an editorial article published in the AMA Journal of Ethics in 2020 which provides an outline of how FDA regulatory failures contributed to the opioid crisis (Kolodny 2020).

I became aware of the legislation change just over a week ago when Pharmac sent out a notice regarding consultation around how Pharmac might manage the legislation change. When I received the email I was in Pain Clinic and forwarded the email to colleagues who mange patients with pain across Aotearoa - they were also surprised and unhappy with the legislation that was being proposed. I then phoned the Schedule Team at Pharmac to express my absolute surprise that the Chair of PTAC who is Pain Medicine Specialist hadn't been made aware of what was happening earlier, given the fact that at least four members of PTAC (myself, Professor Jennifer Martin, Associate Professor Giles Newton-Howes, Melissa Copland) had brought up the importance of trying to avoid an opioid crisis at PTAC meetings multiple times over a period of several years. We had also told the Chair of PTAC at the time that we would like to present to the Pharmac Board about the issues, including how Pharmac could potentially delist or place Special Authority criteria on specific opioids to try to reduce inappropriate prescribing and use of opioids in the community. This of course never happened. Following my call to the Schedule Team I then received a text from a person at the MOH (Trevor) and arranged a phone call with him on Monday evening last week. This lasted an hour and I found out that the consultation that the MOH had performed had been to send

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out individual emails or letters to all prescribers - having spoken to multiple pain medicine colleagues nobody remembers getting any emails or letters regarding this legislation. As clinicians we receive huge amounts of emails on our work and personal email addresses and it is extremely easy to miss emails such as this one, which is why contacting the appropriate colleges and societies is the correct strategy. Furthermore doctors were also focussed on managing COVID at that time. I also found out that the team in charge of the project at MOH level were predominantly pharmacists. I have no issue with pharmacists leading this project, however there is a problem when the consultation received by this team is not adequate. The Minister of Health is responsible for decisions he makes in response to the consultation he receives and is therefore responsible for the potential negative impact the legislation he signs off on has on the people of Aotearoa.

This is not the first time that the Ministry of Health have made poor decisions regarding passing legislation about prescription drugs. The legislation around medicinal cannabis is another example of this. When this legislation was passed no appropriate consultation had occurred with those involved in the care of patients with chronic pain. The consultation that should have been part of this process should have included pain medicine specialists, GP's, addiction medicine specialists, psychiatrists, general physicians, and others involved in the care of patients with chronic pain.

I am hoping that you have contacted Minister Little to make him aware of the issues that I raised in the recent Pharmac Board meeting. When I said that I was willing to 'put my head on the guillotine' in regard to the legislation regarding Class B drugs I did make this statement lightheartedly. I applied to be Chair of PTAC to help improve health outcomes for all people of Aotearoa, and to ensure Te Tiriti obligations were being met within the context of funding of pharmaceuticals. I am appalled at the way due process has been ignored in this particular case and I am also aware that Minister Little probably has no idea about the potential implications this legislation has on our country. I am very happy to speak to Minister Little to help him understand that the consultation in this case has not been appropriate and that he must delay the passing of this legislation until he receives proper consultation to truly inform his decision.

I am a strong advocate for Pharmac and the incredible work that it does to ensure health equity across Aotearoa and to make sure that tax payer monies are spent appropriately to improve health outcomes. However, I do not believe Pharmac should be complicit in a potential opioid and polysubstance use crisis in Aotearoa which began with poor due process at the Ministry of Health. I appreciate the opportunity to express my views at the Pharmac Board meeting and hope that my concerns have been taken seriously by the Board and have been discussed with the Minister of Health.
Nga mihi
Jane

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From: Doris Chong
Sent: Friday, 9 December 2022 1:30 pm
To: Amanda Bennett; Andrew Shaw ; Anrik Drenth; Astrid Saville; Craig Mabon; David Mitchell; Fiona Morris (fiona.morris@health.govt.nz); Healthsoft (Margie Peat); Heather Evans; Jacqui Hooper (jacqui.hooper@health.govt.nz); John Geering; Liz Houlahan (Liz.Houlahan@health.govt.nz); Luke Tilson; Mandy Benson (Mandy.Benson@health.govt.nz); Phoebe Kwan (HealthSoft); Sarah Keen; Scott Pringle (scott.pringle@health.govt.nz); Toniq - contact; Yen Walker
Cc: Kaye Wilson
Subject: 2022-12 Agenda for SOG meeting
Attachments: 2022-12 Agenda for SOG meeting.docx

Hi all

Please find attached the agenda for our video conference next Tuesday.

Join Zoom Meeting
https://pharmac-nz.zoom.us/j/86126595863

Meeting ID: 861 2659 5863
Passcode: 584928

Have a good weekend.

Kind regards
Doris

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

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

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SOG meeting

Meeting – 13 December 2022 at 11 am

Join Zoom Meeting
https://pharmac-nz.zoom.us/j/86126595863

Meeting ID: 861 2659 5863
Passcode: 584928

Attendees:

PHARMAC: ☐ Kaye Wilson, ☐ Doris Chong, ☐ John Geering, ☐ Anrik Drenth

Sector Operations: ☐ Mandy Benson, ☐ Jacqui Hooper, ☐ Liz Houlahan, ☐ Scott Pringle, ☐ Fiona Morris

RxOne: ☐ Margie Peat, ☐ Yen Walker, ☐ Phoebe Kwan

Toniq: ☐ Andrew Shaw, ☐ Astrid Saville, ☐ Amanda Bennett

NZULM: ☐ Craig Mabon, ☐ David Mitchell

MIMS: ☐ Sarah Keen

NZ Formulary: ☐ Heather Evans

Agenda

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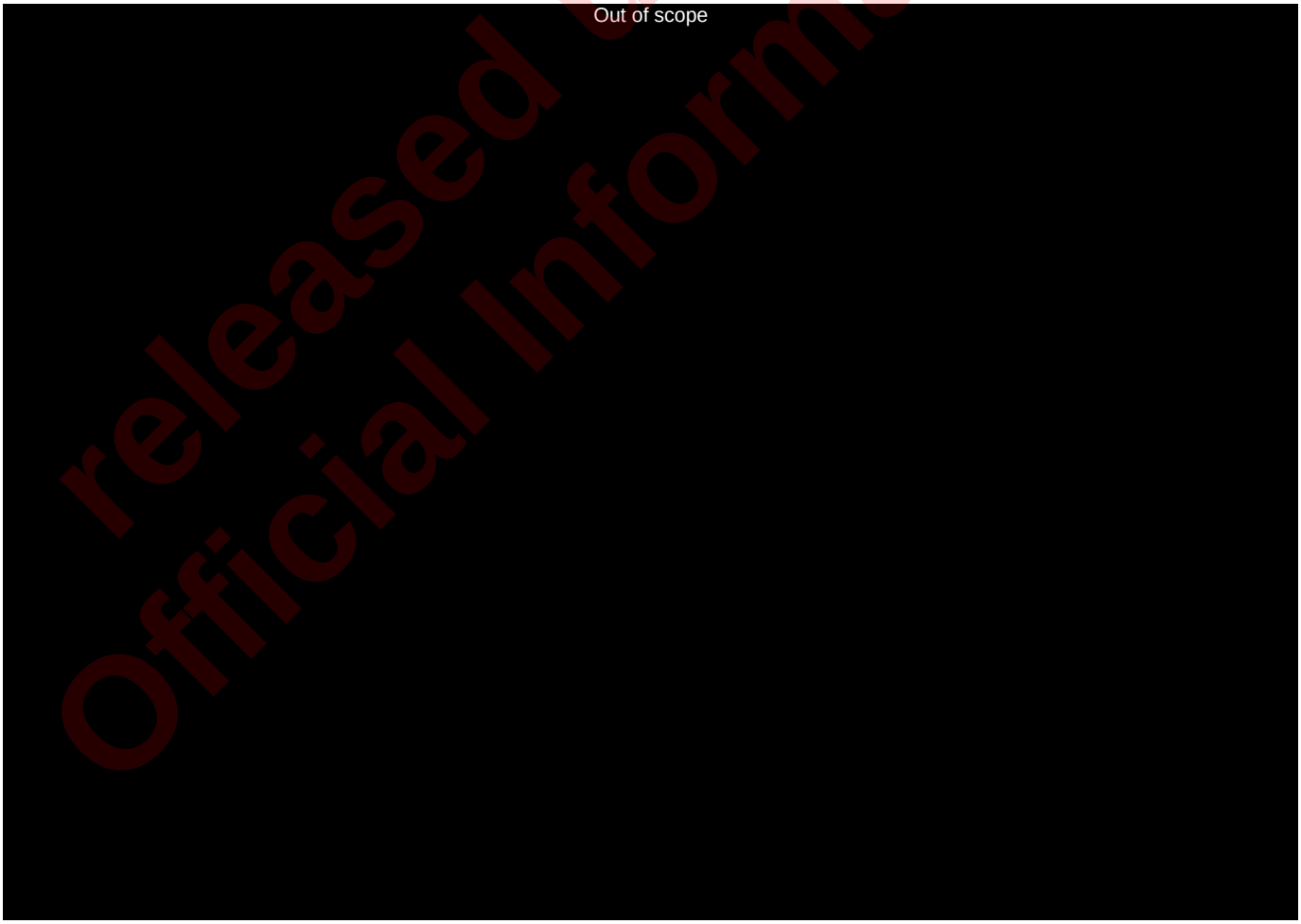

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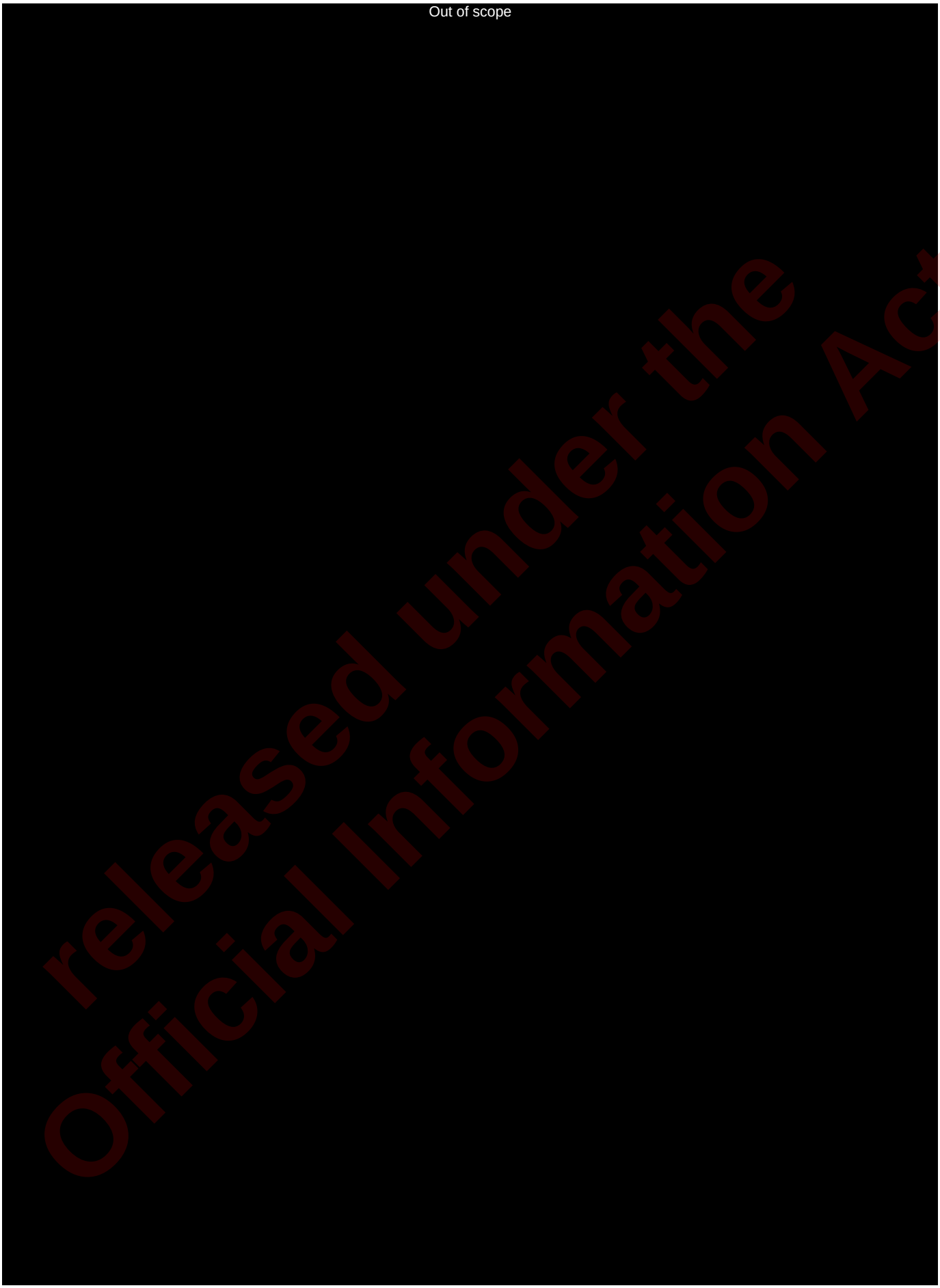

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Out of scope

Possible upcoming changes for 1 February 2023

Out of scope

Out of scope

Out of scope

Out of scope

- General Rules (Section A) changes to support upcoming legislative changes that apply to Class B controlled drug prescribing and dispensing.

Out of scope

Out of scope

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From: David Hughes
Sent: Friday, 9 December 2022 3:37 pm
To: Joe Bourne (Joe.Bourne@health.govt.nz)
Subject: FW: New Zealand Pain Society - Class B controlled drugs
Attachments: Letter to Pharmac_Class B opioid dispensing changes.pdf

Kia ora Joe,

Here it is.

Ngā mihi,
David

From: David Rice <s 9(2)(a)>
Sent: Friday, 9 December 2022 11:25 am
To: Consult <Consult@Pharmac.govt.nz>
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

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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

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P 09 921 9999 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

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New Zealand pain society

PO Box 6087
Invercargill 9841
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.

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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].

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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

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References

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2. Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2022. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
3. https://www.aihw.gov.au/reports/illicit-use-of-drugs/opioid-harm-in-australia/contents/summary
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From: Lisa Williams
Sent: Friday, 14 April 2023 2:27 pm
To: Melody Willis
Subject: FW: Community Pharmacy Hui

From: Trevor Lloyd <Trevor.Lloyd@health.govt.nz>
Sent: Wednesday, December 14, 2022 10:32 AM
To: Lisa Williams <lisa.williams@pharmac.govt.nz>
Subject: RE: Community Pharmacy Hui

Hello Lisa

From my initial discussions with Sean this was always the agreed plan. The only difference being that I thought we were to manage the consultation and spare the Pharmac resource. The intention was that we leave the Pharmac rules as is to retain some level of control while consultation determined the preferred quantities. This allowed us to get the changes through in a more timely manner but to then have a sense check and reset if required. We understand that Pharmac would prefer to not be the gatekeeper and I understand that your rules will not prevent people who choose to pay for their meds from getting around the Pharmac rules, however for CD meds this would be a red flag.

Maybe we should have an informal chat at some stage?

Ngā mihi

Trevor Lloyd B.Pharm
NZePS Change Manager
Data and Digital

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

Te Whatu Ora
Health New Zealand

Te Whatu Ora – Health New Zealand

From: Lisa Williams <lisa.williams@pharmac.govt.nz>
Sent: Wednesday, 14 December 2022 10:19 am
To: Trevor Lloyd <Trevor.Lloyd@health.govt.nz>
Cc: Billy Allan <Billy.Allan@health.govt.nz>
Subject: Community Pharmacy Hui

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Hi Trevor,

Just touching base as I see you're on the agenda to talk about the Misuse of Drugs Amendment Regs today. As you may be aware we're consulting on rule changes to the pharmaceutical schedule to implement the reg changes and it has resulted in significant unsupportive feedback from pain physicians (mainly focused on the reg changes themselves) and pharmacy (related to storage impacts). We have engaged with Maree Roberts at the MOH who advises that the MOH will be re-looking at these reg changes & we'll be collaborating with MOH to determine what we should do wrt the proposed Schedule rule changes in the meantime. Hopefully you have engaged with her/her team and are aware of this? Not sure if there is agreed messaging to share with sector players on the future plans yet?

Lisa

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

Lisa Williams (she/her) | Director of Operations

Te Pātaka Whaioranga | Pharmac | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
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From: Peter Alsop
Sent: Wednesday, 14 December 2022 4:38 pm
To: Maree Roberts; Allison Bennett
Subject: This has just gone .....
Attachments: A1641724.pdf

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PHARMAC
TE PĀTAKA WHAIORANGA

Briefing

Pharmac's involvement in the consultation process on Misuse of Drugs (Classification and Presumption of Supply) Order 2022

Date: **14 December 2022**

To: **The Hon Andrew Little (Minister of Health)**

Copies to: Director General of Health
Pharmac Board
Lead DHB Chief Executive, Pharmaceuticals
Manager, Governance and Crown Entities, Ministry of Health
Principal Advisor, Governance and Crown Entities, Ministry of Health

Contact(s)

Sarah Fitt, Chief Executive s 9(2)(a)
Peter Alsop Director and Engagement and Implementation
(Acting Chief Executive week commencing 19 December 2022) s 9(2)(a)

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Purpose

As requested, this briefing provides you with information on Pharmac's involvement in consultation process on Misuse of Drugs (Classification and Presumption of Supply) Order 2022; on our usual process for advising our expert advisory network of clinicians on changes to legislation; on the process that Pharmac undertook to address the concerns raised by Dr Jane Thomas; and whether concerns were raised with the Ministry of Health.

Background

Pharmac was informally consulted by the Ministry of Health early on in its process for developing the Cabinet paper for the Misuse of Drugs (Classification and Presumption of Supply) Order 2022 and Misuse of Drugs (Fentanyl and Tramadol) Amendment Regulations 2022. Discussions between officials took place in June and July 2022. This paper was passed by Cabinet in August 2022 [CAB-22-MIN-0316 refers], and the changes are due to come into effect on 22 December 2022.

On 18 October 2022 Pharmac was formally consulted by the Ministry of Health on amendment regulations which did not require new policy decisions from the Cabinet Legislation Committee. Our feedback was sought on operational detail.

To give effect to the amended regulations, changes are required to Pharmac's Pharmaceutical Schedule General Rules (the Schedule Rules). We subsequently began consultation on the amendments to the Schedule Rules to bring funding rules in line with legislative changes.

Pharmac's consultation process alerted various groups to the legislative changes. In other words, there wasn't high awareness of the legal changes that had already been made; it was our process that seemed to raise awareness. including with Dr Jane Thomas, who is the chair of Pharmac's Pharmacology and Therapeutics Advisory Committee (PTAC).

Several changes are brought about by the amended regulations

The amendments to the Misuse of Drugs (Classification and Presumption of Supply) Order 2022 and Misuse of Drugs (Fentanyl and Tramadol) Amendment Regulations 2022 were endorsed by Cabinet in August 2022. Policy changes agreed include:

- enabling controlled drugs to be prescribed electronically via the NZePS
- allowing prescriptions for Class B drugs to be prescribed and dispensed in greater amounts when issued through the NZePS
- codifying the waiver that allows electronic prescribing into the regulations
- ensuring designated pharmacist prescribers and designated nurse prescribers are able to continue to prescribe certain medicines when they become controlled drugs.

Class B drugs include opioid based medicines and attention deficit hyperactive disorder (ADHD) treatments.

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Pharmac began consultation on a proposal to amend the Pharmaceutical Schedule Rules on 28 November 2022

In the case of regulatory changes, such as this, Pharmac's approach has been to take steps necessary to give effect to the new regulations, which often means changes to the Pharmaceutical Schedule.

Pharmac is currently consulting on a proposal to amend the Pharmaceutical Schedule General Rules (the Schedule Rules) to bring funding rules in line with regulatory changes to the prescribing and dispensing of controlled drugs. Our consultation closes 21 December 2022.

While the *regulatory changes* come into effect on 22 December 2022, Pharmac's proposal is to change the Schedule rules (which govern the dispensing frequency allowed for subsidised medicines) from 1 February 2023.

We are seeking feedback to guide decision-making about timeframes for the rule changes, and on implementation support considerations. We have sought feedback from people who are prescribed controlled drugs, their caregivers, whānau and communities, prescribers authorised to prescribe controlled drugs, pharmacists and pharmaceutical suppliers, and wholesalers.

As indicated above, immediate feedback indicated that stakeholders were not aware of the regulatory changes before the Pharmac consultation was issued and, as a result, some people see the proposed changes as being initiated by Pharmac (even though we sought to clearly explain the basis for the change).

Pharmac has set processes for consulting

Under the Pae Ora (Health Futures Act) 2022 Pharmac must, when it considers it appropriate to do so,—

> (a) consult on matters that relate to the management of pharmaceutical expenditure with any sections of the public, groups, or individuals that, in the view of Pharmac, may be affected by decisions on those matters; and
>
> (b) take measures to inform the public, groups, and individuals of Pharmac's decisions concerning the pharmaceutical schedule.

Pharmac consults whenever we are proposing to fund a new product or change access criteria for an existing product and when a change is proposed to amend the Pharmaceutical Schedule Rules (even if this has been instigated by a legislative change).

As noted above, we also use our consultation process to support implementation of regulatory changes. We distribute our consultations to people who have subscribed to receive them and to stakeholders who we identify who might be affected by the issue where consulting on (including members of our network of advisory committees).

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Concerns have been raised by stakeholders

Concerns have been raised in consultation feedback by stakeholders. Some stakeholders have raised concerns that the regulatory change, allowing for class B controlled drug to be prescribed over a three-month period instead of the current one-month period, would lead to inappropriate prescribing and abuse. This matter has also been raised by the chair of PTAC, Dr Jane Thomas.

Stakeholders, including Dr Thomas, have pointed out that governments from around the world are working to restrict access to opioids which is in direct contrast to the proposed changes.

The chair of PTAC, Dr Jane Thomas' area of speciality in clinical practice is anaesthesia and pain management so, while she is the chair of PTAC, Pharmac staff have met with Dr Thomas to discuss and hear her concerns in person. As Chair of PTAC, Dr Jane Thomas is an observer at meetings of the Pharmac Board and was able to share her concerns with the Board at its meeting in early December.

At the Board's request, the Chief Executive of Pharmac subsequently ensured that the Director-General of Health was aware of the concerns we were hearing from stakeholders in response to our consultation. We have also had discussions with the Ministry's Chief Medical Officer, Dr Joe Bourne and Deputy Director-General, System Strategy and Policy, Maree Roberts.

Pharmac is collaborating with the Ministry of Health on the concerns that have been raised

Pharmac's consultation process made a wider group of people aware of the regulatory changes, and they have been providing us with feedback (both supportive and unsupportive) about these changes.

Pharmac is currently working with officials in the Ministry of Health Strategy and Policy Directorate and with staff in Te Whatu Ora who are leading the changes to the NZePS to ensure they are aware of the feedback that we are receiving, and to ensure that the Ministry can respond to concerns about the impacts of the regulatory changes. Ministry of Health officials have noted that they are keen to explore whether opioids can be treated differently from ADHD treatments. However, we understand that there are legislative barriers which may prevent this.

Pharmac is keen to support the management of this issue and one of the ways we can do this is to delay making changes to the Pharmaceutical Schedule rule if this would be appropriate. We are working closely with the Ministry of Health to determine the best way forward and to ensure there are aligned and consistent communications to stakeholders who might be affected by this issue.

Sarah Fitt

Chief Executive

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From: Doris Chong
Sent: Thursday, 15 December 2022 1:06 pm
To: Belinda Ray-Johnson
Cc: Kaye Wilson
Subject: RE: Class B controlled drugs

Hi Belinda

Thanks for the heads up.

Toniq will support a decision to delay, the expressed concerned at the February date when we had our video conference on Tuesday.

Thanks
Doris

From: Belinda Ray-Johnson <belinda.ray-johnson@pharmac.govt.nz>
Sent: Thursday, 15 December 2022 12:55 pm
To: Doris Chong <doris.chong@pharmac.govt.nz>
Cc: Kaye Wilson <Kaye.Wilson@Pharmac.govt.nz>
Subject: Class B controlled drugs

Hi

I just wanted to give you an early heads up that it's looking increasingly likely that MoH will want us to delay a decision on the Class B rules while they do some further work their end.

We are hoping to agree on comms to send to consult stakeholders this side of Christmas.

I'm on leave next week, but I'll be handing over within SSD before I go and will include a note that Andrew/Luke at Toniq should be directly emailed the info as I know they are concerned about implementation timeframes and I've only been able to tell them so far that we'd be making a decision in January.

Cheers

B

Ngā mihi

Belinda

Belinda Ray-Johnson | Schedule Development Manager
Te Pātaka Whaioranga | Pharmac |PO Box 10-254 | Level 9, 40 Mercer Street, Wellington
DDI: s 9(2)(a) | P: +0800 660 050| M: s 9(2)(a) www.pharmac.govt.nz

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

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From: Sean Dougherty
Sent: Thursday, 15 December 2022 12:03 pm
To: Suzanne Townsend; Belinda Ray-Johnson
Cc: Eddy Sommers; Meg Larken
Subject: RE: Class B reg changes.

Hi Suzanne,

We're meeting internally tomorrow morning to sort out our plan. It might be best to catch-up after that. How does 11 tomorrow work for you?

Sean

Sean Dougherty | Manager, Schedule Strategy and Development

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

From: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>
Sent: Wednesday, 14 December 2022 4:32 pm
To: Sean Dougherty <sean.dougherty@pharmac.govt.nz>; Belinda Ray-Johnson <belinda.ray-johnson@pharmac.govt.nz>
Cc: Eddy Sommers <Eddy.Sommers@health.govt.nz>; Meg Larken <Meg.Larken@health.govt.nz>
Subject: Class B reg changes.

Hi

I've just been told that it has been agreed by Maree and Peter that we will do joint comms on this issue before Christmas. I'm not yet sure what that will be. Can we touch base tomorrow to see how we can make this happen.

Thanks

Suzanne

Suzanne Townsend
Manager, Regulatory Policy
Strategy, Policy and Legislation | Te Pou Rautaki
M s 9(2)(a)
E suzanne.townsend@health.govt.nz

Manatū Hauora, 133 Molesworth Street
Thorndon, Wellington 6011

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MINISTRY OF HEALTH

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From: David Hughes
Sent: Monday, 19 December 2022 2:36 pm
To: Billy Allan
Subject: RE: Update: Misuse of Drugs Amendment Regulations 2022

ta

Ngā mihi,
David

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

From: Billy Allan <Billy.Allan@health.govt.nz>
Sent: Monday, 19 December 2022 2:35 pm
To: David Hughes <david.hughes@pharmac.govt.nz>
Subject: RE: Update: Misuse of Drugs Amendment Regulations 2022

Hi David

I do not anticipate any further comms until Manatū Hauora has undertaken their review of opioid access.

Noting I am no longer in the inner circle of Manatū Hauora decision making, so the position may change.

Nga mihi

Billy Allan (he/him)
Manager | Pharmacy Team

waea pūkoro: s 9(2)(a) | **īmēra:** billy.allan@health.govt.nz
133 Molesworth Street, Wellington | PO Box 5013 Wellington 6140

Te Whatu Ora
Health New Zealand

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

From: David Hughes <david.hughes@pharmac.govt.nz>
Sent: Monday, 19 December 2022 1:36 pm
To: Billy Allan <Billy.Allan@health.govt.nz>
Subject: RE: Update: Misuse of Drugs Amendment Regulations 2022

Kia ora Billy,

Just checking whether there will be further communication from the Ministry on this matter?

Ngā mihi,
David

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

From: Billy Allan <Billy.Allan@health.govt.nz>
Sent: Monday, 19 December 2022 1:27 pm
To: Matt Doogue <s 9(2)(a)>; Shaheeda Othman <Shaheeda.Othman@hqsc.govt.nz>; Matthew Coulson <Matthew.Coulson@hqsc.govt.nz>; Caroline Tilah <Caroline.Tilah@hqsc.govt.nz>; Chris James <Chris.James@health.govt.nz>; Clive Bensemann <s 9(2)(a)>; Janine Ryland <Janine.Ryland@acc.co.nz>; Jerome Ng <s 9(2)(a)>; Joanne.Beachman <s 9(2)(a)>; John Barnard <s 9(2)(a)>; lucyandblair <s 9(2)(a)>; marghuttonhand <s 9(2)(a)>; Dr Michael Tatley <s 9(2)(a)>; Rob Ticehurst-EXT <s 9(2)(a)>; Scott Pearson <s 9(2)(a)>; Sharon Kletchko - Work <s 9(2)(a)>; sharonkletchko49 <s 9(2)(a)>; Sunita Goyal <Sunita.goyal@acc.co.nz>; Vidhya Makam <Vidhya.Makam@health.govt.nz>; Martin Thomas <Martin.Thomas@hqsc.govt.nz>; David Hughes <david.hughes@pharmac.govt.nz>; Sarah Kirk <s 9(2)(a)>
Cc: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>
Subject: Update: Misuse of Drugs Amendment Regulations 2022

Kia ora koutou

The Misuse of Drugs Amendment Regulations 2022 will come into effect on 22 December 2022 (please see the attached FAQ document to find more details).

Manatū Hauora has been made aware of concerns related to the prescribing and use of opioids, which are impacted by these amendments. As a result Manatū Hauora, along with out health partners, will be undertaking an assessment of the current system settings that influence access to opioids.

As you may be aware, Pharmac is currently consulting on proposed amendments to the Pharmaceutical Schedule relating to the prescribing of Class B controlled drug medicines (you can have your say here 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/). We have asked Pharmac to delay decision making on changes to the Schedule, until we have undertaken our review of opioid access.

Suzanne Townsend
Manager, Regulatory Policy
Strategy, Policy and Legislation | Te Pou Rautaki
M s 9(2)(a)
E suzanne.townsend@health.govt.nz

Manatū Hauora, 133 Molesworth Street
Thorndon, Wellington 6011

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Misuse of Drugs Amendment Regulations 2022 – FAQs

When do the changes under the Misuse of Drugs Amendment Regulations 2022 come into effect?

The Misuse of Drugs Amendment Regulations 2022 will come into effect on 22 December 2022. The amendment regulations can be viewed at **https://www.legislation.govt.nz/regulation/public/2022/0303/latest/LMS784021.html**

What do the changes mean for how controlled drugs are prescribed on the NZePS?

From 22 December 2022 signature-exempt prescriptions for controlled drug medicines will be enabled when prescribing through the NZePS. Prescribers will no longer need to provide a hard copy, signed version of any prescription for a controlled drug as long as they generate the script using an approved system which is integrated with the NZePS.

More detailed information, about how this may work in practice for you, can be found at **https://www.health.govt.nz/our-work/digital-health/other-digital-health-initiatives/emedicines/new-zealand-eprescription-service**

What do the changes mean for the amount of Class B drug than can be prescribed on the NZePS?

A description of the changes can be found at **https://www.health.govt.nz/news-media/news-items/expansion-new-zealand-eprescription-service-include-controlled-drug-medicines**

The changes establish an exemption clause which allows certain prescribers (medical practitioners, nurse practitioners, designated prescriber pharmacists, and designated prescriber nurses) to issue 3-month **NZePS** prescriptions for Class B controlled drugs. Prescribers must (under reg 31A(6A)) direct on that script the appropriate number of intervals for dispensing, which can be on 3 or more occasions (no more than 1 months' worth at a time).

This change only affects the period of supply that a **Class B, NZePS** prescription can cover. The maximum dispensing amount has not changed and remains at a quantity that must not exceed supply

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for a period of 1 month. Prescribers must continue to take a cautious approach to prescribing controlled drug medicines.

The immediate impact of these changes will be minimal as prescribers and dispensers are still required to meet the rules of the Pharmaceutical Schedule, which limits the amount of Class B controlled drugs that can be prescribed or dispensed to be eligible for subsidy.

What about scripts that are not for Class B controlled drugs on the NZePS?

The **existing restrictions** remain for any scripts not covered under the exemption. In other words, the exemption only applies to prescriptions for **Class B controlled drugs that are issued through NZePS**.

For designated pharmacist prescribers and designated nurse prescribers this means that **existing supply restrictions remain for non-NZePS prescriptions**. Designated pharmacist prescribers can only prescribe
3-days' worth of Class B (when not through NZePS) and Class C controlled drugs; designated nurse prescribers can only prescribe 7-days' worth of Class B (when not through NZePS) and Class C controlled drugs.

What about Class C controlled drugs? What can be prescribed?

All controlled drugs will now be able to be prescribed on the NZePS without also needing a signed, hard copy version.

However, there has been no increase to the maximum prescribing amounts for Class C controlled drugs. Regardless of whether NZePS is used or not, regulations 21(4) and (5) remain, and designated pharmacist prescribers can only prescribe 3-days' worth of Class C controlled drugs; designated nurse prescribers and dentists can only prescribe 7-days' supply; and medical prescribers and nurse practitioners can prescribe 3-months' supply.

Why was the duration of supply for Class C controlled drugs prescribed by designated pharmacist prescribers and designated nurse prescribers not changed?

The amendment extended the length of supply for Class B controlled drugs if prescribed using the NZePS (the approved system). No change was made to the regulations to provide the same extension for Class C controlled drugs.

The Ministry of Health will be reviewing the impact of these changes and exploring further improvements that could be made to prescribing regulations.

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

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No. Prescribers will still be required to operate within the limits of the Pharmaceutical Schedule managed by Pharmac. As a result of the amendments to the regulations, Pharmac is currently consulting on proposed amendments to the Pharmaceutical Schedule to determine what appropriate controls should be placed on specific Class B controlled drug medicines.

You can have your say on the proposed amendments by making a submission before 21 December 2022: **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/**.

Does this mean NZePS prescriptions for Class B controlled drugs will NOT require a signature but can still only be funded for one month supply, until amendments are made to the Pharmaceutical Schedule?

Yes. The Misuse of Drugs Amendment Regulations 2022 come into effect on 22 December 2022 and will remove the signature requirement for controlled drug NZePS scripts. However, to receive funded medicines the Pharmaceutical Schedule rule must be followed. The current rule states that Class B Controlled Drugs will be subsidised '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 the period of validity for NZePS prescriptions change from 7 days to 3 months for Class B controlled drugs?

The period of validity for Class B controlled drugs will remain at 7 days for both NZePS and non-NZePS scripts after the Misuse of Drugs Amendment Regulations 2022 come into effect on 22 December 2022.

Do the amended regulations affect the upcoming reclassification of fentanyl, zopiclone, zolpidem and tramadol?

The Misuse of Drugs Amendment Regulations 2022 have no impact on the upcoming reclassifications of fentanyl, zopiclone, zolpidem and tramadol under the Misuse of Drugs (Classification and Presumption of Supply) Order 2022. The details of these reclassifications are set out in the following table.

Controlled drug	**Reclassification date**	**Reclassification**
Fentanyl	1 July 2023	B1
Zopiclone and Zolpidem	1 July 2023	C5
Tramadol	1 October 2023	C2

Please note that each of these controlled drugs will be subject to the Misuse of Drugs Regulations 1977

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as and when its reclassification comes into effect under the Misuse of Drugs (Classification and Presumption of Supply) Order 2022. Further information on this will be available closer to the commencement dates.

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From: Dan Jackson <Dan.Jackson@health.govt.nz>
Sent: Tuesday, 20 December 2022 11:01 am
To: Suzanne Townsend; Sean Dougherty
Subject: RE: Proposed comms on prescribing changes

You don't often get email from dan.jackson@health.govt.nz. Learn why this is important

Hi Suzanne and Sean

The changes to the regulations are briefly described on the NZePS pages of the Ministry of Health website and the FAQs can now be downloaded from the bottom of the relevant section. Here is a link to that section: https://www.health.govt.nz/our-work/digital-health/other-digital-health-initiatives/emedicines/new-zealand-eprescription-service#expanding.

By the way, the Ministry's Comms team has identified that the NZePS pages/resources could do with a bit of a tidy up and we have made a note to look at this in the New Year.

Regards
Dan

Dan Jackson
Senior Communications and Engagement Advisor
Government & Executive Services | Te Pou Whakatere Kāwanatanga
s 9(2)(a)
dan.jackson@health.govt.nz
Manatū Hauora, 133 Molesworth Street Thorndon, Wellington 6011

From: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>
Sent: Tuesday, 20 December 2022 10:39 am
To: Sean Dougherty <sean.dougherty@pharmac.govt.nz>
Cc: Dan Jackson <Dan.Jackson@health.govt.nz>
Subject: RE: Proposed comms on prescribing changes

Sure

Dan can you help out?

From: Sean Dougherty <sean.dougherty@pharmac.govt.nz>
Sent: Tuesday, 20 December 2022 10:37 am

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To: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>
Subject: RE: Proposed comms on prescribing changes

Is this on your website somewhere? I'd like to link to it if possible.

Thanks,

Sean

Sean Dougherty | Manager, Schedule Strategy and Development

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

From: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>
Sent: Monday, 19 December 2022 2:10 pm
To: Sean Dougherty <sean.dougherty@pharmac.govt.nz>
Subject: RE: Proposed comms on prescribing changes

E-mails have started going out.

From: Sean Dougherty <sean.dougherty@pharmac.govt.nz>
Sent: Monday, 19 December 2022 11:16 am
To: Eddy Sommers <Eddy.Sommers@health.govt.nz>; Belinda Ray-Johnson <belinda.ray-johnson@pharmac.govt.nz>
Cc: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>; Allison Bennett <s 9(2)(a)>
Subject: RE: Proposed comms on prescribing changes

Hi,

Thanks for sending these through. No comments from our end.

Can you please let us know when this has gone out. Thanks.

Sean

Sean Dougherty | Manager, Schedule Strategy and Development

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

From: Eddy Sommers <Eddy.Sommers@health.govt.nz>
Sent: Friday, 16 December 2022 12:11 pm
To: Sean Dougherty <sean.dougherty@pharmac.govt.nz>; Belinda Ray-Johnson <belinda.ray-johnson@pharmac.govt.nz>
Cc: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>; Allison Bennett <s 9(2)(a)>
Subject: Proposed comms on prescribing changes

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Kia ora Sean and Belinda

As discussed please find attached our FAQs to be distributed through our network and uploaded on MOH website. Also below are some proposed lines that we would send along with the FAQ doc.

Let us know if you're happy with these.

Proposed comms:

The Misuse of Drugs Amendment Regulations 2022 will come into effect on 22 December 2022 (please see the attached FAQ document to find more details).

Manatū Hauora has been made aware of concerns related to the prescribing and use of opioids, which are impacted by these amendments. As a result Manatū Hauora, along with our health partners, will be undertaking an assessment of the current system settings that influence access to opioids.

As you may be aware, Pharmac is currently consulting on proposed amendments to the Pharmaceutical Schedule relating to the prescribing of Class B controlled drug medicines (you can have your say here 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/). We have asked Pharmac to delay decision making on changes to the Schedule, until we have undertaken our review of opioid access.

Ngā mihi

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

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From: YiYan Chuah <YiYan.Chuah@health.govt.nz>
Sent: Wednesday, 21 December 2022 2:22 pm
To: Peter Alsop; Anne Stewart; Allanah Andrews; Michael Johnson; Andi Shirtcliffe
Cc: Alison Cossar; Susanna Chung; Peter Jane; Laurence Holding; Allison Bennett; Maree Roberts
Subject: Meeting minutes - Pharmac/Ministry strategic Bi-monthly - 14 Dec 2022
Attachments: Agenda - Bi-monthly - 14 December - minutes - sent .docx

Good afternoon all,

Thank you all for attending the recent Pharmac/Ministry of Health strategic bi-monthly, recently held on 14 December 2022.
Please find the drafted minutes from the meeting and updated action tracker for your comment and feedback.

Kind regards,

YiYan Chuah (he/him)
Senior Policy Analyst
Strategy, Policy & Legislation
Mobile: s 9(2)(a)
yiyan.chuah@health.govt.nz
Manatū Hauora, 133 Molesworth Street
Thorndon, Wellington 6011

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Agenda

Bi-Monthly MoH/PHARMAC Strategic Meeting

Date:	14 December 2022
Time:	2:30 pm to 3:30 pm
Attendees:	Pharmac: Michael Johnson, Peter Alsop, Allanah Andrews Ministry: Maree Roberts, Allison Bennett, Laurence Holding, Peter Jane, YiYan Chuah, Alison Cossar (PHA)
Apologies	Andi Shirtcliffe, Anne Stewart

Agenda	Item	Lead
1.	**Welcome** [redacted]	Chair – Maree
2.	[redacted] [redacted] [redacted] [redacted] [redacted] [redacted] [redacted]	Peter/ Maree

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4.	Out of Out of scope Out of scope Out of scope Out of scope Out of scope Out of scope Out of scope Out of scope Out of scope	All

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	[redacted] [redacted] [redacted] [redacted] **Medicines control (Ministry)** Ministry outlined the issue: change of regulation of prescribing for class B drugs. • Ministry proposed a scoping discussion in the new year with Pharmac input on related medicines control and system linkages arising. Noting the links to the future Medicines strategy, medicines control and the suitability of systems. • Pharmac proposed waiting on whether a review was needed, given it was not fully aware of the issues and the system's busy work programmes. • Ministry clarified the review scope was TBD; but a review was required as issues raised are broad (eg, prescriber behaviour relates to clinical training and practice) and links to other work (eg, checks and balance on system). The proposed review enables a broader response than review of regulations, however this meeting will help form the scope of work ahead. Covering compliance with schedule rules will that be covered. • Pharmac notes interest on issues (clinical governance and quality) and agrees on an exploratory discussion on scope in the new year. **[Action]**: Ministry to organise an exploratory discussion on medicines control for January 2023	
5.	[redacted] [redacted] [redacted]	Pharmac

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6.	Out of scope Out of scope Out of scope Out of scope Out of scope Out of scope Out of scope Out of scope Out of scope Out Out of scope Out of scope Out of scope Out of scope Out of scope Out of scope	Pharmac
7.	Out of scope	**All**

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Action tracker

Action raised *What is the proposed action?* *When will it be completed?*	**Date raised**	**Assigned** *Who is assigned to complete task*	**Due date**	**Status** *In progress* *Completed*
Out of scope				
Ministry to organise an exploratory meeting on Medicines controls	14 Dec	Ministry	January 2023	In progress
Out of scope				

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From: Web Enquiry
Sent: Tuesday, 10 January 2023 2:11 pm
To: Isabelle Parkin
Subject: RE: ADHD Medication - A1635265

Kia ora Isabelle,

Thank you for contacting Pharmac and apologies for the delay in our response.

Pharmac is involved in the funding of ADHD medications. The Special Authority criteria allows eligible patients to access funded supply of these medications. The Special Authority criteria for ADHD medications have been established following recommendations from the Mental Health Specialist Advisory Committee and the Pharmacology and Therapeutics Advisory Committee (PTAC).

Should a patient not meet the Special Authority criteria, but their clinician deems the product appropriate for the patient and believe that it should be funded for them, their clinician can apply for a Special Authority Waiver on behalf of the patient, which Pharmac can then consider. More information regarding this can be found on our website: https://pharmac.govt.nz/medicine-funding-and-supply/make-an-application/special-authority-waiver/

As it stands, the legislation regarding the maximum quantity of supply for Class B Controlled Drugs has changed but the Pharmaceutical Schedule funding rules have not, therefore the current funding rules for methylphenidate still applies ie: only 1 month maximum supply per prescription. More information regarding the change in rules in Class B Controlled Drugs can be found on our website and through Te Whatu Ora.

We also note that the Ministry of Health, has indicated that they would like to revisit the regulatory arrangements for opioids. They have asked Pharmac to delay making a decision on the proposed changes to the Schedule Rules to support this work.

We have agreed to this delay, meaning that the proposed changes will not happen in February as initially planned. We will keep everyone updated as this work progresses.

I hope this information helps.

Ngā mihi,

EJ Gariando | he/him | Schedule Advice Lead
Te Pātaka Whaioranga | Pharmac | PO Box 10-254, Wellington 6140 | Level 9, 40 Mercer Street, Wellington
M: s 9(2)(a) | P: 0800 660 050 | www.pharmac.govt.nz

From: Isabelle Parkin <Isabelle.Parkin@health.govt.nz>
Sent: Thursday, 8 December 2022 7:50 am
To: Web Enquiry <enquiry@Pharmac.govt.nz>
Subject: FW: ADHD Medication - A1635265

> You don't often get email from isabelle.parkin@health.govt.nz. Learn why this is important

Dear Casie,

We have received this forwarded email from s 9(2)(a) enquiring about recent changes relating to the access to funded ADHD medications, in particular the special authority process.

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Medicines Control don't administer Special Authorities and we understand that Pharmac set the criteria for Special Authority. https://www.health.govt.nz/new-zealand-health-system/claims-provider-payments-and-entitlements/special-authority
Are you please able to advise here?

Kind regards,
Isabelle Parkin (she/her) | Advisor Medicines Control | Medsafe | Ministry of Health | s 9(2)(a) | isabelle.parkin@health.govt.nz

From: s 9(2)(a)
Sent: Sunday, 4 December 2022 10:57 am
To: Medicines Control <medicinescontrol@health.govt.nz>
Subject: Re: ADHD Medication - A1635265

Hello

I'm following up on my email. Is it possible to get a response?

Thank you,
s 9(2)(a)

On Wed, 23 Nov 2022 at 14:51, s 9(2)(a) wrote:

> Hello,
>
> I'm enquiring about access to ADHD medication in NZ. I see that the health sector has recently committed to change in this area, in particular the special authority process - as it's causing harm and putting people at risk.
>
> Can you please tell me what medsafe is doing about this and when it will be actioned?
>
> Thanks
> s 9(2)(a)
>
> ---------- Forwarded message ---------
> From: **Web Enquiry** <enquiry@pharmac.govt.nz>
> Date: Thu, 17 Nov 2022 at 11:54
> Subject: RE: ADHD Medication - A1635265
> To: s 9(2)(a)
>
> Kia ora s 9(2)(a)
>
> Thank you for contacting Pharmac. We are sorry to hear of the challenges you are facing to receive access to medicines for the treatment of ADHD.

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The funding restrictions currently in place for the supply of methylphenidate and dexamfetamine align with the legislation from the Misuse of Drugs Regulations 1977, which you can read more about on Medsafe's website, here.

We recommend contacting Medsafe for further information about this. You can find their contact details here.

I hope this is helpful. Please let me know if you have any further questions.

Ngā mihi

Casie

Casie Hanrahan | Implementation Lead

Pharmac | Te Pātaka Whaioranga | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington
DDI: s 9(2)(a) | M: s 9(2)(a) www.pharmac.govt.nz

From: s 9(2)(a)
Sent: Wednesday, 16 November 2022 1:09 pm
To: Web Enquiry <enquiry@Pharmac.govt.nz>
Subject: ADHD Medication - A1635265

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

I've recently been diagnosed with ADHD as an adult, and am experiencing significant distress and barriers with receiving asses to medication. I know I'm not alone in this, and that representatives from Pharmac have also publicly said it's time for a system rethink, as this issue is deeply systematic.

While I see there's been commitment across the health sector, including from Pharmac (all which is great), I can't find information on what is actually being done and when we might see some change. I'm also worried that everyone involved, including Pharmac, might not truly understand how this is affecting many people in NZ's quality of life, as well as putting them at serious health risk with mental health under immense strain due to not being able to access medication.

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I'd really like to know more about Pharmac's role in this and how they are working with the health sector to help people receive access to medication etc. I don't know if this falls all with the government and ministry of health, or if broader.

I'm doing everything I can to try and receive medication, but I still haven't received it.

Thank you

s 9(2)(a)

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From: Media
Sent: Tuesday, 10 January 2023 9:28 am
To: Skara Bohny
Subject: RE: Media, Sophie Harris, Stuff, Challenges of ADHD medication

Thanks Skara, will check now and come back to you 😊

Ngā mihi

Jane Wright | Senior Communications Advisor/Team Leader

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

From: Skara Bohny <Skara.Bohny@health.govt.nz>
Sent: Tuesday, 10 January 2023 9:26 am
To: Media <media@pharmac.govt.nz>
Subject: Fwd: Media, Sophie Harris, Stuff, Challenges of ADHD medication

Kia ora team,

We are responding to some queries on ADHD and medication, and a couple of them include aspects which we thought might benefit from Pharmac having a quick check – especially Q2 here which references Pharmac specifically.

Are you able to have a look at these to see if you're satisfied our response is accurate re: Pharmac's actions and purview?

RESPONSE:

1. ***Is Health New Zealand aware of the challenges those with ADHD are describing when trying to access medication?***

Yes, there is awareness of the current challenges. Last year an ADHD Parliamentary hui held in August that ADHD NZ convened, with key stakeholders including health entities where a range of actions were discussed. Following this, the Ministry is participating in a collaborative group of stakeholders on further joint discussion and action. There is valuable work happening in some key areas to improve treatment and medication access for those with ADHD for example:

- The Misuse of Drugs Act 1975 has been amended to allow Class B controlled drugs (which includes ADHD medication) to be electronically prescribed for up to 3 months, rather than just one month. The new regulations came into force on 22 December 2022
- The RNZCGP (Royal Australian and New Zealand College of Psychiatrists) has agreed to endorse the Australian ADHD Professionals Association (AADPA) guidelines in the interim with a view to tailoring for the local Aotearoa New Zealand context – especially in terms of Te Tiriti o Waitangi compliance. These were developed in consultation with RANZCP.

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2. ***Are you also aware Pharmac's chief medical officer has said it is time to look at changing the criteria for prescribing ADHD medication? Would changing the criteria be something the government would consider?***

We are aware of this. Further to the ADHD Parliamentary hui held in August, Pharmac and the Ministry of Health agreed to look at changes to special authority rules and improving access to ADHD medicine by addressing issues with special authority renewal and considering new medicines not currently available in Aotearoa New Zealand, as outlined below:

- Pharmac is looking at the potential to review the current requirement for a Special Authority to be obtained from a paediatrician or psychiatrist every 2 years for medication to be continued.
- Pharmac has committed to improve awareness of the waiver that enables continued prescriptions after the authorisation period elapses in circumstances where there are long wait times to access a psychiatrist.
- Medsafe is progressing work on aligning the regulatory requirements for lisdexamfetamine for the treatment of ADHD with other commonly used ADHD medications, once it is scheduled as a controlled drug

Following the health reforms that took place in July 2022, Te Whatu Ora and Te Aka Whai Ora are responsible for commissioning and delivering health services within new localities across the country. There are opportunities for new localities to provide health services based on the needs of their local populations which includes services to improve support for people with ADHD.

Ngā mihi
Skara Bohny (she/her)
Senior Media Advisor, s 9(2)(a)
media@health.govt.nz
info for media: https://www.health.govt.nz/news-media/media-centre

Manatū Hauora, 133 Molesworth Street Wellington 6011

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From: Media
Sent: Tuesday, 10 January 2023 9:49 am
To: Skara Bohny; Media
Subject: RE: Media, Sophie Harris, Stuff, Challenges of ADHD medication

Kia ora Skara,

One small change:

1. ***Are you also aware Pharmac's chief medical officer has said it is time to look at changing the criteria for prescribing ADHD medication? Would changing the criteria be something the government would consider?***

We are aware of this. Pharmac is the government agency that makes decisions about access criteria for funded medicines, while Medsafe is the safety and quality regulator that assesses new medicines for availability in Aotearoa New Zealand. Further to the ADHD Parliamentary hui held in August, Pharmac and the Ministry of Health-[should this be Medsafe?] agreed to look at changes to special authority rules and improving access to ADHD medicine by addressing issues with special authority renewal and considering new medicines not currently available in Aotearoa New Zealand, as outlined below:

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Ngā mihi

Jane Wright | Senior Communications Advisor/Team Leader

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

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Sent: Tuesday, 10 January 2023 9:26 am
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Ngā mihi

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