From: David Hughes
Sent: Thursday, 26 January 2023 9:19 am
To: Joe Bourne; Anna Skinner
Subject: RE: Flu vaccination 2023

Kia ora Joe,
I raised the stimulants issue in the meeting and was a bit surprised to be told by Suzanne that Pharmac were not interested in this area. It was made clear that opioids were the focus of the meeting, despite the regulation changes including the stimulants. I shared Pharmac's view that it would be important to consider all the issues / concerns in the class B space and that we would want to implement changes as a whole rather than piecemeal.
My message to the sector about changes to stimulant prescribing is that it needs legal, clinical and health economic advice. The current regulatory requirement for written recommendation by a paediatrician / psychiatrist has led to the special authority renewal criteria placing a 2 year currency on the recommendation. This followed concerns from those specialists that their names were being used many years after the initial recommendation.
I think this would be an opportune time to review the need for the written specialist endorsement and consult broadly on any change proposed.

Ngā mihi,
David

From: Joe Bourne <Joe.Bourne@health.govt.nz>
Sent: Wednesday, 25 January 2023 6:02 pm
To: David Hughes <david.hughes@pharmac.govt.nz>; Anna Skinner <Anna.Skinner@health.govt.nz>
Subject: RE: Flu vaccination 2023

Hi David

Sorry to miss your email – just trying to get to things now.

If you were at the meeting yourself today you will have met @Anna Skinner and hopefully you were able to raise your concerns. Happy for either of you to contact me if there is something that I need to consider in more detail.

Joe

Dr Joe Bourne
FRNZCGP | MPH | MBChB
Chief Medical Officer
Ngā Āpiha Hauora | The Chief Health Officers
Manatū Hauora | Ministry of Health

From: David Hughes <david.hughes@pharmac.govt.nz>
Sent: Wednesday, 25 January 2023 8:53 am
To: Joe Bourne <Joe.Bourne@health.govt.nz>
Subject: RE: Flu vaccination 2023

Kia ora Joe,

Out of scope

Out of scope

On a different matter, are you going to the class B discussion this morning? I am a little concerned that stimulants have dropped off the agenda and given the interest in this area it would be good to seize the opportunity to discuss regulations and special authority criteria for this section of the class B medicines.

Ngā mihi,
David

From: Joe Bourne <Joe.Bourne@health.govt.nz>
Sent: Tuesday, 24 January 2023 7:38 pm
To: David Hughes <david.hughes@pharmac.govt.nz>
Subject: FW: Flu vaccination 2023

Out of scope

Joe

Dr Joe Bourne
FRNZCGP | MPH | MBChB
Chief Medical Officer
Ngā Āpiha Hauora | The Chief Health Officers
Manatū Hauora | Ministry of Health

From: Andrew Old <Andrew.Old@health.govt.nz>
Sent: Tuesday, 24 January 2023 5:41 pm
To: Joe Bourne <Joe.Bourne@health.govt.nz>
Subject: RE: Flu vaccination 2023

Out of scope

Dr. Andrew Old (he/him)
Deputy Director-General
Public Health Agency | Te Pou Hauroa Tūmatanui
s 9(2)(a) | andrew.old@health.govt.nz

From: Joe Bourne <Joe.Bourne@health.govt.nz>
Sent: Tuesday, 24 January 2023 4:23 pm
To: Andrew Old <Andrew.Old@health.govt.nz>
Subject: RE: Flu vaccination 2023

Out of scope

Joe

Dr Joe Bourne
FRNZCGP | MPH | MBChB
Chief Medical Officer
Ngā Āpiha Hauora | The Chief Health Officers
Manatū Hauora | Ministry of Health

From: Andrew Old <Andrew.Old@health.govt.nz>
Sent: Tuesday, 24 January 2023 10:49 am
To: Joe Bourne <Joe.Bourne@health.govt.nz>
Subject: RE: Flu vaccination 2023

Kia ora Joe,

Out of scope

Out of scope

Out of scope

Out of scope

Ngā mihi, Andrew

Dr. Andrew Old (he/him)
Deputy Director-General
Public Health Agency | Te Pou Hauroa Tūmatanui
s 9(2)(a) | andrew.old@health.govt.nz

From: Joe Bourne <Joe.Bourne@health.govt.nz>
Sent: Tuesday, 24 January 2023 9:49 am
To: Andrew Old <Andrew.Old@health.govt.nz>
Subject: Flu vaccination 2023

Kia Ora Andrew

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Out of scope

Ngā mihi

Joe

Dr Joe Bourne
FRNZCGP | MPH | MBChB
Chief Medical Officer
Ngā Āpiha Hauora | The Chief Health Officers

Manatū Hauora | Ministry of Health

Mobile/waea pūkoro: s 9(2)(a) | Email/**īmēra:** joe.bourne@health.govt.nz

From: David Hughes
Sent: Thursday, 26 January 2023 4:46 pm
To: John Zonnevylle; Diana Suggate
Cc: Kieran Moorhead
Subject: RE: Quick caatch-up re the second and third months of ADHD scripts

Kia ora tatou,

Following on from the discussion,
Here is the gazette notice from medsafe in 2011; Restriction on Supply of Methylphenidate-Approval to Prescribe, Supply and Administer (No. 2011/Meth/2) - 2011-go8541 - New Zealand Gazette
And update in 2015: Restriction on the Supply of Methylphenidate—Approval to Prescribe, Supply and Administer (Approval No.: 2015/AP001) - 2015-go760 - New Zealand Gazette

Ngā mihi,
David

From: John Zonnevylle <John.Zonnevylle@health.govt.nz>
Sent: Thursday, 26 January 2023 2:56 pm
To: Diana Suggate <Diana.Suggate@health.govt.nz>; David Hughes <david.hughes@pharmac.govt.nz>
Cc: Kieran Moorhead <Kieran.Moorhead@health.govt.nz>
Subject: RE: Quick caatch-up re the second and third months of ADHD scripts

Kia ora, I'm from now until end of day … I also have time available tomorrow between 10am and 3pm

John Zonnevylle (he/him)
Chief Clinical Advisor (Acting)
Mental Health & Addictions
System Performance & Monitoring|Te Pou Mahi Pūnaha
+64 4 496 2000 / s 9(2)(a)
John.Zonnevylle@health.govt.nz
Manatū Hauora, 133 Molesworth Street
Thorndon, Wellington 6011

For updates on our mahi in Mental Health and Addictions:
https://www.health.govt.nz/our-work/mental-health-and-addiction/updates-mental-health-and-addiction-directorate#subscribe

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From: Diana Suggate <Diana.Suggate@health.govt.nz>
Sent: Thursday, 26 January 2023 2:35 pm
To: David Hughes <david.hughes@pharmac.govt.nz>
Cc: Kieran Moorhead <Kieran.Moorhead@health.govt.nz>; John Zonnevylle <John.Zonnevylle@health.govt.nz>

Subject: Quick caatch-up re the second and third months of ADHD scripts
Importance: High

Could we do that this afternoon 3pm or thereafter? I'm available and hoping John and Kieran maybe too

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From: David Hughes <david.hughes@pharmac.govt.nz>
Sent: Thursday, 26 January 2023 2:27 pm
To: Diana Suggate <Diana.Suggate@health.govt.nz>
Cc: Kieran Moorhead <Kieran.Moorhead@health.govt.nz>
Subject: RE: Question about paying for the second and third months of ADHD scripts

Shall we set up a teams meeting?

Ngā mihi,
David

From: Diana Suggate <Diana.Suggate@health.govt.nz>
Sent: Thursday, 26 January 2023 1:55 pm
To: David Hughes <david.hughes@pharmac.govt.nz>
Cc: Kieran Moorhead <Kieran.Moorhead@health.govt.nz>
Subject: RE: Question about paying for the second and third months of ADHD scripts

Hi David I'd like to understand better what's going on here within MoH. I sent a message to Suzanne Townsend, but is there someone else I should be asking?
I'm aware the Health Committee on 15 February 2023 is discussing the response to Laura William's petition on ADHD, and it would be good to be well informed on activities given an oral submission must be made by MoH.
Many thanks

From: David Hughes <david.hughes@pharmac.govt.nz>
Sent: Thursday, 26 January 2023 9:51 am
To: Suzanne <suzanne@adhd.org.nz>
Cc: ADHD New Zealand <info@adhd.org.nz>; Diana Suggate <Diana.Suggate@health.govt.nz>; Darrin Bull <darrin@diffusion.co.nz>
Subject: RE: Question about paying for the second and third months of ADHD scripts

Kia ora Suzanne,

The Ministry of Health has asked Pharmac not to implement the changes to the schedule planned for February 1. This will allow the MoH, Medsafe and Pharmac to consider the substantial feedback from the sector on the regulatory and schedule changes proposed in the consultation across all Class B medicines.

Ngā mihi,
David

From: Suzanne <suzanne@adhd.org.nz>
Sent: Thursday, 26 January 2023 9:29 am
To: David Hughes <david.hughes@pharmac.govt.nz>
Cc: ADHD New Zealand <info@adhd.org.nz>; Diana Suggate <Diana.Suggate@health.govt.nz>; Darrin Bull <darrin@diffusion.co.nz>
Subject: Re: Question about paying for the second and third months of ADHD scripts

Morning David

A further question, is it correct that changes to the Pharmaceutical Schedule will come into effect on 1 Feb 2023 and from that point on the second and third months on a 3 months e-script for ADHD medication will be subsidised? If 1 Feb is not a firm date, could you please update me on the status of the proposed changes to the Schedule.

I'm looking at this page on the Pharmac website

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/

As I'm sure you know, many children take a meds-holiday over summer and this means there will be an increase in scripts dispensed in the next week or so. I've talked to pharmacists, specialists and families and there is much confusion!

Thanks
Suzanne

From: David Hughes <david.hughes@pharmac.govt.nz>
Date: Friday, 20 January 2023 at 3:23 PM
To: Suzanne <suzanne@adhd.org.nz>
Cc: ADHD New Zealand <info@adhd.org.nz>, Diana Suggate <Diana.Suggate@health.govt.nz>
Subject: RE: Question about paying for the second and third months of ADHD scripts

Kia ora Suzanne,
Here is our prepared statement going out to prescribers:

Pharmaceutical Schedule funding rules on prescribing and dispensing of Class B controlled drugs

Manatū Hauora, the Ministry of Health, have asked Pharmac to delay making a decision on the proposed changes to the Schedule funding Rules for Class B controlled drugs.

What this means:
Although the legislative changes for Class B controlled drugs came into effect on 22 December 2022, the Schedule Rules on prescribing and dispensing of Class B controlled drugs have not changed. This means a quantity sufficient to provide treatment for a period of up to 1 month in total will be subsidised.

Further information can be found on our website: Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs - Pharmac | New Zealand Government

Ngā mihi,
David

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

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

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From: Suzanne <suzanne@adhd.org.nz>
Sent: Friday, 20 January 2023 2:29 pm
To: David Hughes <david.hughes@pharmac.govt.nz>

Cc: ADHD New Zealand <info@adhd.org.nz>; Diana Suggate <Diana.Suggate@health.govt.nz>
Subject: Question about paying for the second and third months of ADHD scripts

Kia ora David

Happy New Year and I hope you have had a relaxing break.

We are getting quite a few questions about the changes under the Misuse of Drugs Amendment Regulations 2022. People with ADHD are now receiving a three month script for stimulant medication. However, when they turn up at the pharmacy to get their second month and third month script fulfilled they are being charged about $100 a time. As you can imagine this is causing some confusion and stress when faced with the unexpected expense.

Do you have some suggested comms we can send out across our channels to clarify? Would the below wording work?

Why am I being charged for the second and third months of my three month prescription for my ADHD medication?

Changes to the Misuse of Drugs regulations at the end of 2022 allowed prescribers to issue a prescription for up to three months for ADHD stimulant medication. However, the rules of the Pharmaceutical Schedule did not change and that means only one month at a time can be subsidised. This many change in future, but for the moment it is best to stick to one month scripts at a time to avoid paying the unsubsidised amount for the second and third months.

Many thanks
Suzanne

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This e-mail message has been scanned for Viruses and Content and cleared by the Ministry of Health's Content and Virus Filtering Gateway

From: David Hughes
Sent: Thursday, 26 January 2023 3:02 pm
To: John Zonnevylle; Diana Suggate
Cc: Kieran Moorhead
Subject: RE: Quick caatch-up re the second and third months of ADHD scripts

Free now – meeting ended early

Ngā mihi,
David

From: John Zonnevylle <John.Zonnevylle@health.govt.nz>
Sent: Thursday, 26 January 2023 2:56 pm
To: Diana Suggate <Diana.Suggate@health.govt.nz>; David Hughes <david.hughes@pharmac.govt.nz>
Cc: Kieran Moorhead <Kieran.Moorhead@health.govt.nz>
Subject: RE: Quick caatch-up re the second and third months of ADHD scripts

Kia ora, I'm from now until end of day … I also have time available tomorrow between 10am and 3pm

John Zonnevylle (he/him)
Chief Clinical Advisor (Acting)
Mental Health & Addictions
System Performance & Monitoring|Te Pou Mahi Pūnaha
+64 4 496 2000 / s 9(2)(a)
John.Zonnevylle@health.govt.nz
Manatū Hauora, 133 Molesworth Street
Thorndon, Wellington 6011

For updates on our mahi in Mental Health and Addictions:
https://www.health.govt.nz/our-work/mental-health-and-addiction/updates-mental-health-and-addiction-directorate#subscribe

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Sent: Thursday, 26 January 2023 2:35 pm
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Cc: Kieran Moorhead <Kieran.Moorhead@health.govt.nz>; John Zonnevylle <John.Zonnevylle@health.govt.nz>
Subject: Quick caatch-up re the second and third months of ADHD scripts
Importance: High

Could we do that this afternoon – 3pm or thereafter? I'm available and hoping John and Kieran maybe too

From: David Hughes
Sent: Thursday, 26 January 2023 2:55 pm
To: Diana Suggate
Cc: Kieran Moorhead; John Zonnevylle
Subject: RE: Quick caatch-up re the second and third months of ADHD scripts

In a meeting til 3.30.

Ngā mihi,
David

From: Diana Suggate <Diana.Suggate@health.govt.nz>
Sent: Thursday, 26 January 2023 2:35 pm
To: David Hughes <david.hughes@pharmac.govt.nz>
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Sent: Thursday, 26 January 2023 9:51 am
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Cc: ADHD New Zealand <info@adhd.org.nz>; Diana Suggate <Diana.Suggate@health.govt.nz>; Darrin Bull <darrin@diffusion.co.nz>
Subject: RE: Question about paying for the second and third months of ADHD scripts

From: Meg Larken <Meg.Larken@health.govt.nz>
Sent: Tuesday, 31 January 2023 11:21 am
To: Anna Skinner; Suzanne Townsend; Michael Haynes; Trevor Lloyd; Andi Shirtcliffe; Teei Kaiaruna; Rawiri McKree Jansen; David Hughes; Melissa Copland; Shaheeda Othman; Billy Allan; John Crawshaw; Eddy Sommers; Annie Hindle
Subject: Access to opioids WG - minutes of first meeting 25 January 2023
Attachments: Meeting minutes 25 January 2023 - Safe Access to opioids working group.docx; Medsafe Monitoring Activities.pptx; 2023-01 Themed feedback Pharmac CD consultation - for working group.pdf

Kia ora koutou,

Please see attached the minutes, slides on Medsafe Monitoring Activities (thank you Michael), and feedback from Pharmac consultation (thank you David).

Kind regards,

Meg Larken (she/her)
Senior Policy Analyst
Regulatory Policy, Te Pou Rautaki
s 9(2)(a)
meg.larken@health.govt.nz
s 9(2)(a)
Manatū Hauora, 133 Molesworth Street, Wellington

Minutes

Safe access to opioids working group

Date: 25 January 2023

Time: 9.30-11.30

Location: 3S.1 133 Molesworth Street, Microsoft Teams

Chair: Anna Skinner (Manatū Hauora)

Attendees: Michael Haynes (Manatū Hauora), Billy Allan (Te Whatu Ora), Rawiri McKree Jansen (Te Aka Whai Ora), Annie Hindle (Te Aka Whai Ora), David Hughes (Pharmac), Melissa Copland (Pharmac), Andi Shirtcliffe (Manatū Hauora), John Crawshaw (Manatū Hauora), Shaheeda Othman (HQSC), Suzanne Townsend (Manatū Hauora), Trevor Lloyd (Te Whatu Ora)

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

Apologies: Teei Kaiaruna (Te Aka Whai Ora), Anna-Lee Annett (Te Aka Whai Ora)

Item	Notes
1	**Welcome, introductions and apologies**
2	**Agree Terms of Reference** It was agreed that members of the group should arrange for a delegate from their organisation to attend meetings if they can't attend. It was agreed that there be a quorum if one member from each agency is present. David Hughes raised a query about the scope of the project and whether it should include Class B controlled stimulants (for ADHD), noting that it would be good to have a consensus on the prescribing and dispensing rules for these medicines. The group discussed this and there was some agreement to include stimulants in the project. On the other hand, the Chair noted that the directive from the Director-General was to look at opioids at speed and it was a sizeable piece of work. Suzanne Townsend noted that there was a separate workstream underway on stimulants, which we could enquire about and report back to the group. The group agreed to await this information. It was suggested that if stimulants are not to be considered by this working group then that should be clearly communicated to interested stakeholders.
3	**Background paper** Suzanne outlined the paper and asked for the group to provide feedback, and if more information was needed. David said he would share with the group the feedback Pharmac had received from the sector on their recent consultation round. He also shared the original 1991 notice from the

	Department of Health directing for 10-day dispensing, noting that there was no reason given other than it aligned with pack sizes.
4	**New Zealand context and issues** The Chair asked the group what was different about New Zealand compared with other countries with regard to opioids. Andi Shirtcliffe highlighted the different drug use profile in NZ. John Crawshaw also noted NZ's lower illicit opiate use. The Opioid Substitution Treatment (OST) services regulate themselves well, being careful about takeaways. NZ has not been influenced by practices in the US promoted by pharmaceutical companies. In contrast, Tasmania had a problem with a high death rate due to over-prescribed opioids, and measures to address this included the introduction of real-time monitoring alerts, which reduce the risk of doctor shopping. Another important measure is education of doctors. There was a discussion about what factors or limits in the current system keep prescribing of opioids under control. Comparison with peers is influential to doctors. Currently GPs can get BPAC comparisons on their prescribing, but this data is not centrally monitored. Rawiri McKree Jansen said that if clinicians get the message that three-month prescribing is the maximum, they will likely do three-month prescribing. The metaphor came up of people driving to the speed limit on the roads. Once people know there are longer prescriptions available, this will increase the risk that patients will be put under pressure to divert. There was discussion about the need to have proportionality and nuance in the system, to balance the need for safety with the need for access, especially at end of life. The system needs to take into account that different populations need different approaches.
5	**Medsafe's monitoring activities** Michael Haynes presented slides on Medsafe's monitoring and compliance activities. There are currently approximately 1400 individuals subject to restriction notices. These are people known to be seeking drugs. The notices are about the safety of the individual and do not address diversion. "Privileged statements" and prescribing prohibitions (involving the responsible authorities) are rarely used. There was discussion about data gaps in the system and the potential to fill these in the future. For instance, currently pharmacists can look up if someone is subject to a restriction notice, but in future the pharmacist could get an alert at the time of dispensing.
6	**NZ Electronic Prescribing System (NZePS) and Medicines Data Repository (MDR)** Trevor discussed slides on the NZEPS. Currently, it captures all dispensing, and 70% of prescriptions (this is expected to increase). The new MDR is set to take over monitoring from the old Lotus Notes system in June 2023. It will have a range of real-time data capabilities. The limitations are about the availability of data analysts and other resourcing. In the long-term, the system has the capability to support proactive monitoring and AI. There was discussion about how to set up the new system so that we can tell when something questionable was happening, eg prescribing opioids for non-cancer pain. Can we do "frequency distribution analyses" to see patterns emerging? Trevor answered yes, there is much that is technically possible in this space, and they first need someone to come up with the questions. The Chair suggested that the group could come up with a set of questions.

	Andi suggested the group needs to communicate to clinical leaders what we are progressing re timely monitoring (across the board and targeted). Andi also said we should understand what the strict controls mean for patients in the practical sense. Suzanne asked whether prescribers can currently get information about prescribing patterns when they are with a patient. The answer is no, not across all boundaries. In Australia there is a system called Safescript, which is not in NZ yet, but Trevor said we have the potential to have it. There was discussion about possible improvements that could be made to the system through the MDR, or questions asked of the MDR: • Melissa Copland asked whether indication data can be included. Trevor said prescribers are not consistently adding indications or codes. • Anna raised the issue of Pharmacists "dispensing" medicines without the patient having physically received them. Trevor said that capturing collection is something the system can do, however 1-2 years away. • Should all opioid prescribers be required to use electronic prescribing? • What proportion of individuals are getting high dose prescriptions? • Can there be "pauses" and non-regulatory controls added through the system in relation to opioids and other high-risk prescribing? • Can we start monitoring now the impacts of the regulation change, eg the numbers of patients should not change, and if there are more 30-day scripts, the number of prescriptions should decrease.
7	**Next steps** The Chair asked the group what the priorities are for further work and for the next agenda: • Return to the subject of stimulants • Real-time data – what data is wanted from the new MDR system now? • More information about Australia regulation (Safescript). • Discuss how to consult/engage more widely. It was agreed to meet in a fortnight.

Item	Action	Lead	Due Date
1.	Report back at next meeting on work underway re stimulants	Suzanne	
2.	Circulate recent feedback received by Pharmac	Secretariat	
3.	Circulate the slides on Medsafe's monitoring and the NZePS	Secretariat	
4.	Initial data request for the MDR – recent opioid prescribing	Trevor	
5.	Contact regulators in Australia to discuss their approach, particularly around real time prescribing information (Safescript)	Secretariat	
6.	Michael to report back on Medsafe's requirements for using MDR	Michael	

MEDSAFE
New Zealand Medicines and Medical Devices Safety Authority

Safe Access to Opioids Working Group

Medsafe Monitoring Activities

Michael Haynes, Manager & Licensing Authority
Medicines Control Branch

25 January 2023

Te Kāwanatanga o Aotearoa
New Zealand Government

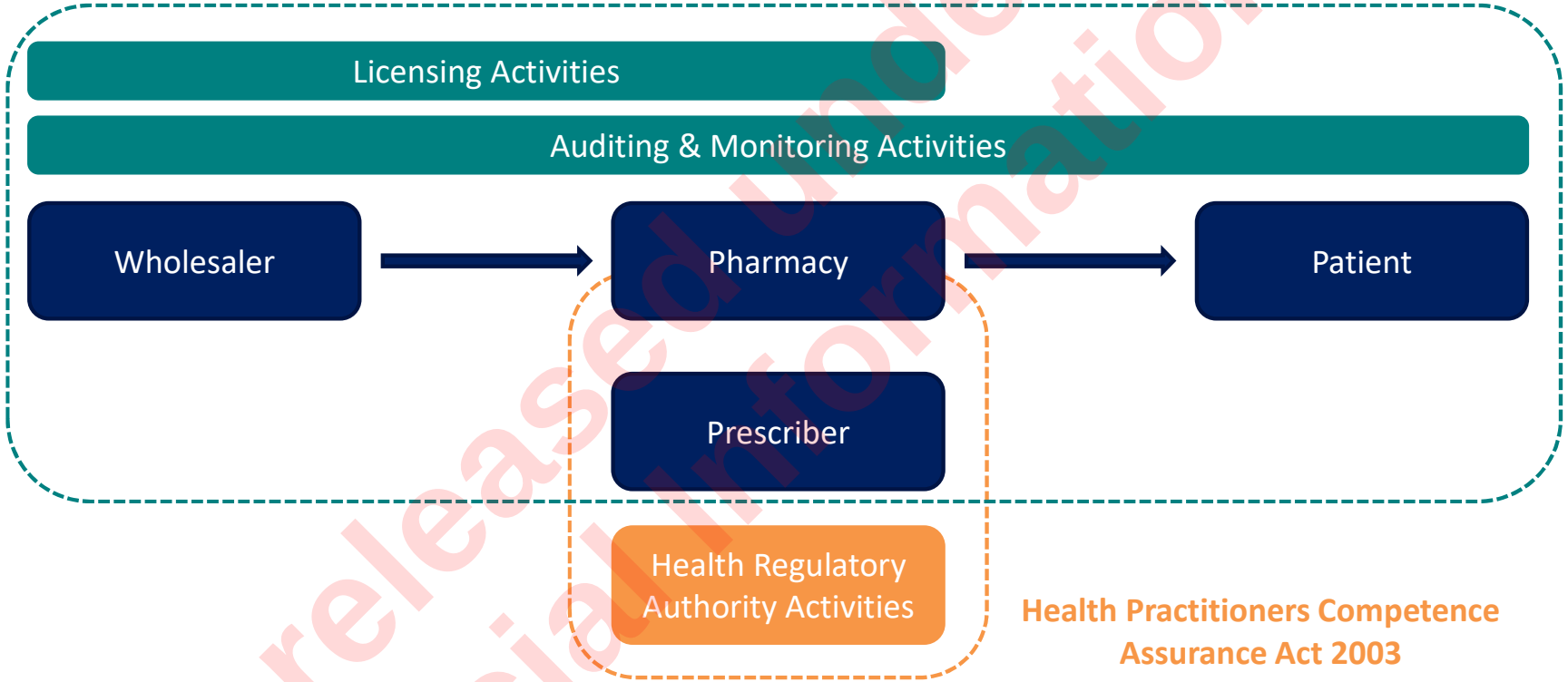
MANATŪ HAUORA

Medsafe

- New Zealand Medicines and Medical Devices Safety Authority
- Responsible for regulating therapeutic products
- Public safety
- A role in administering most aspects of the Medicines Act, Misuse of Drugs Act and their associated Regulations
- Medicines Control branch is responsible for regulating the supply chain of medicines and controlled drugs in New Zealand
- Includes monitoring of prescribing and dispensing activities, with statutory powers
- Medical Officer of Health

Medicines Supply Chain

Medicines Act 1981
Misuse of Drugs Act 1975



Health Practitioners Competence Assurance Act 2003

Examples of Prescribing Issues

- Inappropriate prescribing can be complex, for example:
  - Indiscriminate (not following clinical pathways)
  - Excessive
  - Continuing for longer than clinically necessary
  - Reckless
  - Illegal (practitioners subject to suspension/restrictions on prescribing;
- Treatment of dependency (section 24 MODR)
- Prescribing driven by "patient pressure"
- Patient identity
- *Essential prescribing consideration – is prescribing of this medicine/controlled drug clinically appropriate for the patient under my care?*

Medsafe Toolkit

- **Monitoring of prescribing and dispensing activities**
  - Statutory power
  - Electronic prescription monitoring database
- **Statutory powers to request & access information**
  - Medical Officer of Health (regulations 44B MR & 35 MODR)
  - Medsafe Officers (auditing activities of licence holders)
- **Restriction notices**
  - Medical Officer of Health
  - Issued to restrict prescribing activities relating to a specified individual
- **Privileged statements**
  - Medical Officer of Health
- **Prescribing prohibitions**
  - Minister of Health (administered by Medsafe; delegation held by DG)

Monitoring Capabilities (Current)

- **Electronic Prescription Monitoring (EPM) Database**
  - Medsafe system (direct access)
  - Class A and Class B controlled drugs
  - Established early 1990's
  - Decommissioning in progress (Lotus Notes)

- **Pharmaceutical Warehouse Data**
  - External to Medsafe (indirect access)
  - Prescription medicines

- **Limitations**
  - Case specific queries based on an identified/reported concern, issue or risk.
  - Limited capabilities of the EPM Database (including time lag).
  - Resourcing.

Monitoring Capabilities (June 2023)

- **Medicines Data Repository (MDR)**
  - External system (direct access).
  - All medicines and controlled drugs (NZePS data).
  - Real-time data.
  - Ability to readily search large quantities of data across individuals, prescribers, pharmacies and medicines.
  - Ability to create intuitive queries (e.g. active monitoring of known issues).

- **Limitations**
  - Access to data analysts with expertise in writing queries (building capability and capacity).
  - Hosted processing capacity.
  - Resourcing (including administrative, technical and clinical).

Monitoring Capabilities (Longer Term)

- **Medicines Data Repository (MDR)**
  - Fully functional system to support monitoring activities.
  - Development of complex queries to increase proactive identification of prescribing issues.
  - Automated monitoring.
  - Supported by artificial intelligence capabilities.

- **Limitations**
  - Access to data analysts.
  - Hosted processing capacity.
  - Resourcing (including administrative, technical and clinical).

Examples of Interfaces with Other Roles & Functions

- **Health Regulatory Authorities**
  - Professional practice standards (including prescribing)
  - Code of ethics
  - Scopes of practice (including conditions)
- **Professional Membership Organisations**
  - Education and support
- **Te Whatu Ora**
  - Audit & Compliance functions
- **New Zealand Police**
  - Criminal activities

Responding to Prescribing Issues

- A "trigger".
- Request & access information.
- Engagement with health practitioners required?
- Technical and/or clinical assessment.
- Decision on next steps (toolkit options).
- Engagement and/or referral to other regulatory authorities required?
- Apply Medsafe statutory powers?
- Monitor and assess – assurance that issue is resolved.
- Next steps.

Minutes

Safe access to opioids working group

Date: 10 February 2023

Time: 2-3 pm

Location: 133 Molesworth Street, Microsoft Teams

Chair: Anna Skinner (Manatū Hauora)

Attendees: Michael Haynes (Manatū Hauora), Billy Allan (Te Whatu Ora), Anna-Lee Annett (Te Aka Whai Ora), David Hughes (Pharmac), Melissa Copland (Pharmac), Andi Shirtcliffe (Manatū Hauora), John Crawshaw (Manatū Hauora), Trevor Lloyd (Te Whatu Ora)

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

Apologies:

Suzanne Townsend (Manatū Hauora), Shaheeda Othman (HQSC). Rawiri McKree Jansen (Te Aka Whai Ora).

Item	Notes
1	**Welcome, karakia, introductions and apologies**
2	**Actions from last minutes** Eddy updated the group on the situation with ADHD policy. Pharmac are looking at reviewing their requirement for re-diagnosing every two years, with MHA in support. There was discussion about the need to clarify who can diagnose and how often. Anna said that equity and access issues are pertinent, since some people have to go to the private sector, which costs hundreds of dollars. John noted that a diagnosis often involves a multi-disciplinary assessment.
3	**Medsafe monitoring activities and the Medicines Data Repository (MDR)** Michael Haynes discussed his paper on Medsafe's requirements for using the MDR (managed by Te Whatu Ora) to support monitoring activities. The MDR is on track to be implemented in June 2023 (based on current data analyst capacity), at which point the current electronic prescription monitoring system will be decommissioned. The MDR will collect real-time data and will have the ability to readily search large quantities of data across individuals, prescribers, pharmacies and medicines. More resource is needed to achieve comprehensive monitoring in a way that could form part of the regulatory system (ie identifying signals that can be assessed to determine if

	action is needed, as part of a proactive approach). Medsafe estimates that a dedicated data analyst is needed and an additional advisor. The group discussed the possibilities, and the need to get it resourced. There is a need to understand current patterns and have early signals of harms/concerns. It will be important to capture indication data, in order to identify what prescribing is of concern and needs follow up. There is some poor prescribing happening, with the 10-day dispensing rule keeping it under control. We need robust national guidance linked to a cohesive regulatory system.
4	**Regulatory options** Eddy briefed the group on our recent instructions to report back to the Director-General shortly on the short and long term options and a consultation plan, incorporating the working group's advice. We are working on an options paper, which will be circulated to the group for comment. The longer term proposed option is to develop a system based around a code of practice or standard linked to the MDR's monitoring powers, eventually incorporating the code into the Therapeutic Products Bill's framework. We need to address if a short-term option is also needed, ie a "quick fix" reversal of the November change to the regulations (which would take until June/July to reverse at the earliest). Other changes to the regulations could also be made at the same time but may take longer. Eddy asked if there is an immediate risk that would support a "quick fix" option? And who should we consult with? Caroline suggested we needed more evidence of the problem and asked what has been put in place to monitor the risk. Trevor replied that we can run reports and queries so that any trends can be identified. There was discussion about the controls in Australia (eg a requirement to get approval to prescribe more than 28 days). Eddy mentioned that he and Meg are meeting with the TGA to find out more about their system and we will report back. John mentioned that he will be meeting with Australian psychiatrists early March. With regard to consultation, Anna mentioned dentists. David mentioned Pharmac have an Analgesic Advisory Committee. With regard to risks, Anna noted that the risk factors have not changed because Pharmac's rules are still in place. Melissa said an unfunded prescription is only $30 per month. There was general agreement that there were risks from lax prescribing practices or lack of coordination when the old regulations were in place, and these risks continue. A move to a nuanced, cohesive system of controls is wanted. Meg suggested the secretariat work with Trevor to draft up data queries with a view to producing regular reporting to identify trends and areas for further analysis, including ethnicity data. Melissa said Pharmac has data on dispensing rates that she will share with us.
7	**Next steps** A further meeting will be scheduled.

Item	Action	Lead	Due Date
1.	Circulate Michael's report on the MDR	secretariat	
2.	Draft options paper to be circulated for comment	secretariat	
3.	Eddy and Meg to meet with TGA and report back	secretariat	
4.	Draft data request to be circulated with the group for comment	Secretariat and Trevor	

5.	Pharmac data on dispensing to be shared	Melissa	
7.	Action from last minutes: Initial data request for the MDR – recent opioid prescribing	Trevor/Secretariat	
7.			