From: Belinda Ray-Johnson
Sent: Wednesday, 9 November 2022 9:55 am
To: David Hughes; Jayne Watkins
Subject: Controlled drug legislation and Schedule rules changes

Kia ora David and Jayne

Ministry of Health – Manatū Hauora is planning to make to some legislative changes to controlled drugs that will require some Schedule rules changes to align with this.

Please share this information within Medical as appropriate.

Also, please could you nominate someone from the team for me to engage with on documentation review. Unfortunately the timeframes are tight, therefore likely to require a quick turn around if the legislative amendments occur as per the dates below.

What's happening

There is a draft Cabinet paper for the Cabinet Legislation Committee to bring into effect amendments to the Medicines Regulations 1984 and the Misuse of Drugs Regulations 1977.

The effects of this will be to:

- Enable controlled drug medicines to be prescribed electronically via the New Zealand Electronic Prescribing System (NZePS)
- Allow prescriptions for Class B controlled drugs (opioids, methylphenidate, dexamfetamine) drugs to be prescribed for greater periods than currently - three months instead of one month if the prescription is issued electronically via NZePS
- Paper prescriptions will retain the current limits
- Class B and Class C controlled drug dispensing frequency, when issued in the NZePS, will be monthly unless otherwise specified by the prescriber
- Prescribers will still be able to specify more frequent dispensing under a "Prescription to protect patient or limit quantity in possession" clause

The Ministry have consulted with NZ Police, Customs and the Ministry of Justice on these proposed amendments and, once notified in the Gazette, plan to communicate directly with the impacted health practitioners to ensure they are aware of the new regulations and the implications.

When's it happening

- The Ministry are planning for this come into force on 22nd Dec (soon!)
- Ideally we would want proposed subsidy rule changes to come into force as soon as possible after the legislation to avoid there being a period when there's gap between what the legislation and the subsidy rules allow
- If we have the gazetted changes by end of November, we might be in a position to consult first two weeks in December
- The earliest we are likely to be able to enact the changes in the Schedule is 1 February

Please feel free to give me a shout with any questions.

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: +64 4 460 4990| M: s 9(2)(a) www.pharmac.govt.nz

From: Belinda Ray-Johnson
Sent: Friday, 25 November 2022 2:00 pm
To: Doris Chong
Cc: Kaye Wilson
Subject: RE: Legislative change around Category B Controlled Drugs

Hi Doris

yes those questions are addressed in the consult so if we could just let him know we are aiming to release something on Monday.

Thanks

B

From: Doris Chong <doris.chong@pharmac.govt.nz>
Sent: Friday, 25 November 2022 1:48 pm
To: Belinda Ray-Johnson <belinda.ray-johnson@pharmac.govt.nz>
Cc: Kaye Wilson <Kaye.Wilson@Pharmac.govt.nz>
Subject: FW: Legislative change around Category B Controlled Drugs

Hiya

Looks like Andrew from Toniq is one step head.

Are you happy with me going back to Andrew and letting him know we are finalising a consult which is being released on Monday which will address rule 4.4.1 and we are looking at Schedule rule changes from February next year?

Thanks
Doris

From: Andrew Shaw <s 9(2)(a)>
Sent: Friday, 25 November 2022 1:22 pm
To: Doris Chong <doris.chong@pharmac.govt.nz>
Cc: Luke Tilson <s 9(2)(a)>
Subject: RE: Legislative change around Category B Controlled Drugs

Hi Doris,

Sorry sent that too soon. The 10/10/10 supply rule is set out by 4.4.1 of the General rules of the schedule. Will these be amended prior to the legislative changes come into effect and will pharmacies be able to claim for these changes past the 22nd of December?

Kind regards,

Andrew Shaw
Clinical Product Owner | Pharmacist, M.ClinPharm(*Dist.*), MPS

TONIQ
A Clanwilliam Company

Phone +64 (3) 341 0195
Level 1, 72 Moorhouse Avenue, Addington, Christchurch 8011, New Zealand
PO Box 8831, Riccarton, Christchurch 8440

www.toniq.nz

From: Andrew Shaw
Sent: Friday, 25 November 2022 1:16 pm
To: Doris Chong <doris.chong@pharmac.govt.nz>
Subject: Legislative change around Category B Controlled Drugs

Hi Doris,

I hope you're well. We have been sent a notification that the expected changes to Category B Controlled Substances has been gazetted yesterday (coming into effect on the 22nd of December); these allow pharmacies to supply category B controlled drugs for up to 3 months if pursuant to an electronic prescription and must be supplied at monthly or shorter intervals.

I am keen to understand the implications from a claiming perspective. Currently, the default is to supply medications like morphine in 10 day increments – I am trying to ascertain where this is specifically set but from my understanding is the default. Will the expectation of this change be that pharmacies will typically be supplying in monthly amounts unless the prescriber (or pharmacist) states otherwise?

Kind regards,

Andrew Shaw
Clinical Product Owner | Pharmacist, M.ClinPharm(*Dist.*), MPS

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Level 1, 72 Moorhouse Avenue, Addington, Christchurch 8011, New Zealand
PO Box 8831, Riccarton, Christchurch 8440

www.toniq.nz

Consultation

PHARMAC
TE PĀTAKA WHAIORANGA

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

28 November 2022

What we're proposing

We are seeking feedback on a proposal to amend the Pharmaceutical Schedule General Rules (the Schedule Rules) to bring funding in line with legislative changes to the prescribing and dispensing of controlled drugs.

Submitters should note that this consultation does not seek feedback on the changes in the Medicines Amendment Regulations 2022 and the Misuse of Drugs Amendment Regulations 2022. We note decisions on these regulatory changes have been confirmed, and this proposal relates to supporting that change within the Pharmaceutical Schedule.

Consultation closes at **5 pm on 9 December 2022** and feedback can be emailed to consult@pharmac.govt.nz.

What would the effect be?

This proposal means that people in the community could:

- Be prescribed funded Class B controlled drugs for three months, instead of one month, when an electronic prescription is used. The amount that could be prescribed on a paper prescription would stay as one month.
- Collect Class B controlled drugs from the pharmacy in monthly lots, when an electronic prescription is used (or as a single monthly lot on a paper prescription), unless the prescriber directs dispensing in smaller quantities.

Under the current Schedule Rules, people generally have Class B controlled drugs dispensed at ten-day intervals, with the exception of methylphenidate and dexamfetamine, which may be dispensed in a single monthly lot.

While the change from ten day dispensing to monthly dispensing would increase the amount of a Class B controlled drug able to be given to a person per visit, the total amount being dispensed would not change.

Who we think will be interested

- People who are prescribed controlled drugs, their caregivers, whānau and communities
- Prescribers authorised to prescribe controlled drugs (doctors, nurse practitioners, midwives, dentists, registered nurse prescribers, pharmacist prescribers)
- Pharmacists
- Pharmaceutical suppliers and wholesalers

About this proposal

On 22 December 2022 the Medicines Amendment Regulations 2022 and the Misuse of Drugs Amendment Regulations 2022 will come into force.

This amends the law to enable controlled drugs to be prescribed electronically and, for some controlled drugs, the amount of drug that can be on a single prescription will be increased when using the New Zealand Electronic Prescription Service (NZePS).

Before 22 December 2022, the Misuse of Drugs Act 1975 and Misuse of Drugs Regulations 1977 mean that prescriptions for Class B controlled drugs can legally only be written for a supply of up to one month. The Schedule Rules allow supply for up to one month on a prescription, with dispensing in ten day lots (with the exception of methylphenidate and dexamfetamine, which may be dispensed in a single monthly lot).

This proposal is intended to align funding rules more completely with the updated legislation, by allowing funded prescriptions for Class B controlled drugs to be written for up to three months. In addition, we would be removing the requirement for dispensing in ten day lots, as this is inconsistent with the Regulations.

Why we're proposing this

The legislative changes that will come into force on 22 December 2022 permit Class B controlled drugs to be prescribed for up to three months on a single prescription (depending on the scope of practice of the prescriber) with dispensing in monthly lots, unless smaller amounts are directed by the prescriber. However, the current Schedule Rules for Class B controlled drugs do not allow these medicines to be funded when prescribed or dispensed in this way.

Reducing the frequency prescribers need to issue prescriptions for Class B controlled drugs, when issued through the NZePS, will reduce the number of times people need to visit a prescriber for repeat prescriptions of medications for some chronic conditions, like ADHD. Removing the ten-day dispensing rule from the Schedule would reduce the number of times people need to collect other Class B controlled drugs from a pharmacy, and removes the inconsistency between the Schedule Rules and the Misuse of Drugs Regulations.

These changes would affect the following medicines listed in Section B of the Pharmaceutical Schedule:

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

Details about our proposal

We are proposing the following changes to the General Rules (Section A) of the Pharmaceutical Schedule from 1 February 2023. Only relevant parts of the rules are shown, with changes in bold and strikethrough:

Part 1 – Prescribing and initiating Subsidies for Community Pharmaceuticals

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

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

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

Part 4 – Community Pharmaceutical Dispensing Quantities for Subsidy

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

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

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

4.4.2 A Community Pharmaceutical**, other than a Class B Controlled Drug** may be dispensed in one Lot in the following circumstances:

a a patient or their representative signs the Prescription to qualify for single Lot dispensing. In signing the Prescription, the patient or their nominated representative must certify which of the following criteria the patient meets:

i they have limited physical mobility
ii they live and work more than 30 minutes from the nearest pharmacy by their normal form of transport
iii they are relocating to another area, or
iv they are travelling and will be away when the repeat Prescriptions are due.

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

4.4.3 Community Pharmaceuticals**, other than Class B Controlled Drugs,** identified in the Schedule without the ❊ symbol (where default dispensing is Monthly Lots) and prescribed in a quantity sufficient to provide treatment for more than 1 Month may be dispensed in variable dispensing periods under the following conditions:

a for stock management where the proprietary pack(s) result in dispensing greater than 30 days' supply
b to synchronise a patient's medication where multiple medicines result in uneven supply periods, or
c when the total quantity and dispensing period does not exceed the total quantity and period prescribed on the Prescription.

Part 5 – Community Pharmaceutical Modified Dispensing Quantities

5.2 Residential care: Community Pharmaceuticals**, other than Class B Controlled Drugs,** may be dispensed in modified dispensing quantities to a person whose placement in a Residential Disability Care Institution is funded by the Ministry of Health or Health NZ, or to a person residing in an Age Related Residential Care Facility, on the request of the person, their agent or caregiver provided that the following conditions are met:

5.2.1 The quantity or period of supply to be dispensed at any one time must not be less than:
~~a 7 days' supply for a Class B Controlled Drug, or~~

The legislation requires the prescriber to specify dispensing frequency of Class B controlled drugs. Therefore pharmacist adjustment of dispensing frequency would not apply to Class B controlled drugs under this proposal. Specifically, this applies to Parts 4 and 5 of the Schedule Rules in relation to:

- Long Term Conditions registered patients
- synchronisation of medicines
- single lot dispensing due to patient circumstances
- people in residential care

There are no changes proposed to PSO and BSO requirements for Class B controlled drugs as these are unaffected by the legislative changes.

There are no changes proposed to the rules for the use of Class B controlled drugs in Te Whatu Ora - Health New Zealand hospitals.

Although the legislative changes come into force on 22 December 2022, we propose to implement any changes to the Schedule Rules from 1 February 2023. This is to allow:

- sufficient time for technical and system changes to occur
- pharmacies to consider their controlled drug stockholding and storage requirements
- suppliers to ensure there is sufficient stock in the supply chain to meet any initial increase in demand for funded Class B controlled drugs

The current Schedule Rules will apply to the funded prescribing and dispensing of Class B controlled drugs between 22 December 2022 and the implementation date of any changes to the Schedule Rules.

To provide feedback

Send us an email: consult@pharmac.govt.nz by **5 pm on 9 December 2022**.

All feedback received before the closing date will be considered by Pharmac prior to making a decision on this proposal.

This consultation process is limited to feedback relating to Pharmac's proposal to amend Pharmaceutical Schedule funding rules. Submitters should note that the consultation does not cover the changes to the Misuse of Drugs Amendment Regulations 2022 and Medicines Amendment Regulations 2022 legislation; these fall outside Pharmac's scope of responsibility.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in

a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. Pharmac will give due consideration to any such request.

Pharmac Consultation Groups

Please use the checkbox ☐ in the left column to indicate which groups you would like your consultation to be sent to below, any additional emails to be sent out please list separately on page 2.

Before communicating below need to:

1. Send comms to Adam so he can communicate with specific suppliers (Fiona)
2. Letter to chair of subcommittees (via David) cc Caro, Adrienne, Emma, Ben G (Fiona to action)
    a. Analgesic Advisory Committee
    b. Mental Health Advisory Committee.
3. Call Chris Jay (Fiona/Sean) 04 802 0036

	Below Therapeutic Group are sent via MailChimp:
☐	Alimentary Tract & Metabolism
☐	Allergies
☐	Blood & Blood Forming Organs
☐	Cardiovascular System
☐	Cardiovascular System Renal
☒	Colleges & Professional Societies
☐	Consumer Group
☐	Dermatological
☐	Diabetes
☐	Genito-Urinary System
☐	Hormone Preparations
☐	Immunisation
☐	Immunology
☐	Immunosuppressant
☐	Infections
☐	Infections – Antiretroviral
☐	Musculoskeletal Anti- inflammatory Rheumatology
☐	Musculoskeletal – Osteoporosis
☐	Nephrology
☒	Nervous System – Anaesthetics/Analgesics
☒	Nervous System – Mental Health
☒	Nervous System - Drug and Alcohol Dependency
☐	Nervous System – Neurology
☐	Oncology Agents *(includes MoH Cancer Team, Medical Oncology Work Group, INCOM membership, Cancer Society, BCAC, Breast Cancer Foundation, and CANGO – please do not note these groups as additional groups/emails to be sent out)*
☐	Respiratory
☐	Sensory organs
☐	Special Foods
☐	Tender
	Subcommittees
☒	Analgestic Advisory Committee
☐	Anti-Infective Advisory committee
☐	Cancer Treatments Advisory Committee

☐	Cardiovascular Advisory Committee
☐	Dermatology Advisory Committee
☐	Diabetes Advisory Committee
☐	Endocrinology Advisory Committee
☐	Gastrointestinal Advisory Committee
☐	Haematology Advisory Committee
☐	Immunisation Advisory Committee
☐	Interventional Cardiology Advisory Committee
☒	Mental Health Advisory Committee
☐	Nephrology Advisory Committee
☐	Neurological Advisory Committee
☐	Ophthalmology Advisory Committee
☐	PTAC Members
☐	Rare Disorders Advisory Committee
☐	Reproductive and Sexual Health Advisory Committee
☐	Respiratory Advisory Committee
☐	Rheumatology Advisory Committee
☐	Special Foods Advisory Committee
☐	Tender Clinical Advisory Committee
☐	Transplant Immunosuppressant Advisory Committee
	Other Mailchimp
☒	Updates for Pharmacist (Includes Pharmac Internal)* - formally community pharmacy
☒	Suppliers and wholesalers
	Below groups are sent via Outlook:
☒	Other – GP's (Which is sent by an MD/ Medical Directorate TA)
☒	DHB Chief Pharmacists (List received from EA to Medical Director) *

**All consultation & notifications are to be sent to the following groups unless otherwise stated*

Additional Groups/emails to be sent out:

Please list additional emails/groups here without bullet points

RNZCGP (if not covered by other GPs) rnzcgp@rnzcgp.org.nz

Software vendors –Toniq s 9(2)(a) s 9(2)(a)

Software vendors – RxOne s 9(2)(a) support@rxone.co.nz

s 9(2)(a)

Not in MailChimp

~~Pharmaceutical Society NZ p.society@psnz.org.nz~~

Already in Mailchimp

Updates for Pharmacist

Pharmacy Guild

Green Cross

TAS- Te Whatu Ora pharmacy@tas.health.nz

Toniq LTD

E-mail details

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

Body:

Kia ora

Please find an update here on the Pharmac Consultation regarding proposed changes to the Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs.

Please circulate this e-mail to others who may be interested.

Ngā mihi

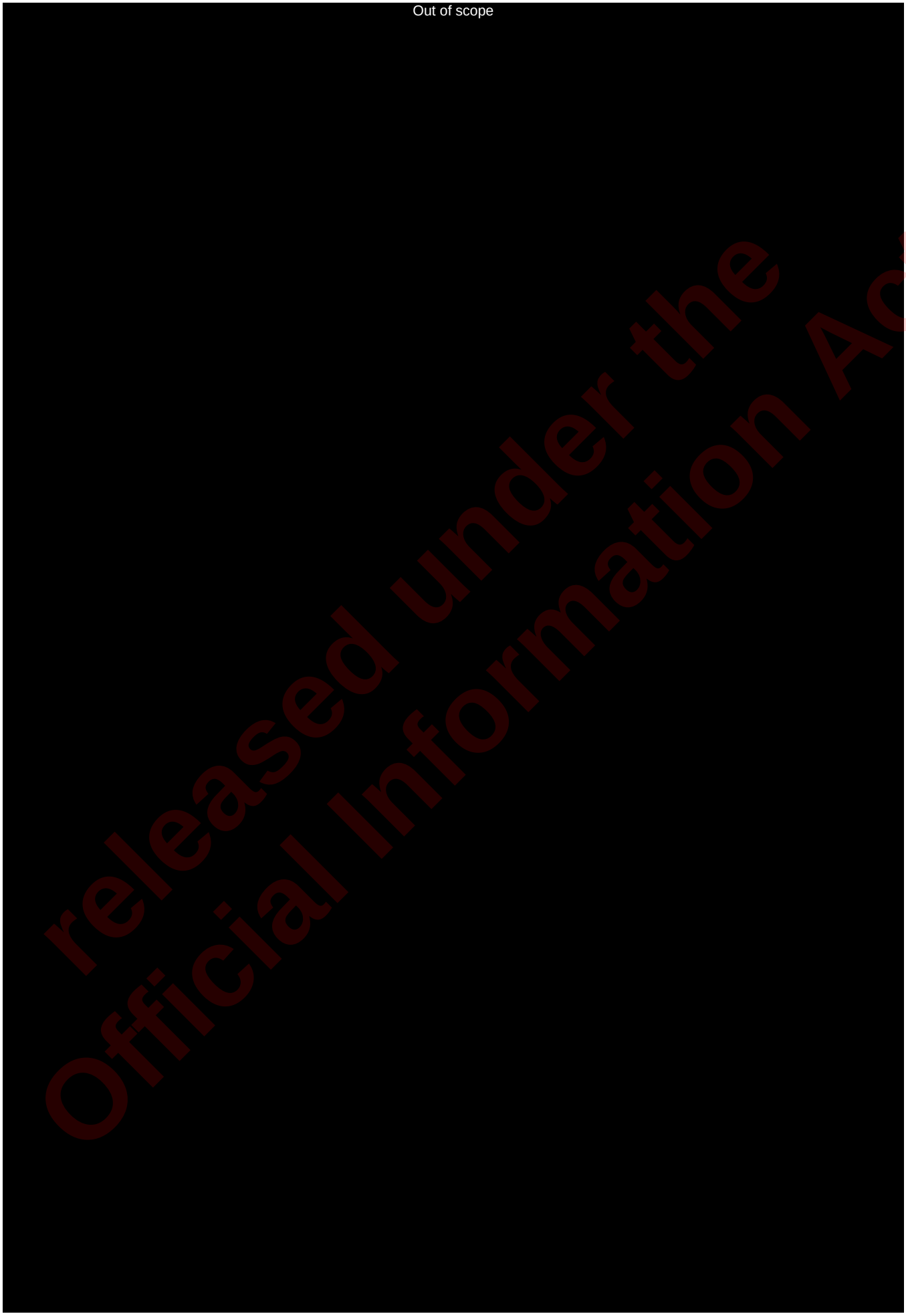
Fiona Moscrop (she/her) | Clinical Lead, Schedule Development

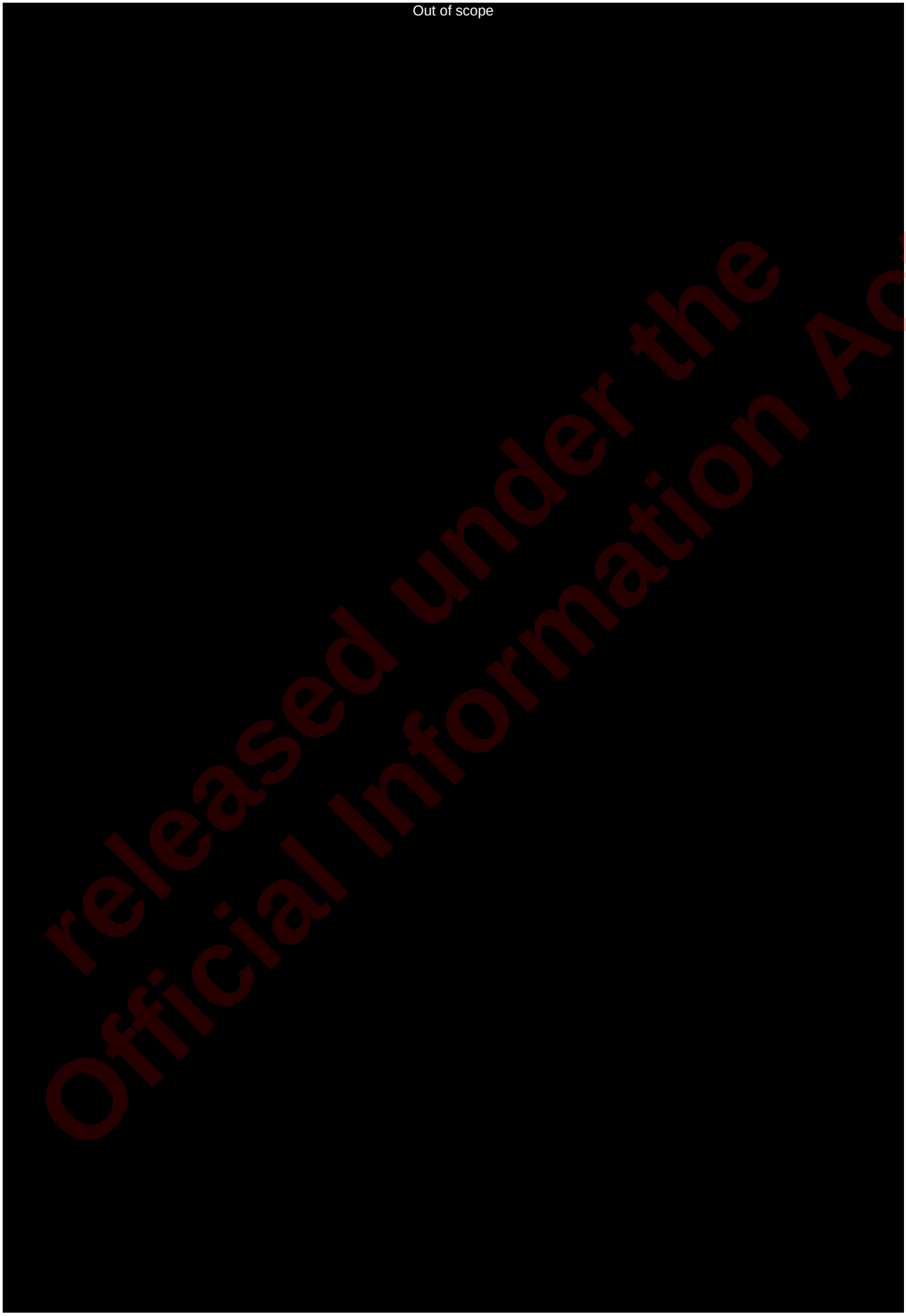
Te Pātaka Whaioranga |Pharmac| PO Box 10 254 |Level 9, 40 Mercer Street, Wellington
Ph: 0800 660 050 | www.pharmac.govt.nz

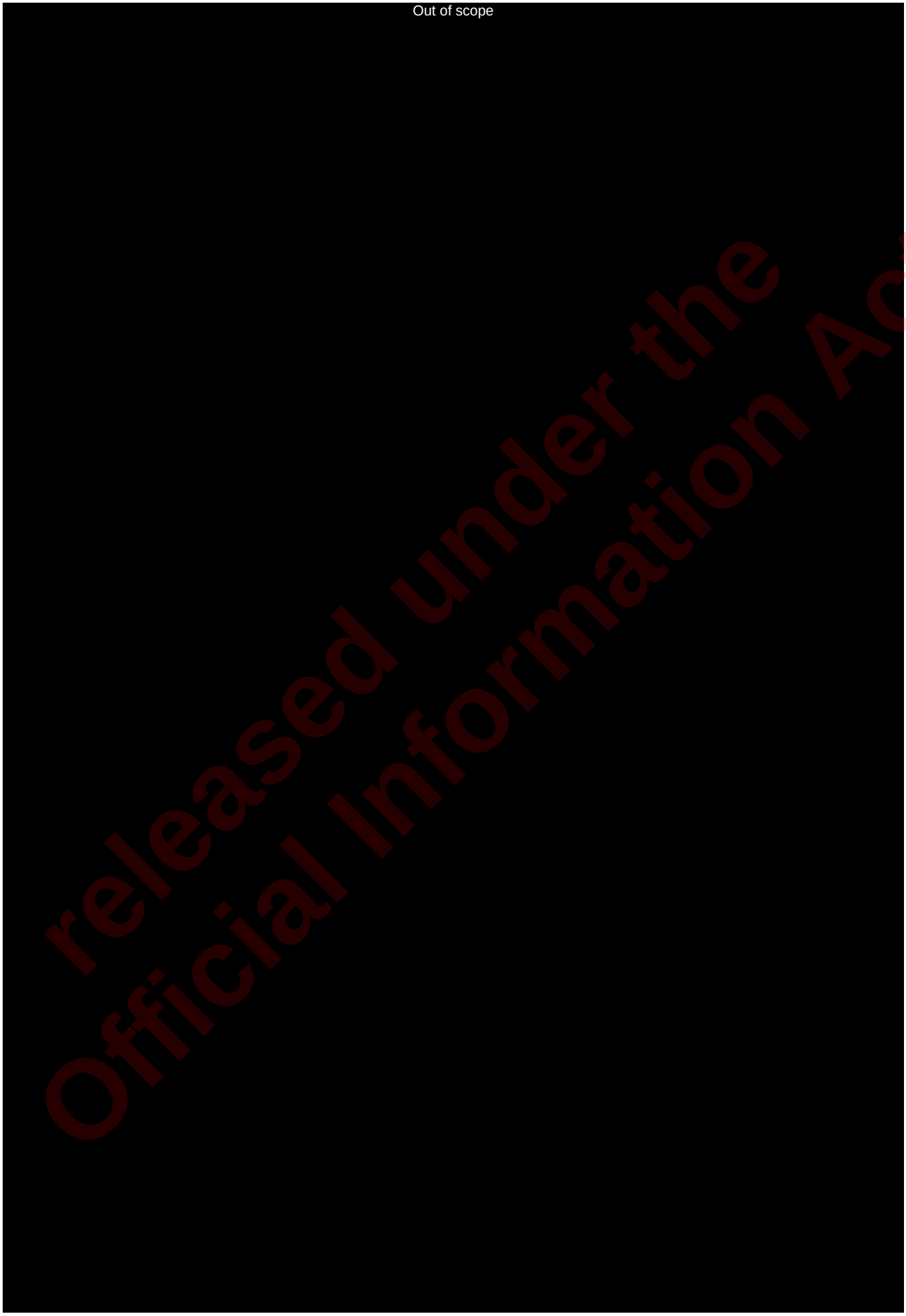
MEMORANDUM FOR BOARD MEETING 2 DECEMBER 2022

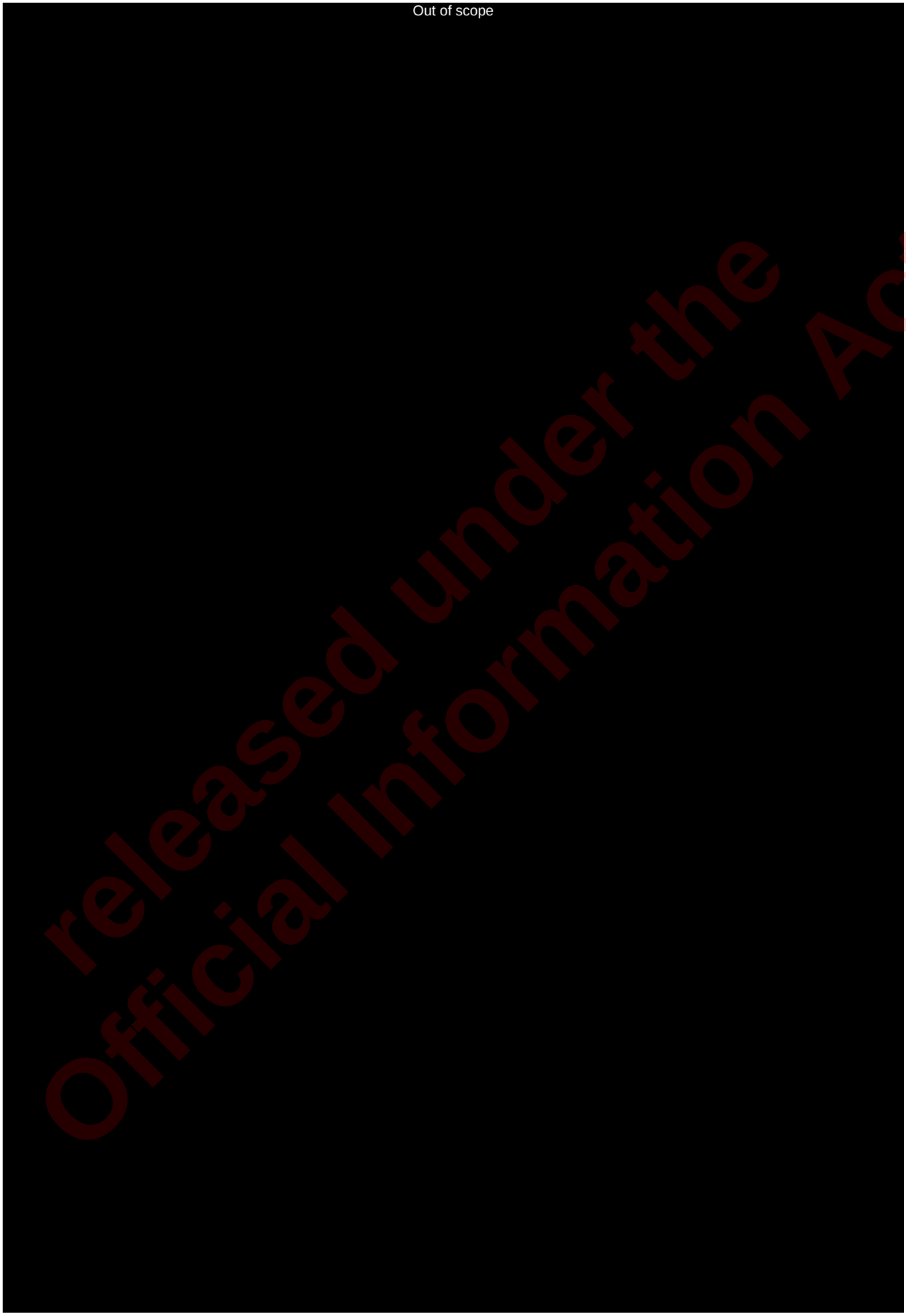
To: Pharmac Directors
From: Chief Executive
Date: November 2022
Item: 8.1

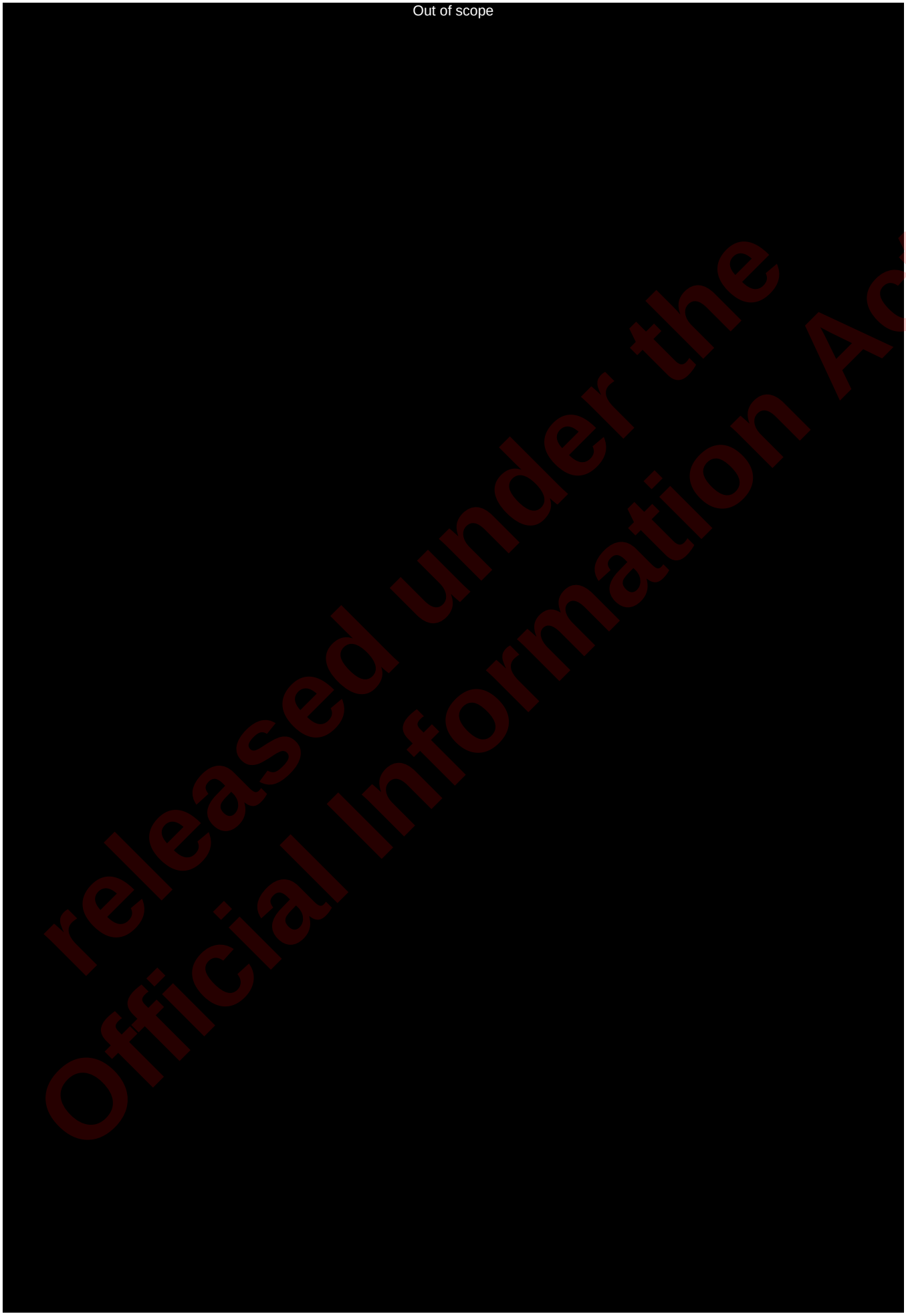
Out of scope











Class B controlled drugs consultation

We are currently consulting on a proposal to amend the Pharmaceutical Schedule General Rules (the Schedule Rules) to bring funding rules in line with legislative changes to the prescribing and dispensing of controlled drugs.

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

Amendments to the Medicines Regulations 1984 and Misuse of Drugs Regulations 1977 have recently been notified to the sector by Manatū Hauora. They will come into force on 22 December 2022.

Our proposed changes are to give effect to these decisions, which have already been made by the Ministry of Health – Manatū Hauora.

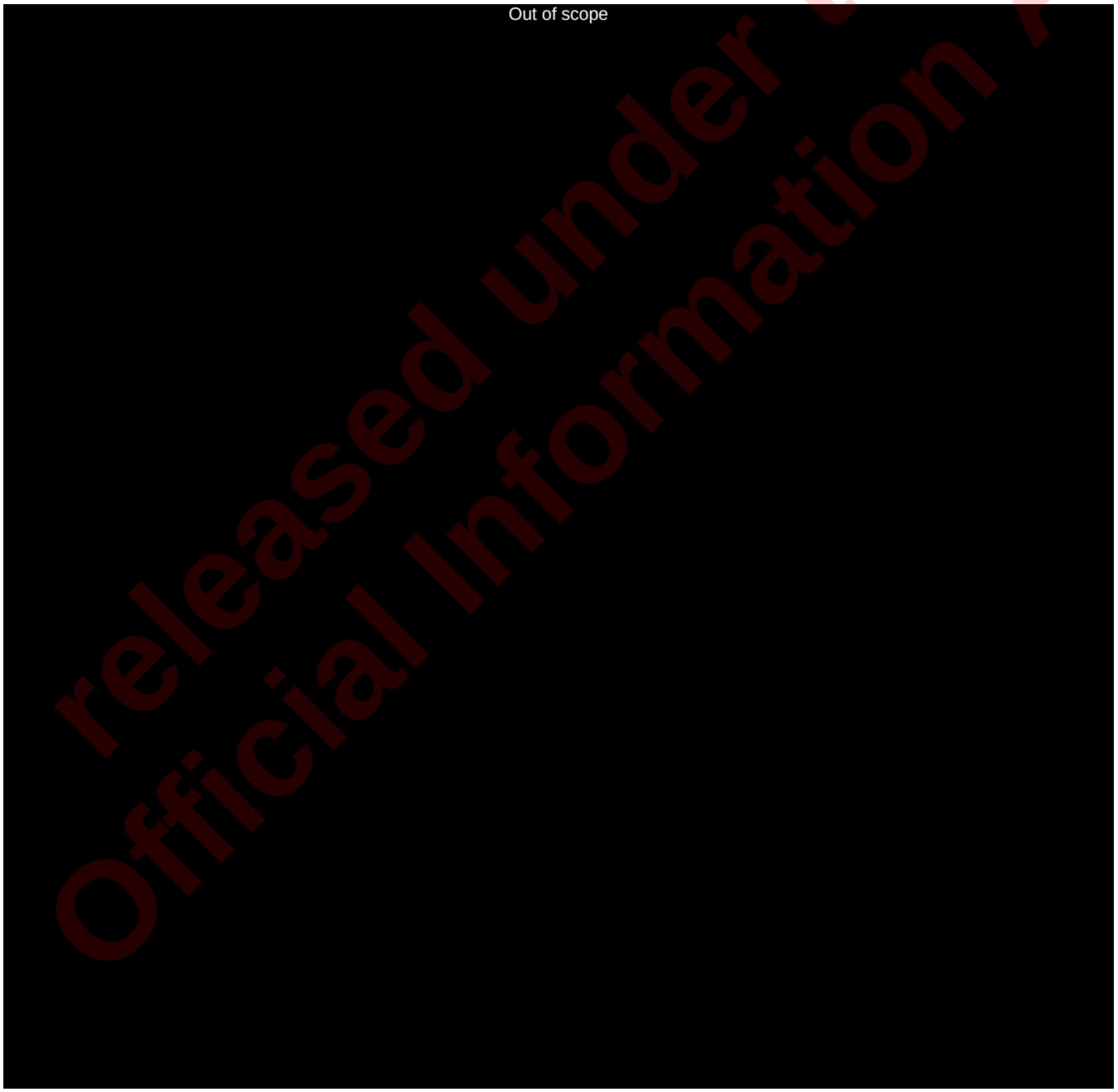
The effects of the legislative changes will be to:

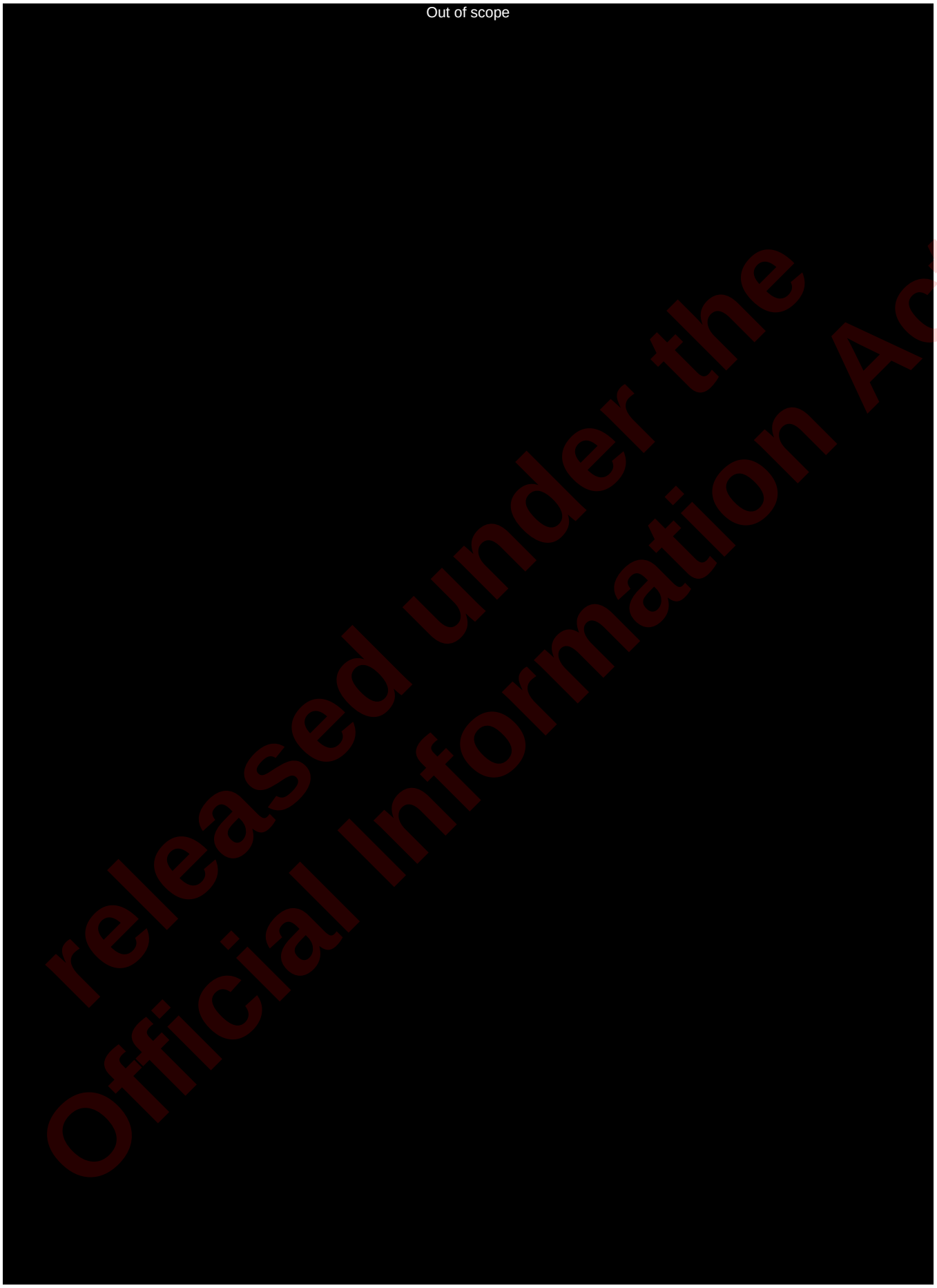
- Enable controlled drugs to be prescribed electronically via the New Zealand Electronic Prescribing System (NZePS)
- Allow prescriptions for Class B controlled drugs to be prescribed for three months (instead of one month) with monthly dispensing if the prescription is issued electronically via the NZePS
- Allow prescribers to direct shorter prescriptions or more frequent dispensing when they issue a prescription

- Reduce the number of times people need to visit a prescriber for repeat prescriptions of Class B controlled drugs for some chronic conditions, like ADHD.

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

Some immediate feedback indicates that stakeholders were not aware of the Regulations changes before the Pharmac consultation was issued and see the proposed changes as being initiated by Pharmac. The main concerns that have been raised by stakeholders are about inappropriate prescribing and abuse. We intend to work with Manatū Hauora to provide stakeholders with key messages and implementation support.





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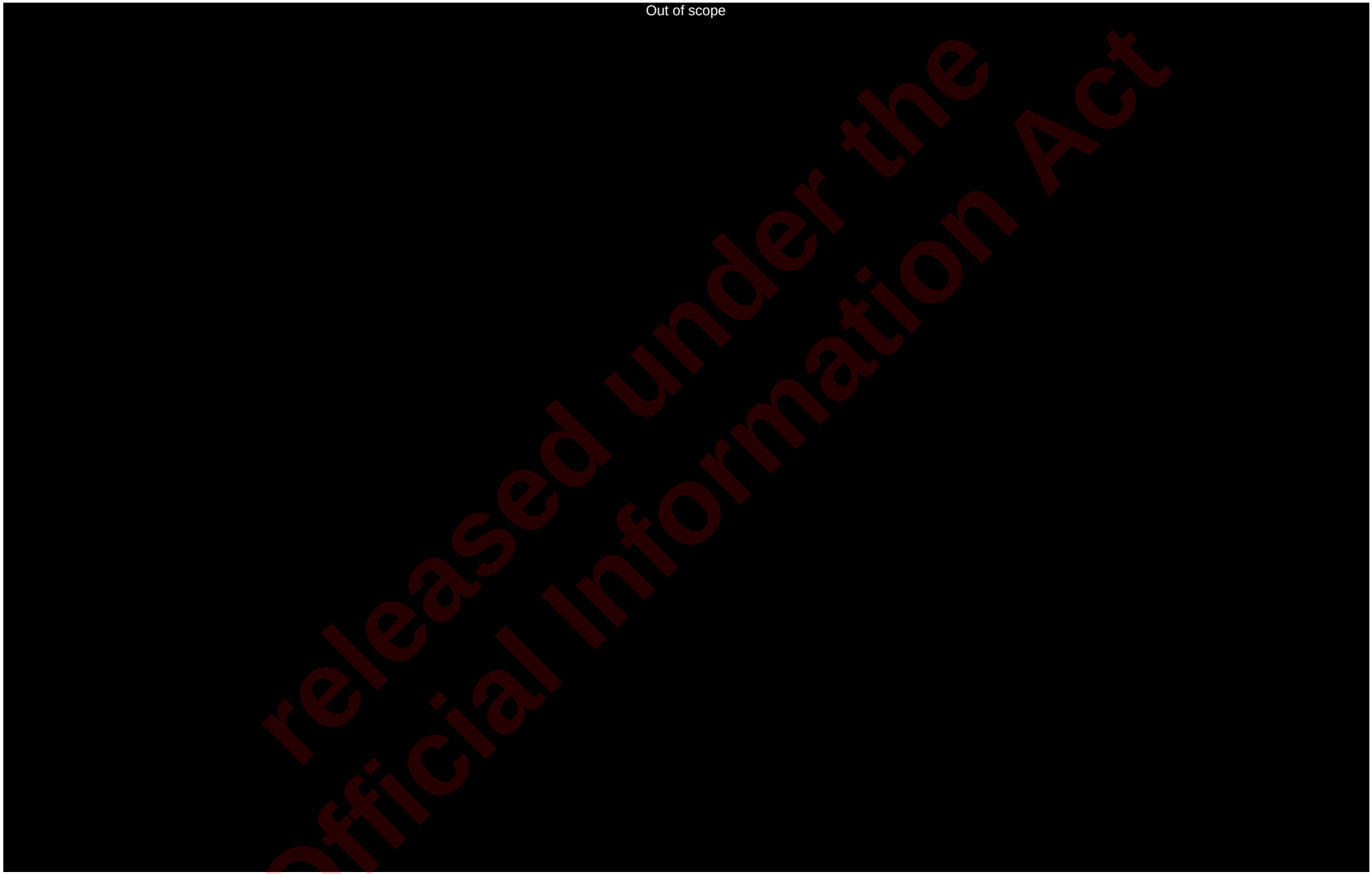

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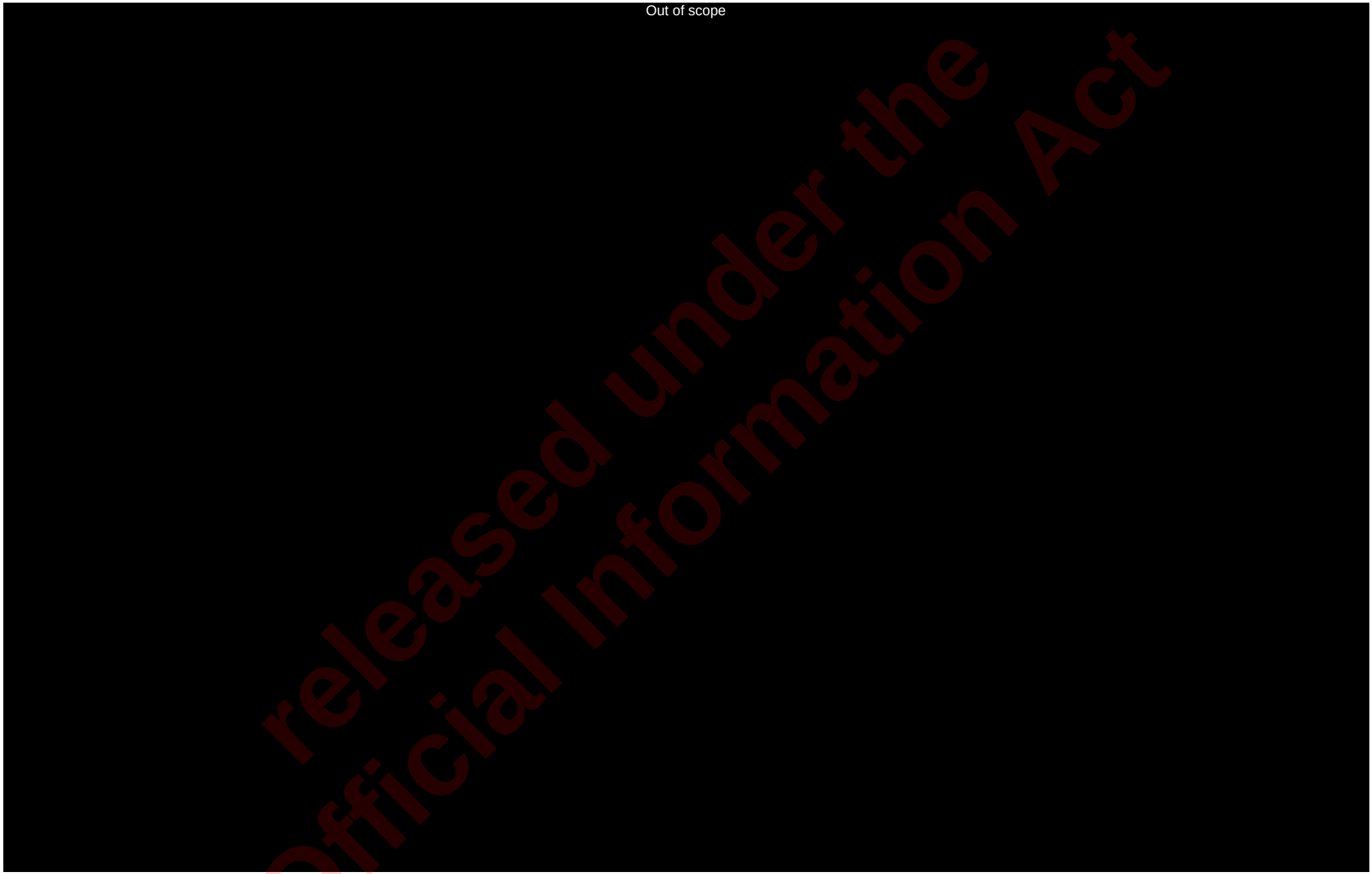

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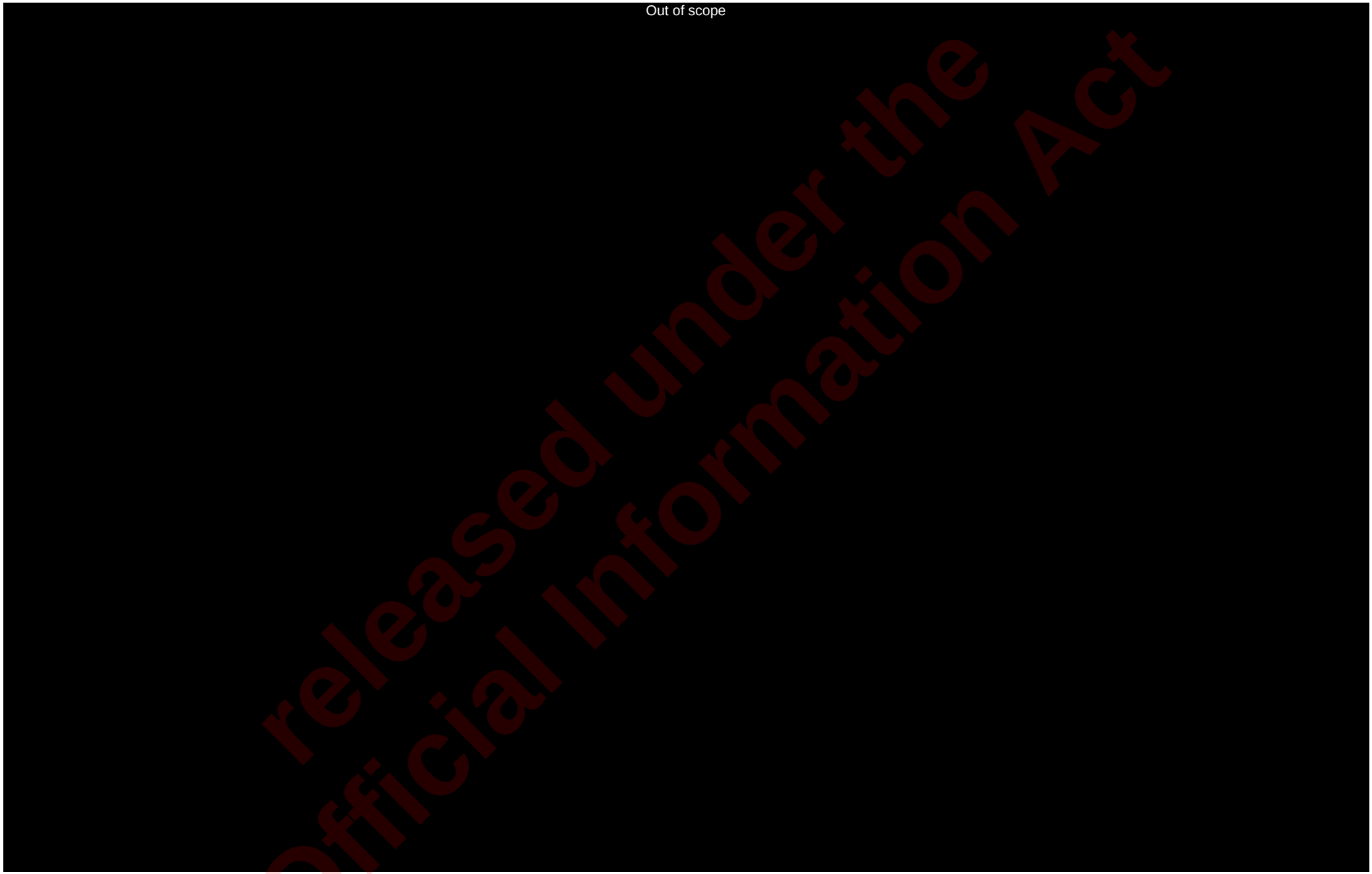

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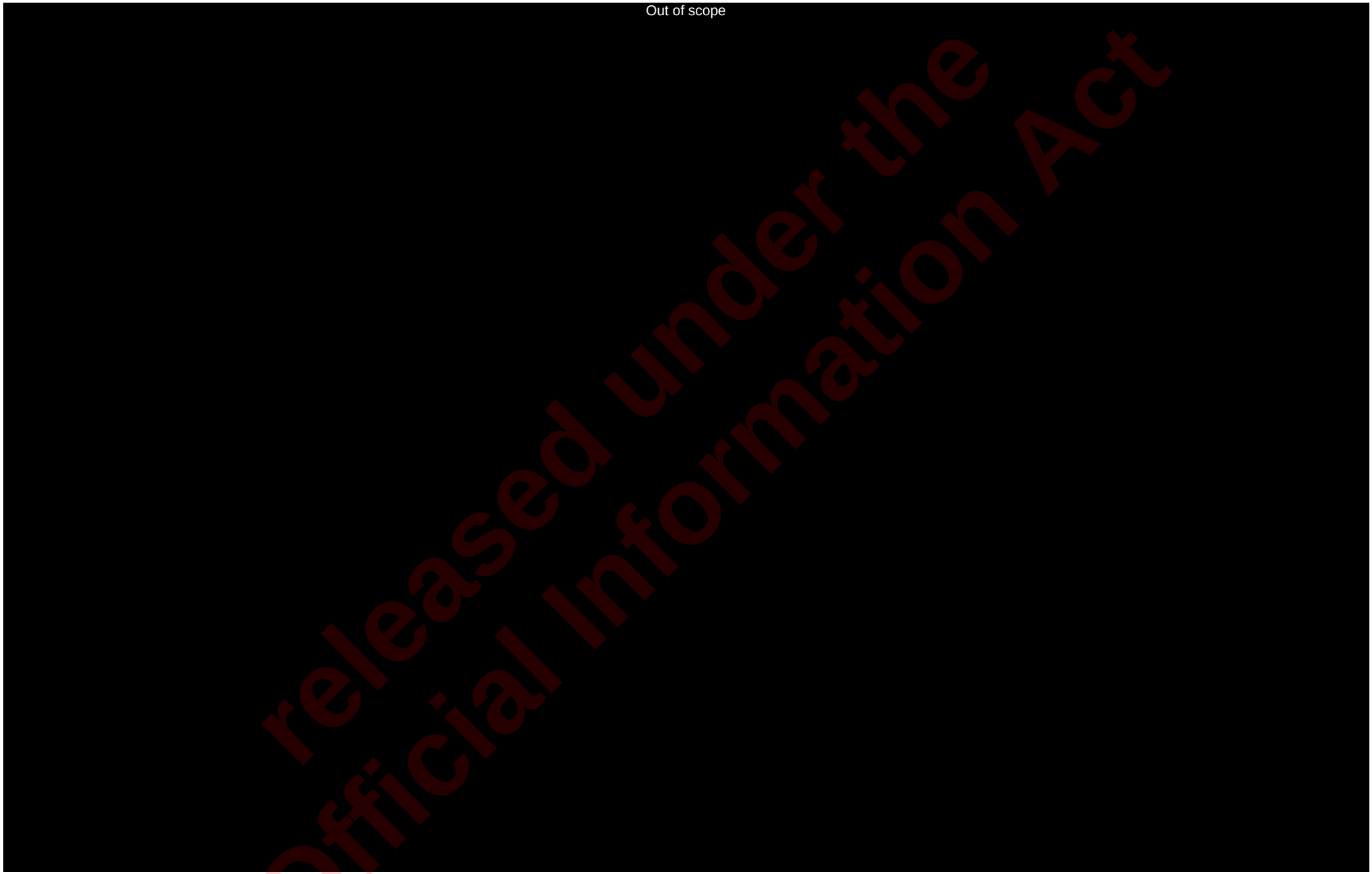

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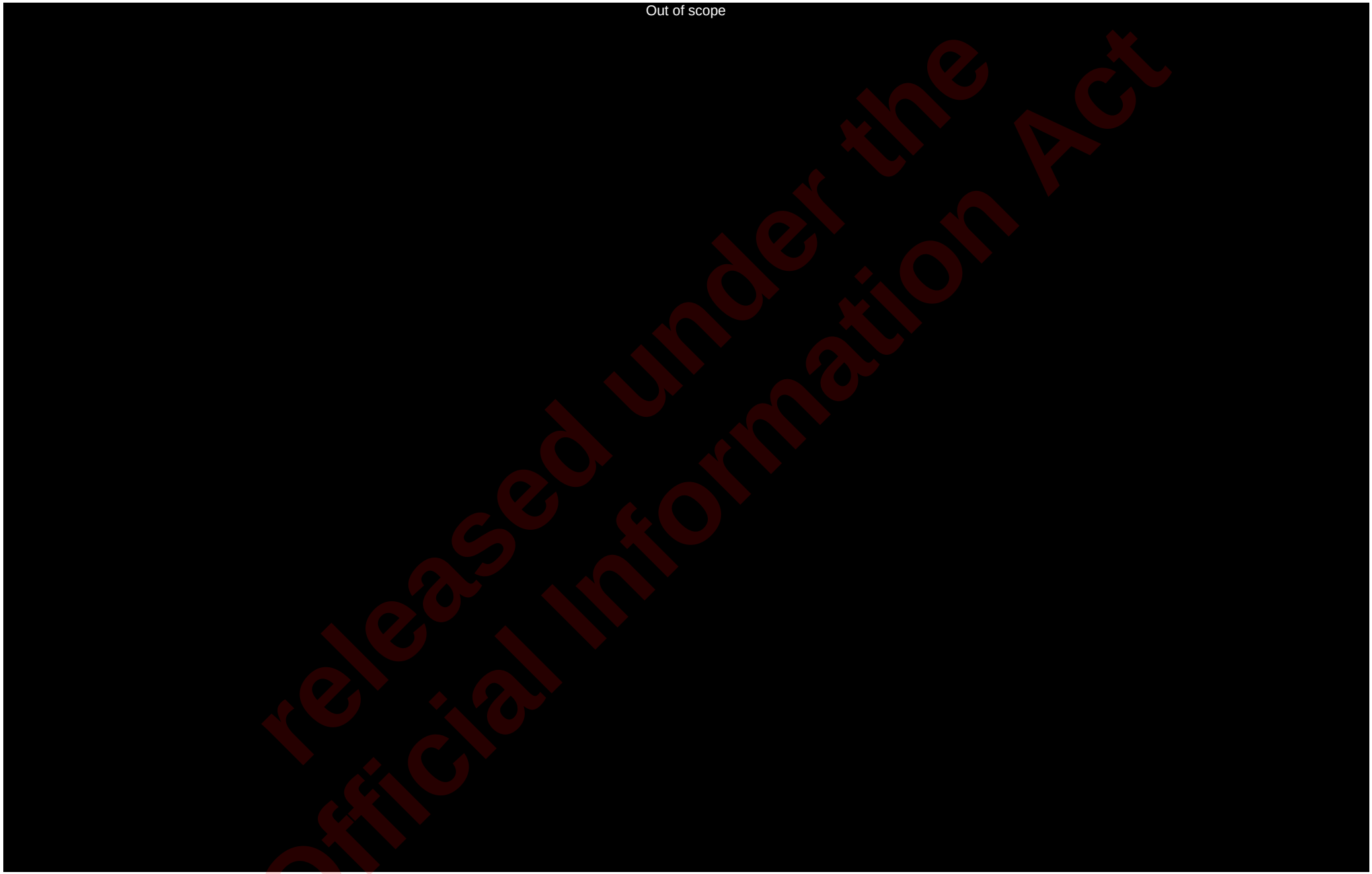

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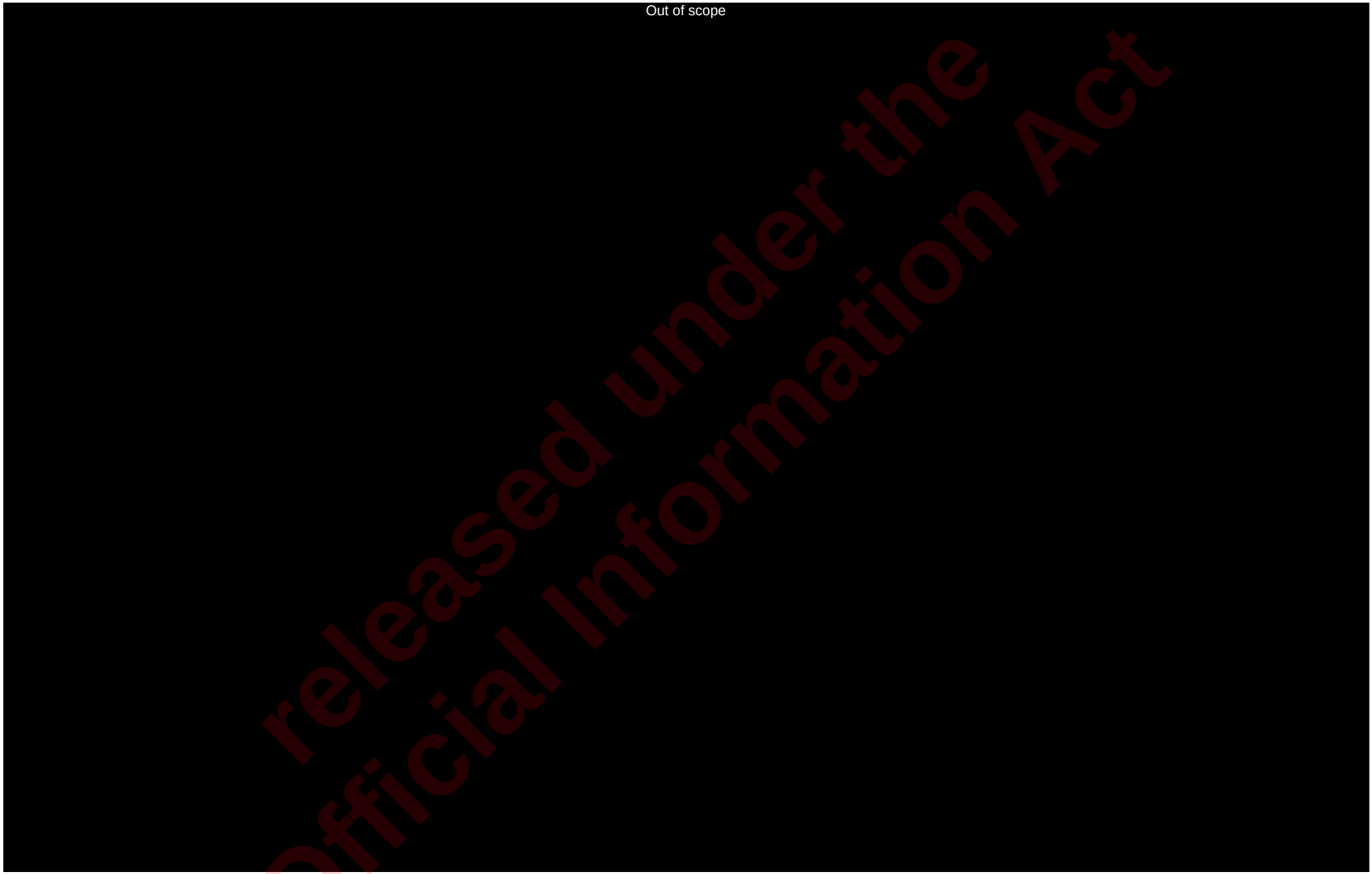

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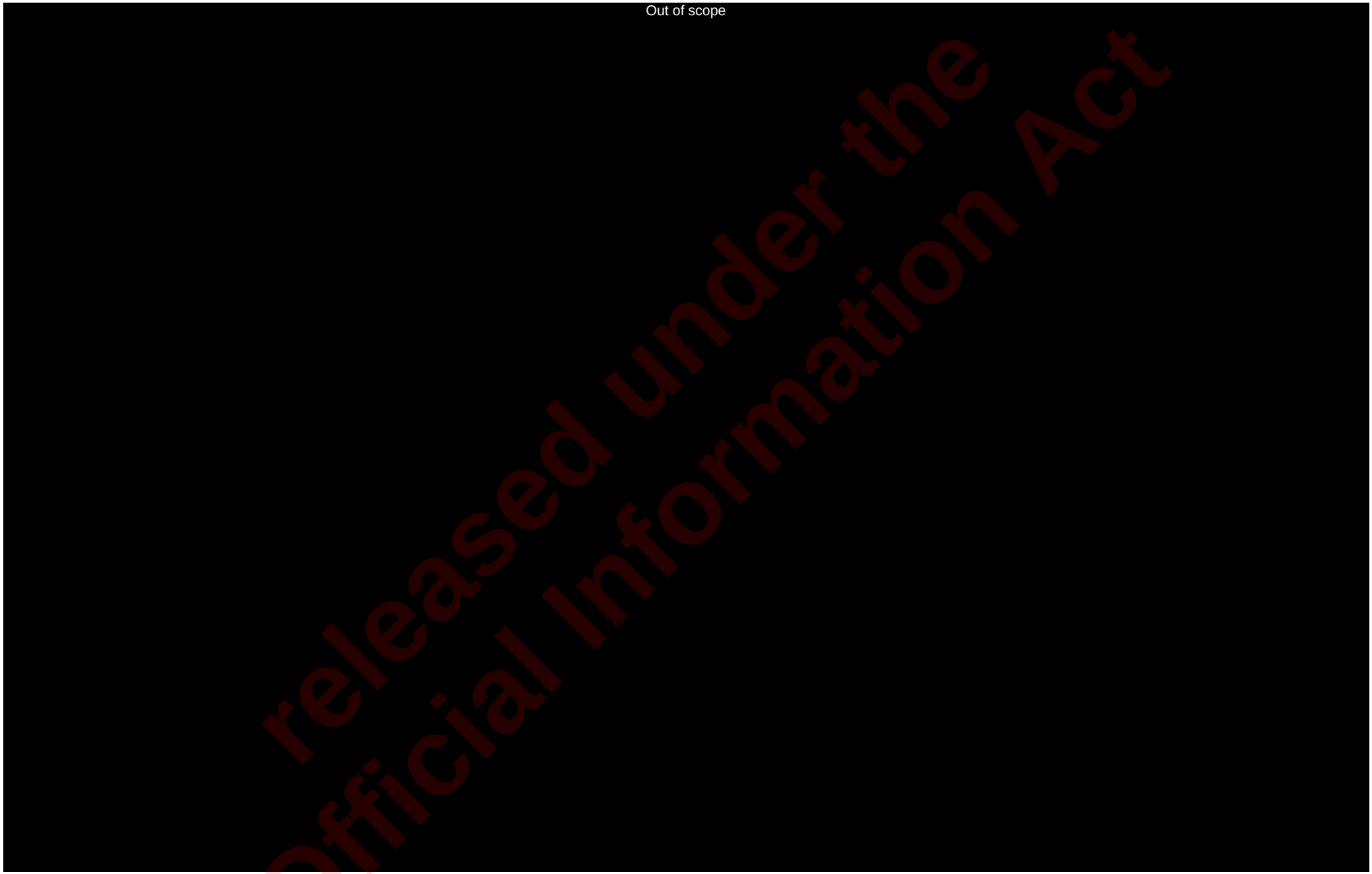

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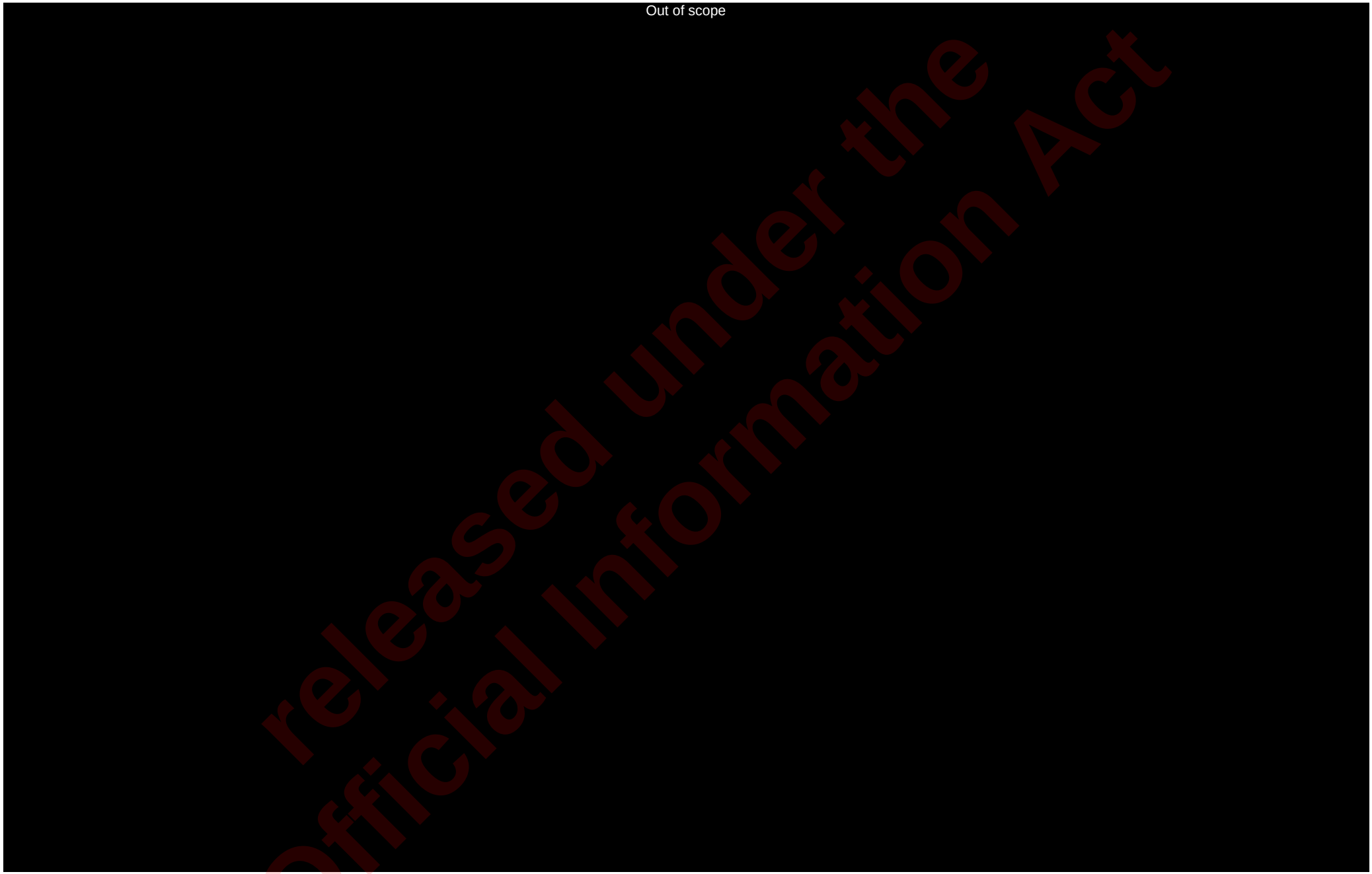

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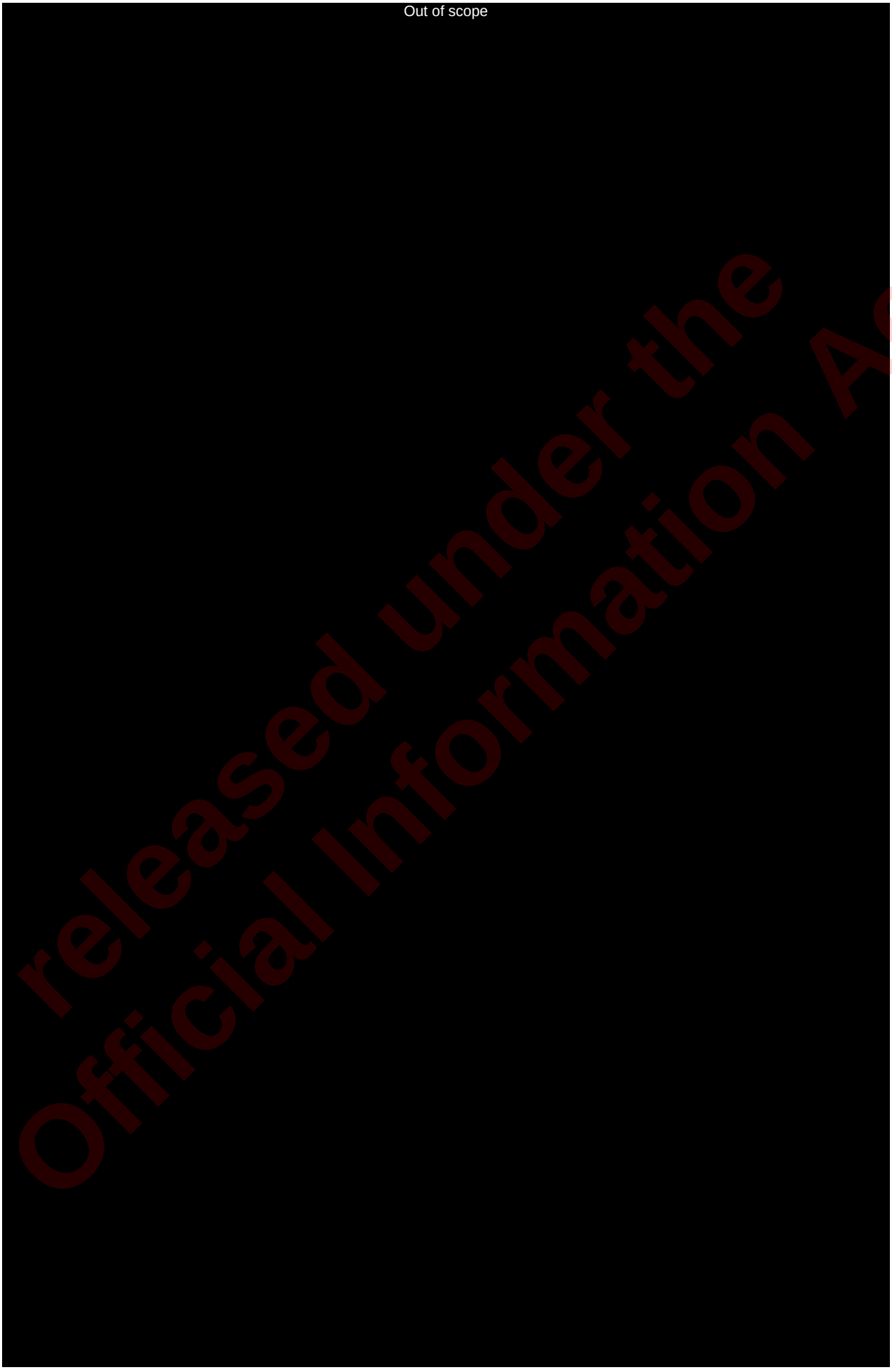

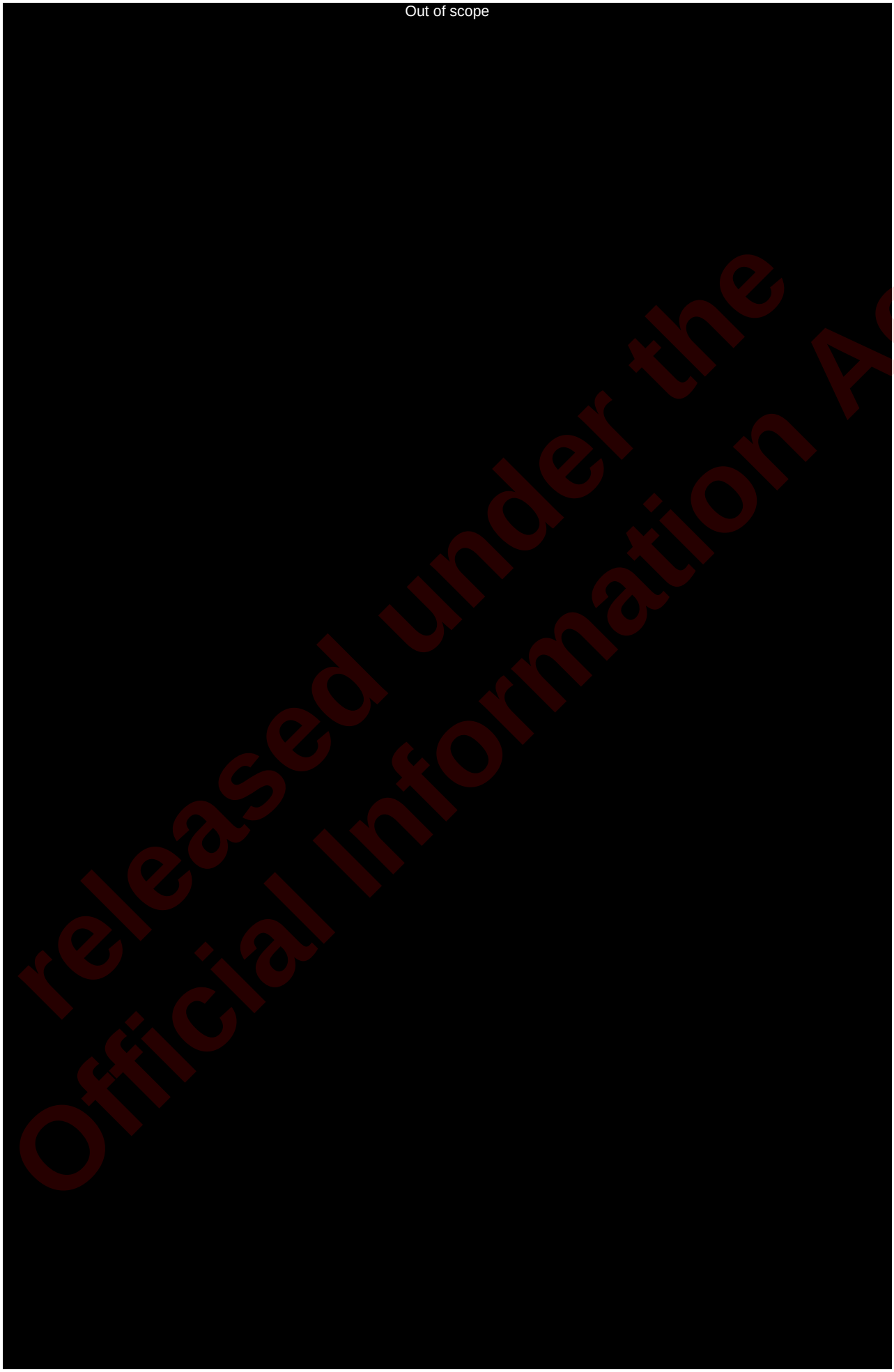

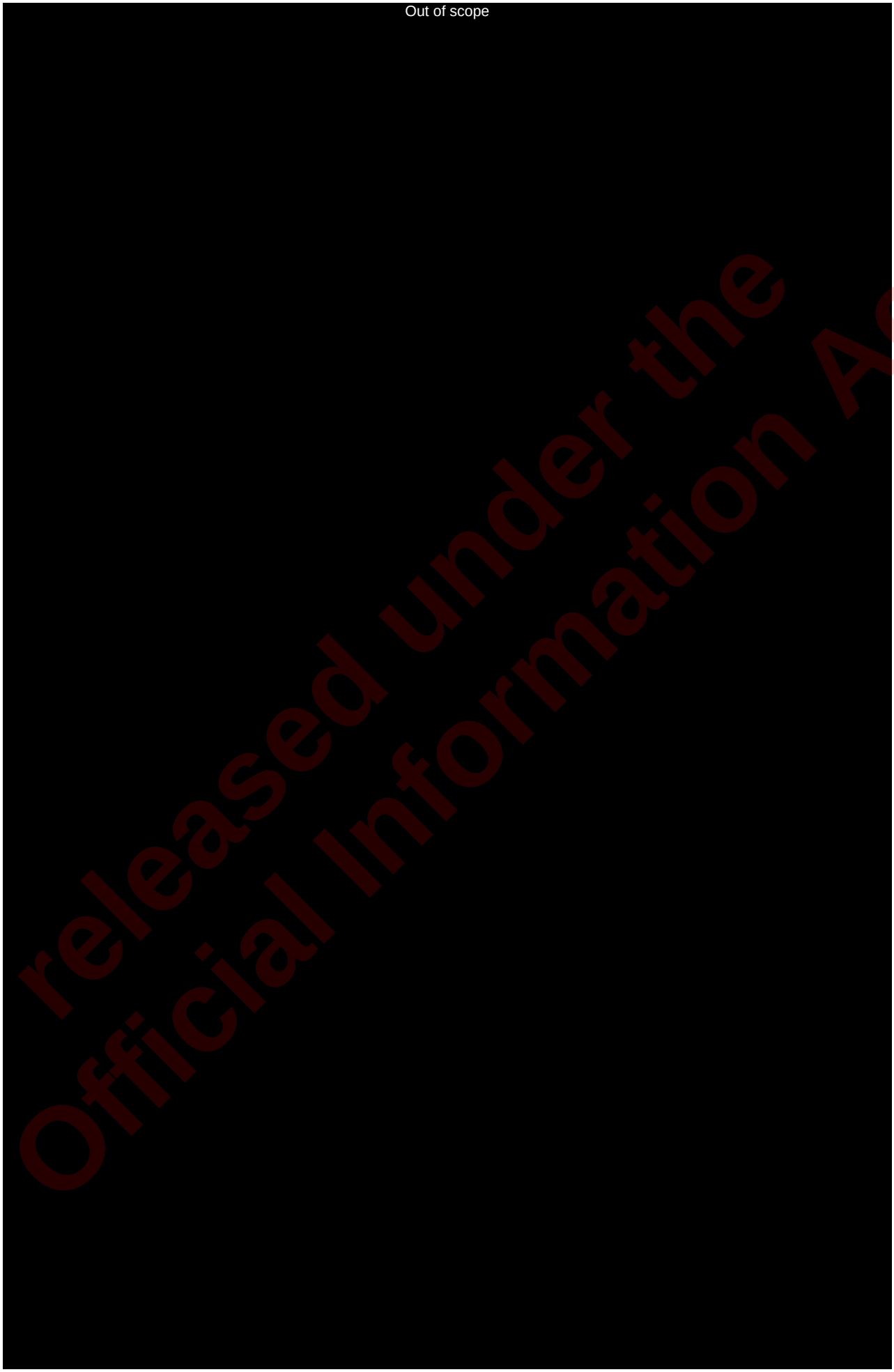

MINUTES OF THE PHARMACEUTICAL MANAGEMENT AGENCY (PHARMAC)

BOARD MEETING HELD 2 DECEMBER 2022

The meeting was held at Pharmac offices, Level 9, 40 Mercer Street, Wellington, and by zoom, and started at 9.00am with the following attendees:

Board members

Steve Maharey ((MA (Hons), CNZM))	Chair
Claudia Wyss ((BHB, MBChB, MBA Harvard))	Deputy Chair (by zoom)
Talia Anderson-Town (BBS, PG Dip Professional Accounting, CA, CPP)	Board member

Board Observers

Peter Bramley	Board Observer, Te Whatu Ora representative
Lisa Lawrence	Board Observer, CAC Chair
Jane Thomas	Observer, PTAC Chair (by zoom)

Pharmac staff in attendance

Sarah Fitt	Chief Executive
Michael Johnson	Director of Strategic Initiatives
Peter Alsop	Director of Engagement and Implementation
Lisa Williams	Director of Operations
Kathryn McInteer	Director of Finance and Corporate
Trevor Simpson	Kaituruki Māori - Director Māori
David Hughes	Chief Medical Officer
Carol Morris	Board Secretary

Attendees joined the meeting to present relevant papers: Graham Durston, Geraldine MacGibbon, Ashton Rounthwaite, Sean Dougherty, Josh Cronin-Lampe, Caroline De Luca, Andrew Oliver, Jannel Fisher, Mako Osborne, Andrew Davies, Danae Staples-Moon (by zoom), Sandy Bhawan, and Yazmin Juned.

The Board Meeting started with a Karakia.

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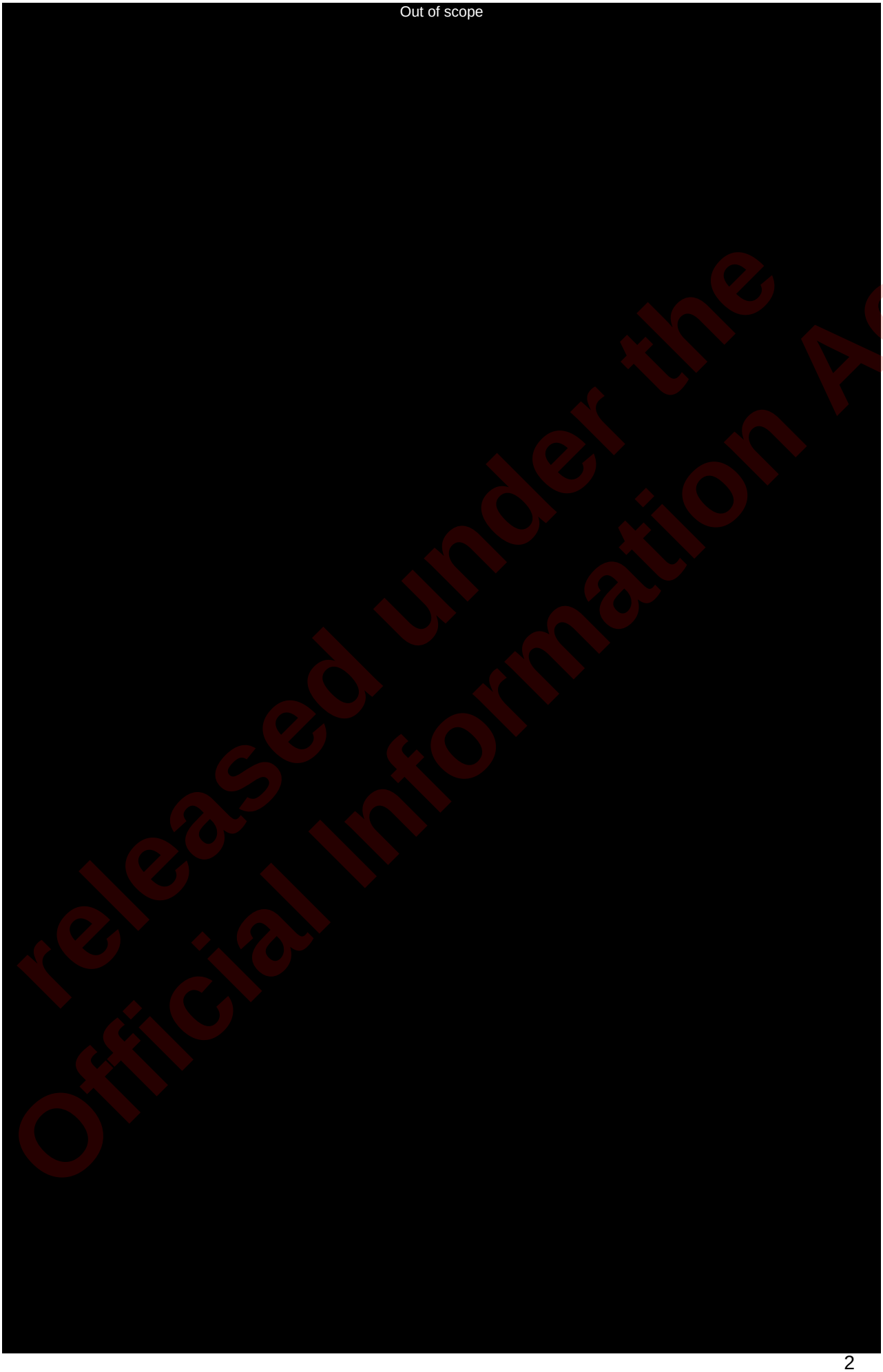

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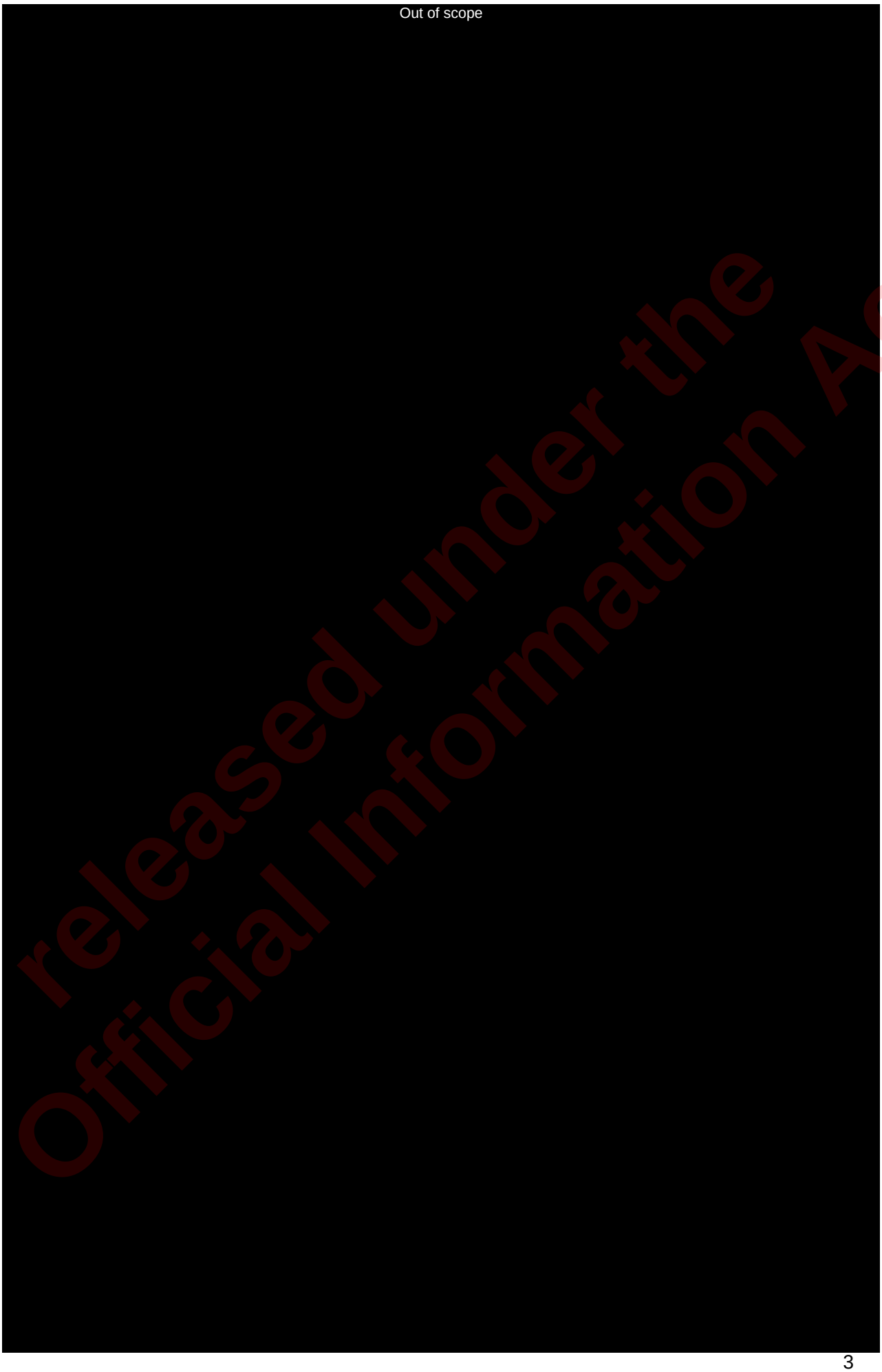

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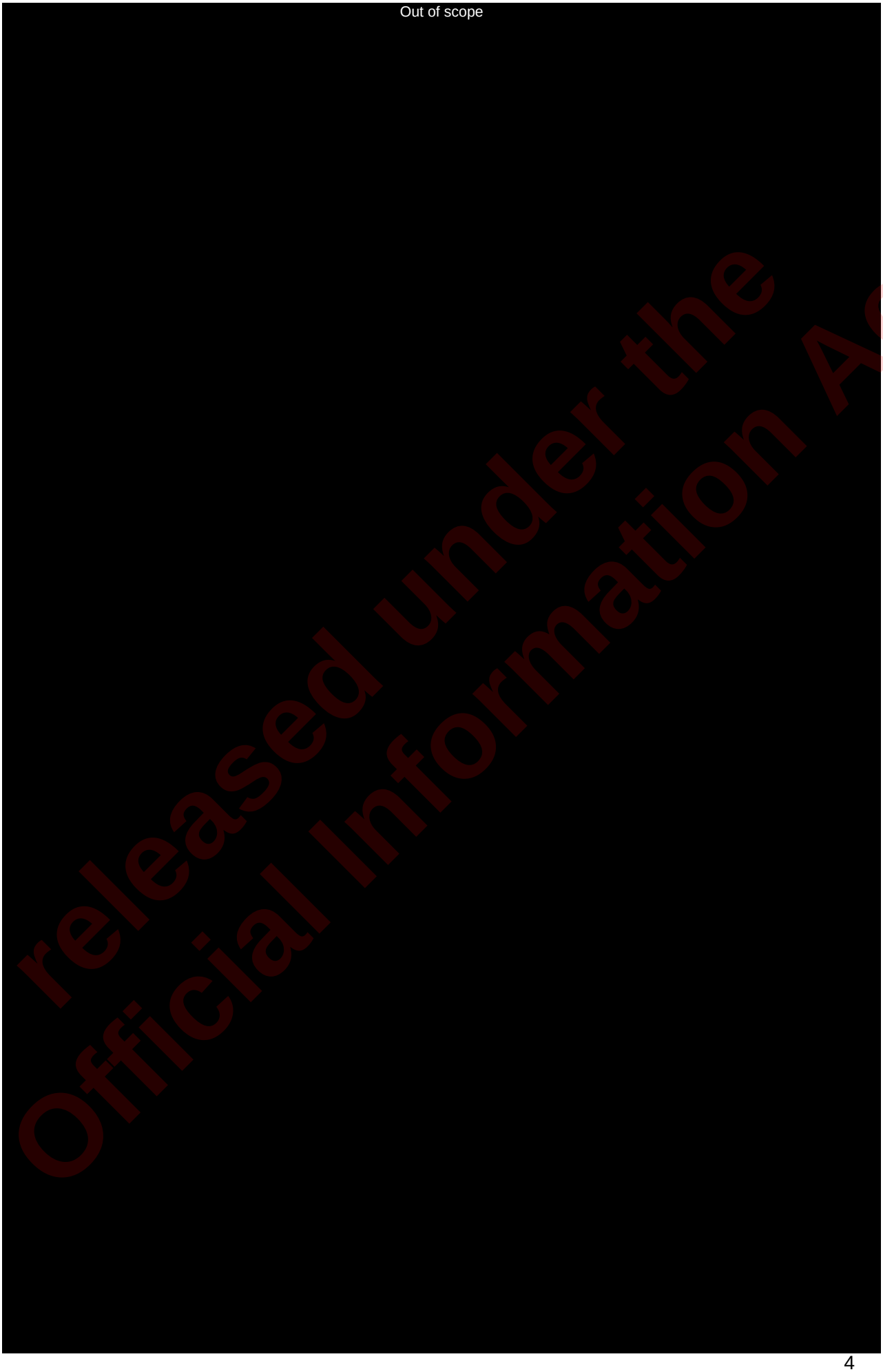

8. Schedule and Funding

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The Board received an update on changes that Manatū Hauora - Ministry of Health are making in the Medicines Amendment Regulations 2022 and the Misuse of Drugs Amendment Regulations 2022. These legislative changes require Pharmac to amend current rules in the Pharmaceutical Schedule which means that people in the community could:

- Be prescribed funded Class B controlled drugs for three months, instead of one month, when an electronic prescription is used. The amount that could be prescribed on a paper prescription would stay as one month.

- Collect Class B controlled drugs from the pharmacy in monthly lots, when an electronic prescription is used (or as a single monthly lot on a paper prescription), unless the prescriber directs dispensing in smaller quantities.

Under the current Schedule Rules, people generally have Class B controlled drugs dispensed at 10-day intervals, with the exception of methylphenidate and dexamfetamine, which may be dispensed in a single monthly lot. While the change from 10-day dispensing to monthly dispensing would increase the amount of a Class B controlled drug was able to be given to a person per visit, the total amount being dispensed would not change.

Concerns were raised about the proposed changes, noting however that this is a legislative change which is out of Pharmac's direct control. Jane Thomas noted strong concerns that the proposed changes could support an opioid epidemic as some overseas countries have experienced. The Board were advised that Pharmac staff have provided a no surprises briefing to the Minister of Health which highlights implications and risks of the proposed changes.

The Chief Executive will discuss this with Director-General of Health.

Talia Anderson-Town and Claudia Wyss **Carried**

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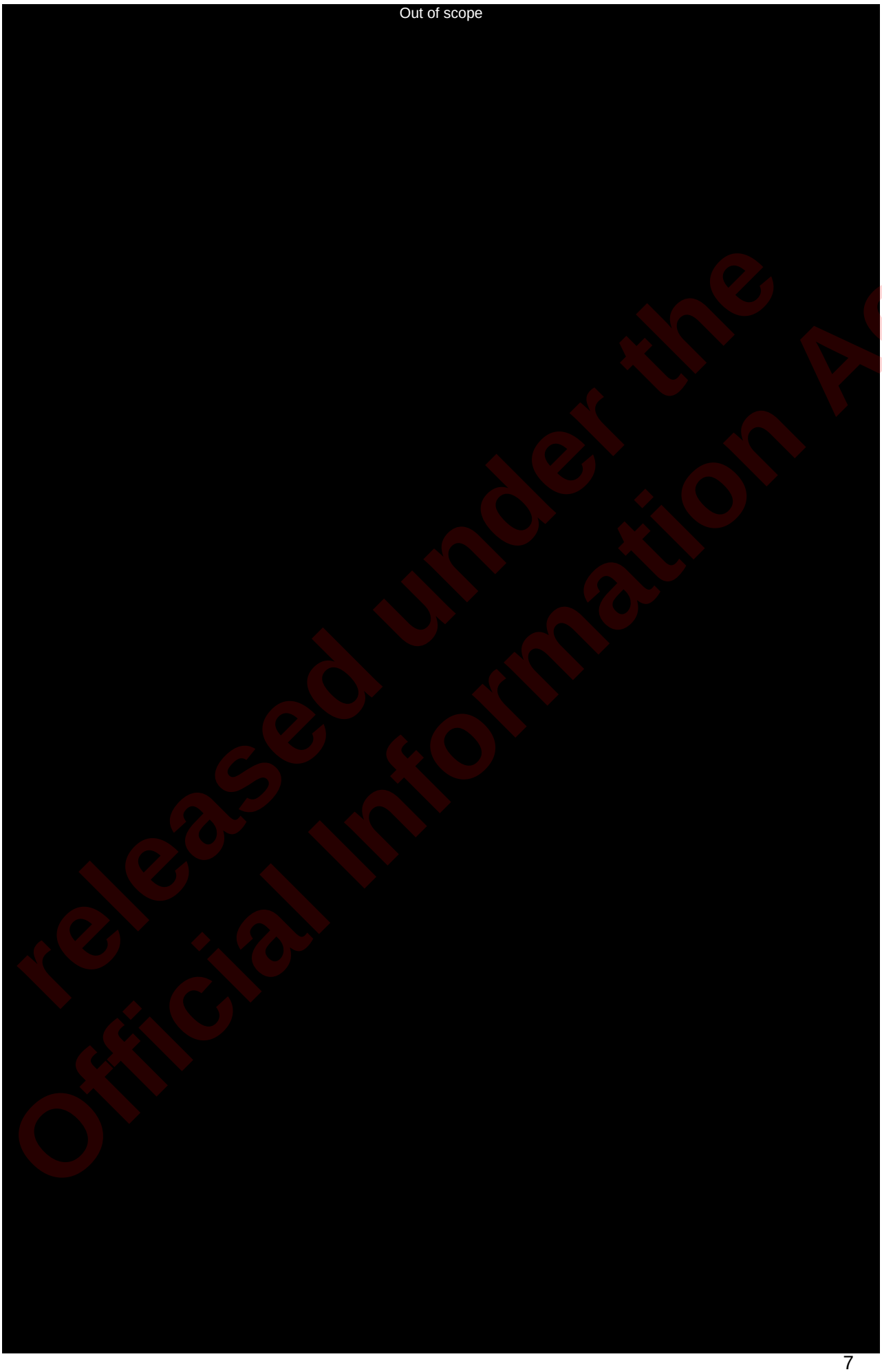

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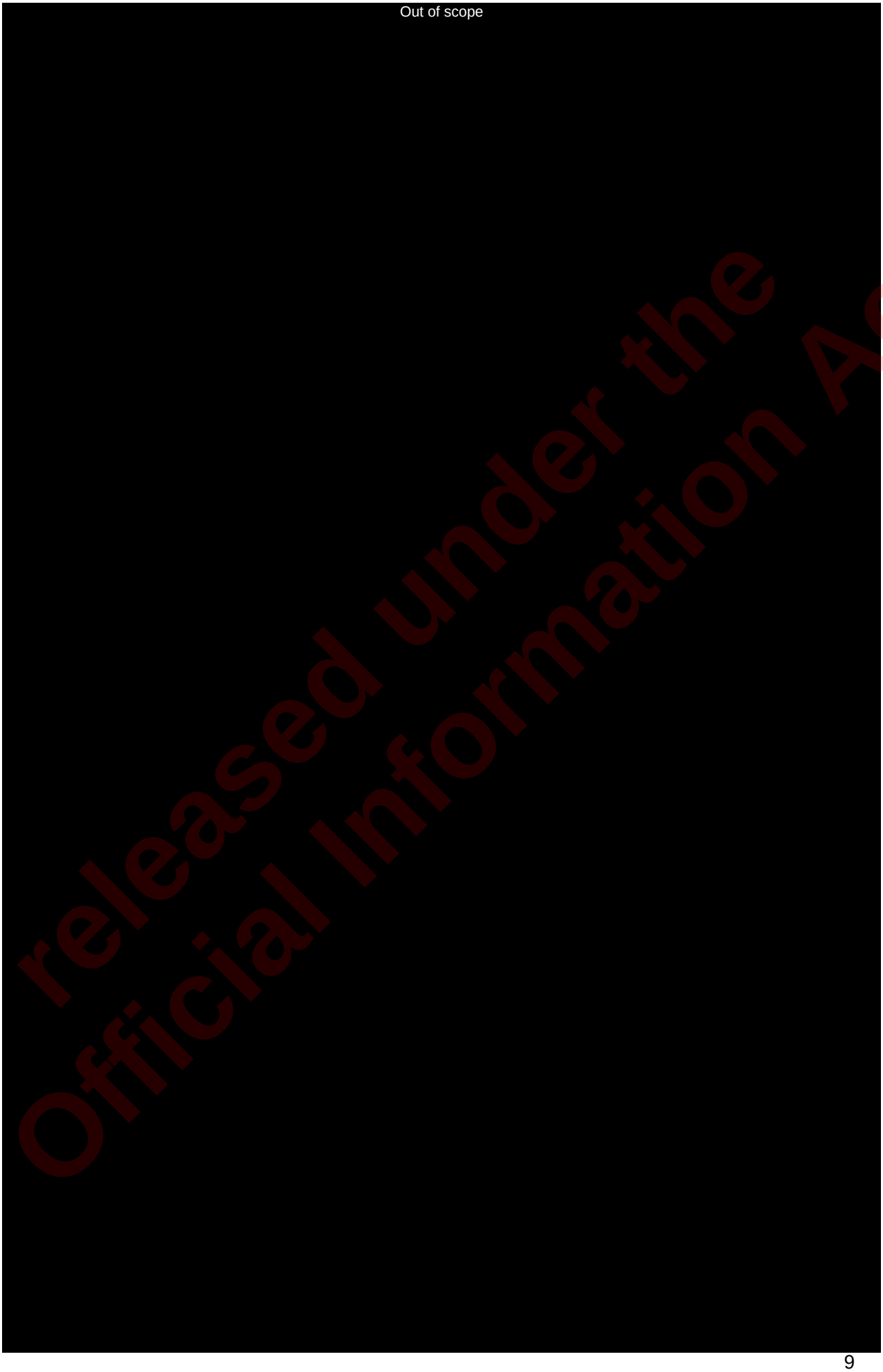

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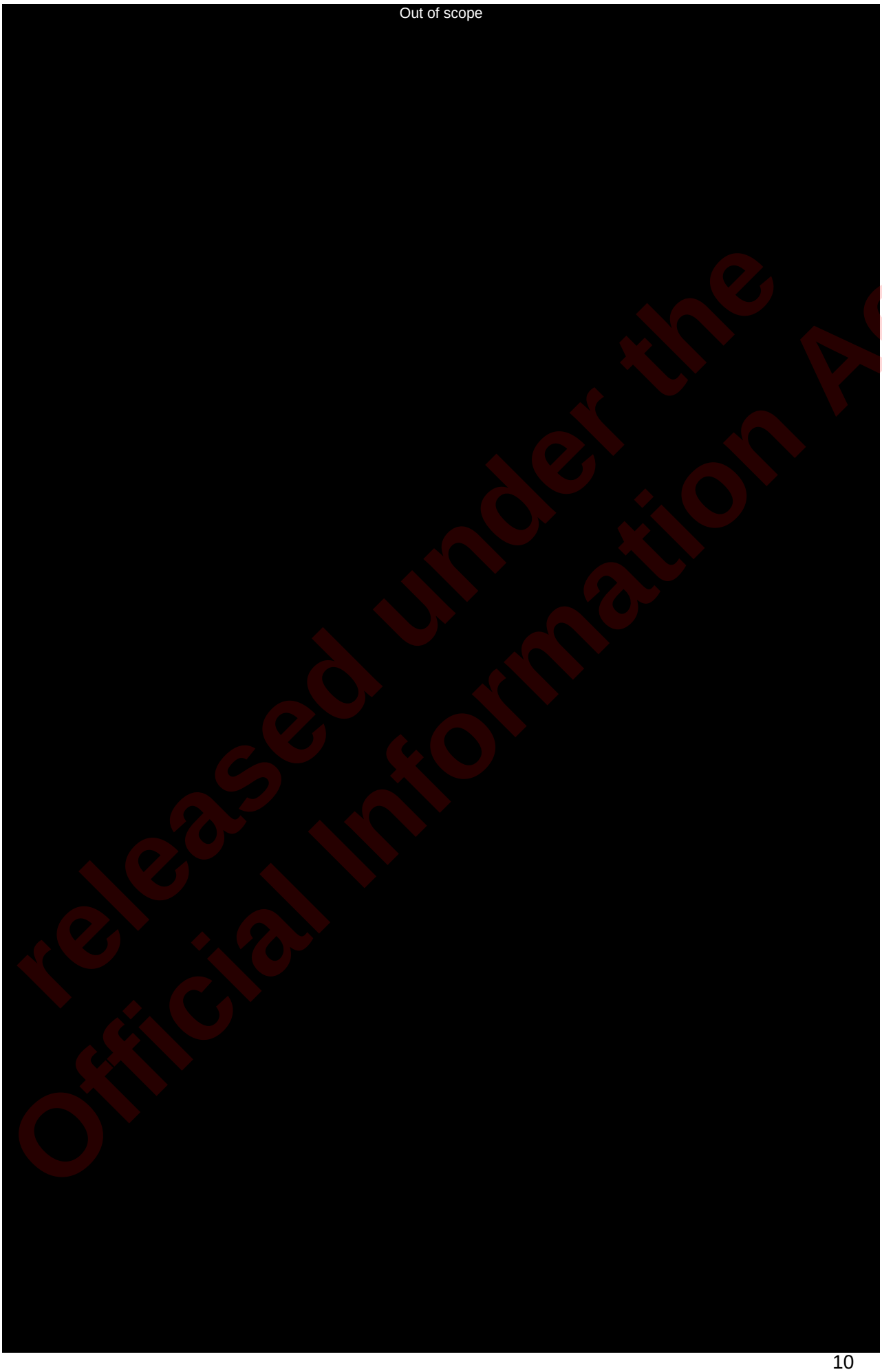

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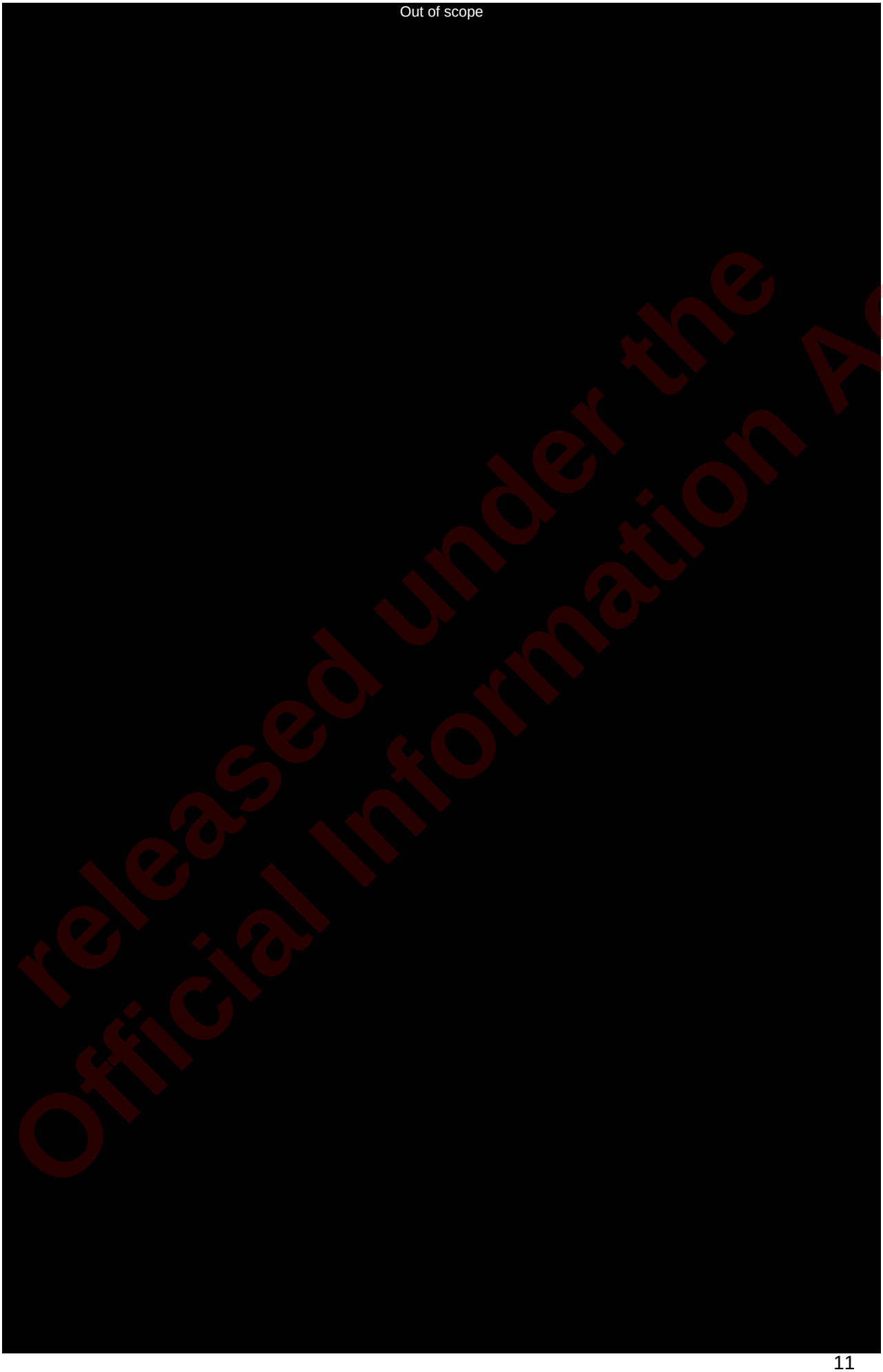

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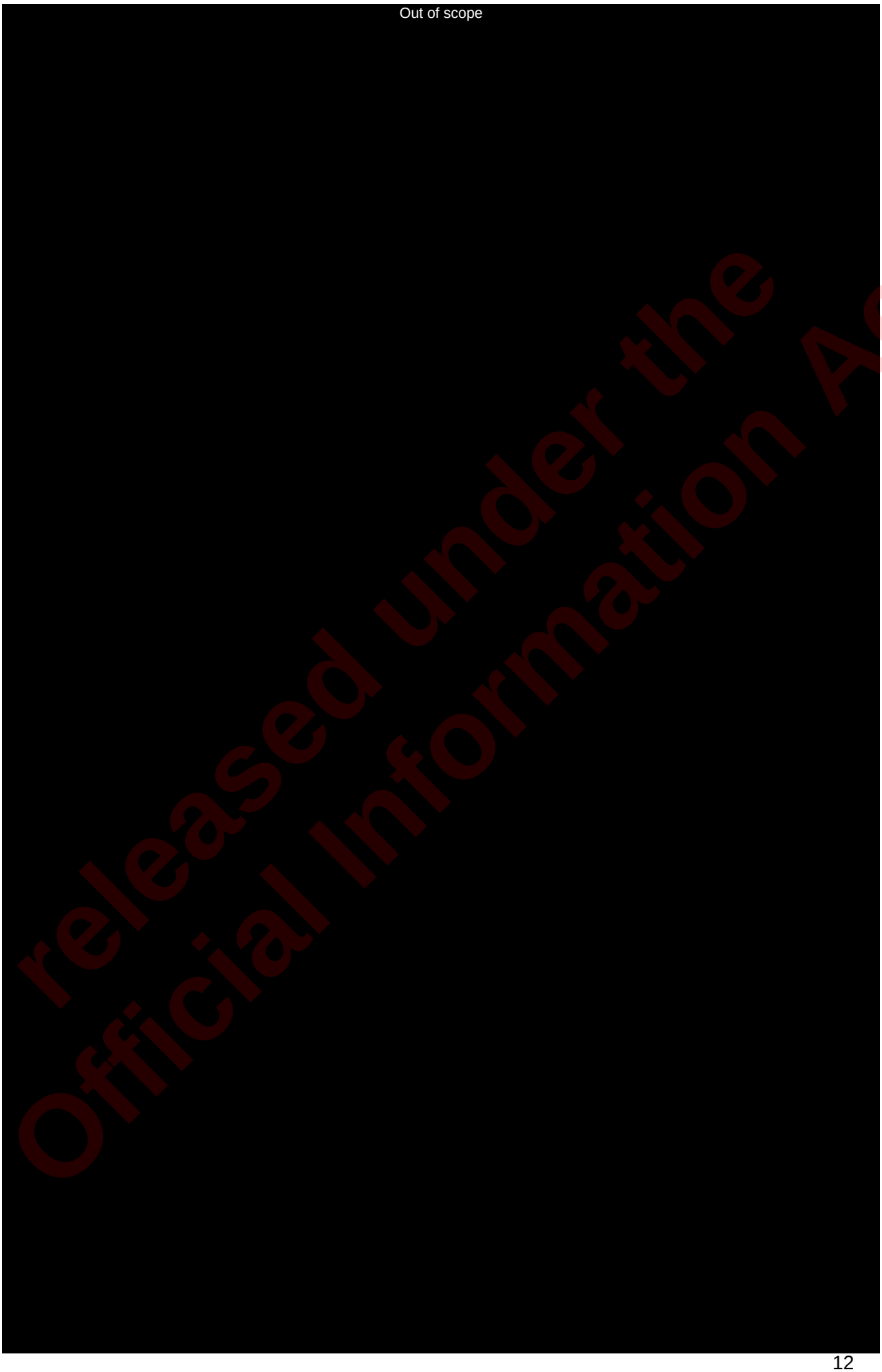

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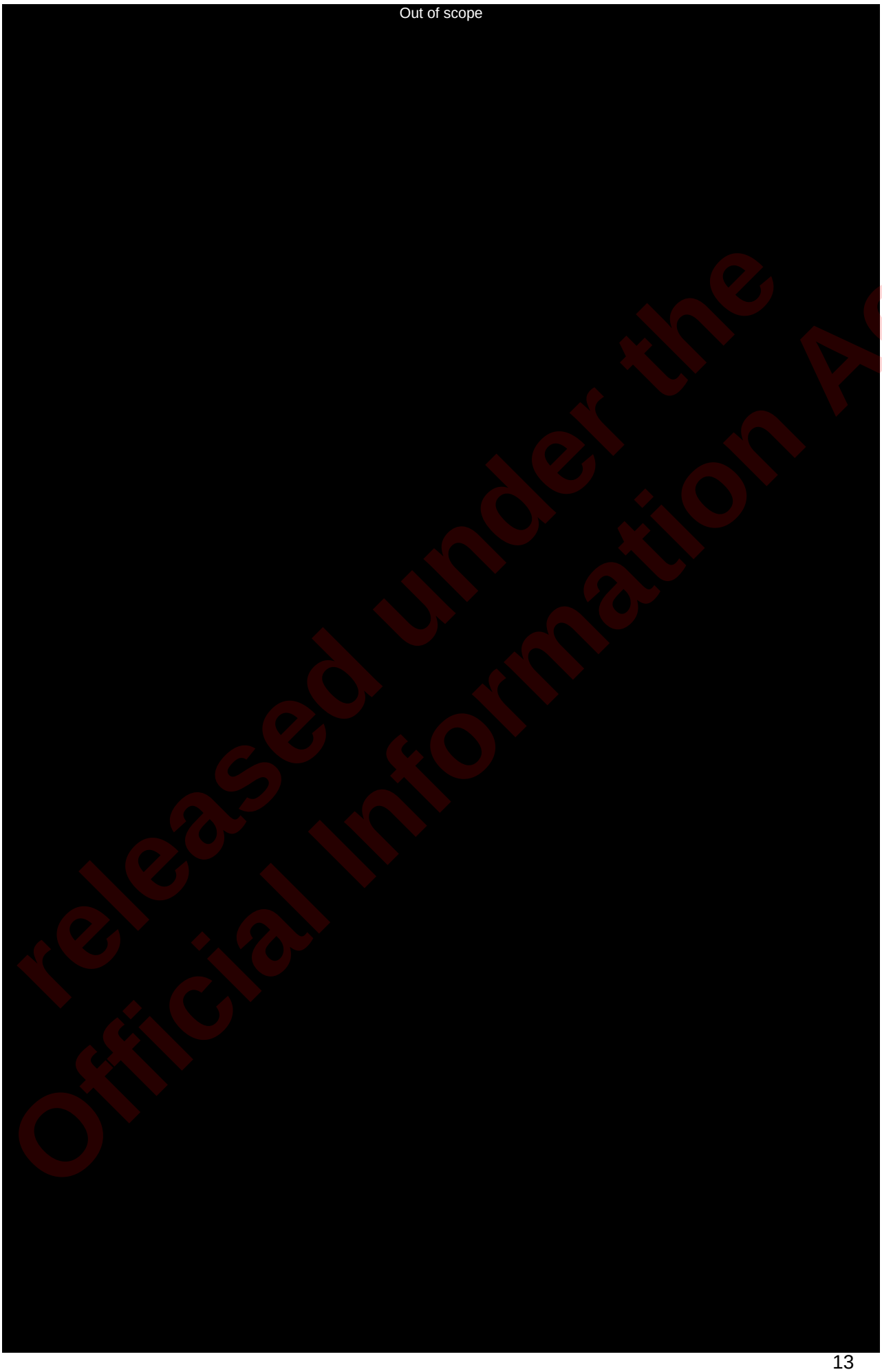

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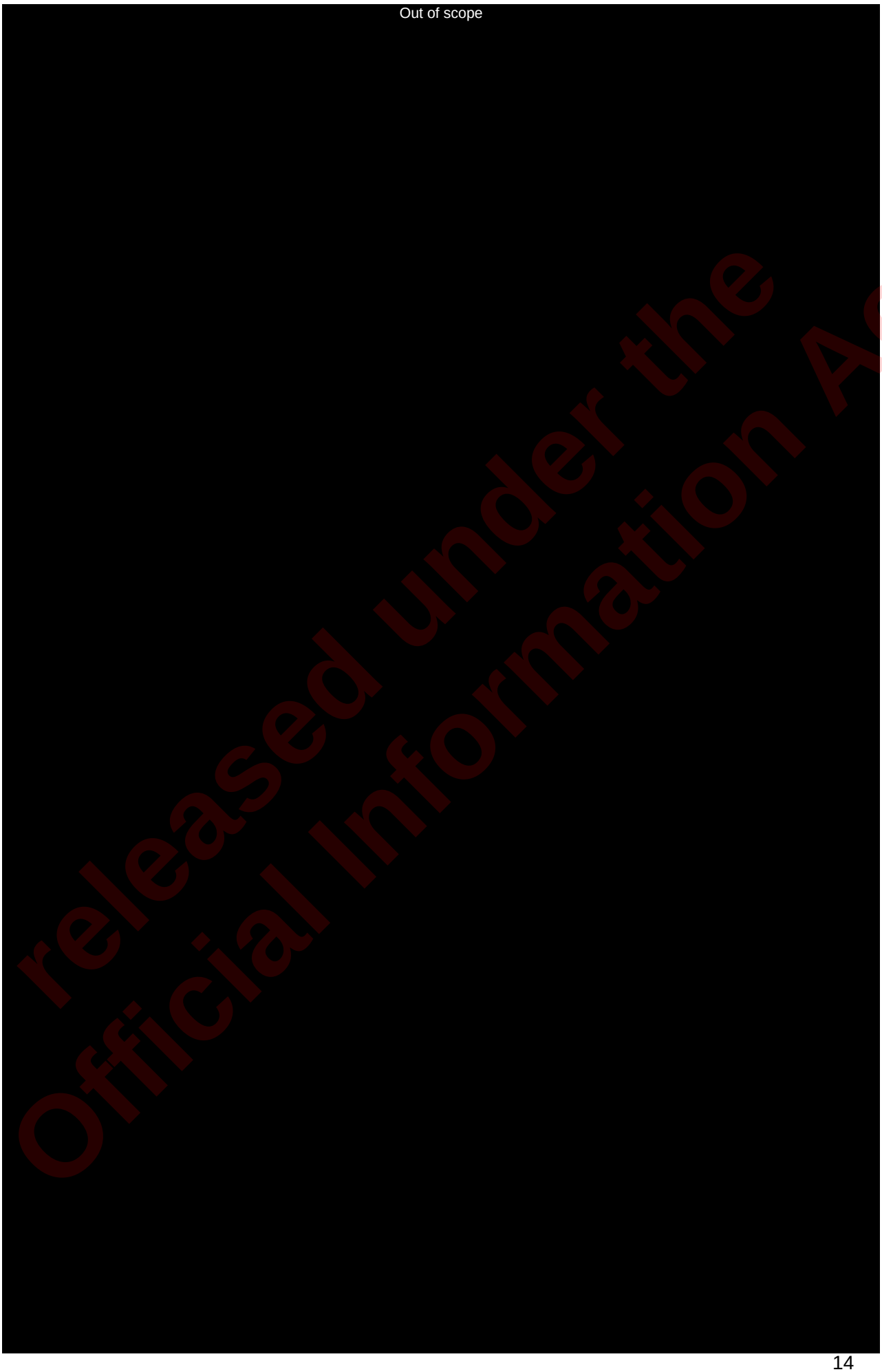

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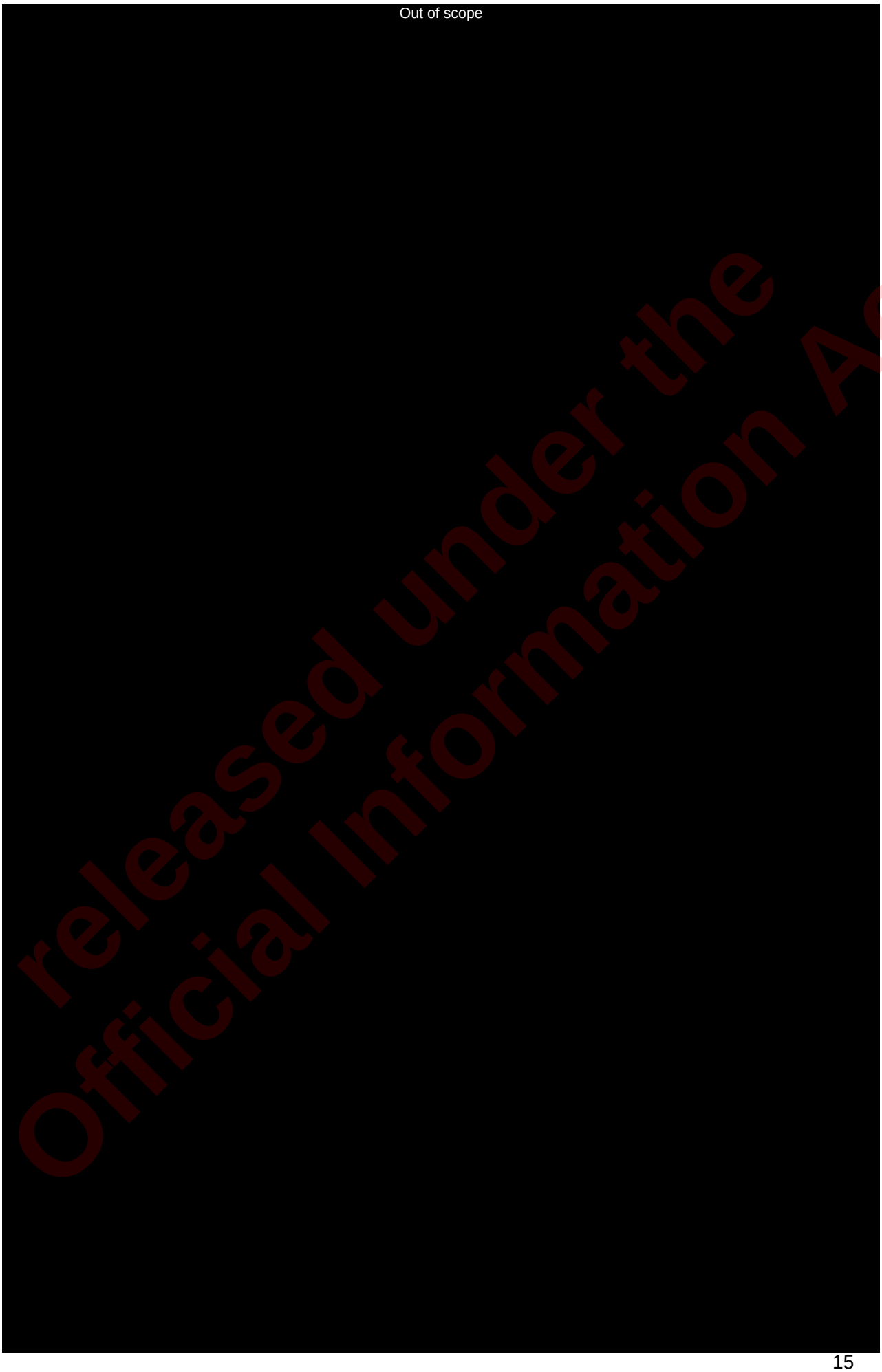


From: Doris Chong
Sent: Tuesday, 29 November 2022 10:32 am
To: Belinda Ray-Johnson
Cc: Kaye Wilson
Subject: FW: Pharmac consultation: proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs

Hiya

I've received some questions below from Toniq. How do you want this handled? Should it be sent to the feedback email?

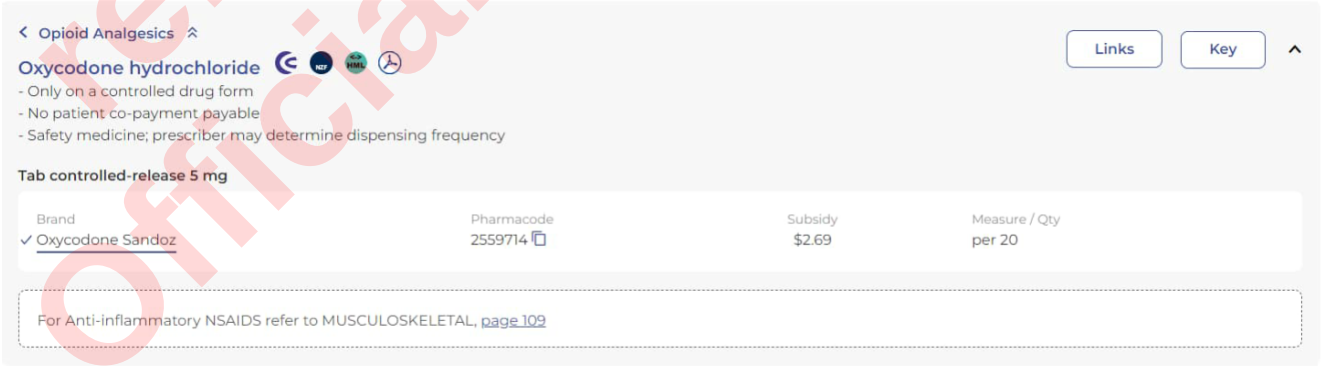
Thanks
Doris

From: Andrew Shaw <s 9(2)(a)>
Sent: Tuesday, 29 November 2022 8:38 am
To: Doris Chong <doris.chong@pharmac.govt.nz>
Subject: RE: Pharmac consultation: proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs

Hi Doris,

Many thanks for sending this out – this answered most of my questions. I do have a couple still if you're able to advise please:

1. On controlled drugs, there is a PHARMAC rule "Only on a controlled drug form" – I am assuming that this will also be removed or adjusted to include wording on the NZePS alternative?



2. On the page, it mentions that BSO/PSO supply is unaffected by these changes. Does this mean paper prescriptions are required for these supplies, or is that part pertaining to the amount that can be supplied?

Kind regards,

Andrew Shaw
Clinical Product Owner | Pharmacist, M.ClinPharm(*Dist.*), MPS

TONIQ
A Clanwilliam Company

Phone +64 (3) 341 0195
Level 1, 72 Moorhouse Avenue, Addington, Christchurch 8011, New Zealand
PO Box 8831, Riccarton, Christchurch 8440

www.toniq.nz

From: Doris Chong <doris.chong@pharmac.govt.nz>
Sent: Monday, 28 November 2022 9:32 am
To: Andrew Shaw <s 9(2)(a)>; Luke Tilson <s 9(2)(a)>; Astrid Saville <s 9(2)(a)>; Healthsoft (Margie Peat) <s 9(2)(a)>; Yen Walker <s 9(2)(a)>; Phoebe Kwan (HealthSoft) <s 9(2)(a)>
Cc: Kaye Wilson <Kaye.Wilson@Pharmac.govt.nz>
Subject: Pharmac consultation: proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs

Hi all

Please find attached the consult regarding the Schedule Rules changes on prescribing and dispensing Class B controlled drugs. Consult closes 9 December 2022 so please provide any feedback by then.

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.

From: Te Pātaka Whaioranga - Pharmac <consult@pharmac.govt.nz>
Sent: Monday, 28 November 2022 9:00 am
To: Doris Chong <doris.chong@pharmac.govt.nz>
Subject: Pharmac consultation: proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs

View this email in your browser

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

Kia ora

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

Pharmac welcomes feedback on this proposal.

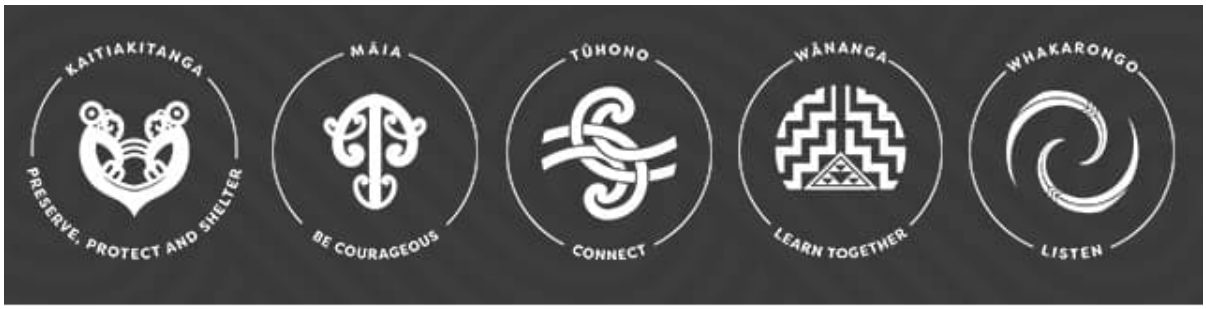
To provide feedback, please email consult@pharmac.govt.nz by **5pm on Friday 9 December 2022**.

Please circulate this email to others who may be interested.

Ngā mihi,

Belinda Ray-Johnson | Schedule Development Manager

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



PHARMAC
TE PĀTAKA WHAIORANGA

Want to change how you receive these emails?
You can update your preferences or unsubscribe from this list.

From: Allanah Andrews
Sent: Wednesday, 30 November 2022 9:37 am
To: Senior Leadership Team
Cc: Sean Dougherty; Belinda Ray-Johnson
Subject: FW: No Surprises - Proposal to amend Pharmaceutical Schedule Rules

FYI

From: Allanah Andrews
Sent: Wednesday, 30 November 2022 8:40 am
To: anna.gillies@parliament.govt.nz
Cc: Adelia Hallett <Adelia.Hallett@parliament.govt.nz>; Talisa Kupenga <Talisa.kupenga@parliament.govt.nz>; Peter.Jane@health.govt.nz; Andi.Shirtcliffe@health.govt.nz; Allison Bennett <Allison.Bennett@health.govt.nz>; Therese Egan <therese.egan@health.govt.nz>; Carol Morris <carol.morris@pharmac.govt.nz>
Subject: No Surprises - Proposal to amend Pharmaceutical Schedule Rules

Kia ora Anna,

This is a no surprises update for the Minister in relation to Pharmac's consultation on a proposal to amend Pharmaceutical Schedule Rules.

Pharmac is currently consulting on a proposal to amend the Pharmaceutical Schedule General Rules (the Schedule Rules) to bring funding rules in line with legislative changes to the prescribing and dispensing of controlled drugs: Proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs - Pharmac | New Zealand Government

Amendments to the Medicines Regulations 1984 and Misuse of Drugs Regulations 1977 have recently been notified to the sector by Manatū Hauora. These amendments will come into force on 22 December 2022.

Our proposed changes are to give effect to these decisions, which have already been made by Manatū Hauora.

The effects of the legislative changes will be to:

- enable controlled drugs to be prescribed electronically via the New Zealand Electronic Prescribing System (NZePS)
- allow prescriptions for Class B controlled drugsto be for longer periods than currently permitted – three months instead of one month if the prescription is issued electronically via the NZePS
- provide that Class B controlled drug dispensing frequency, when issued in the NZePS, will be monthly unless otherwise specified by the prescriber
- allow prescribers to direct shorter prescriptions or more frequent dispensing when they issue a prescription

reducing the frequency prescribers need to issue prescriptions for Class B controlled drugs, when issued through the NZePS, will reduce the number of times people need to visit a prescriber for repeat prescriptions of medications for some chronic conditions, like ADHD.

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

Some immediate feedback indicates that stakeholders were not aware of the Regulations changes before the Pharmac consultation was issued and see the proposed changes as being initiated by Pharmac. The main concerns that have been raised by stakeholders are about inappropriate prescribing and abuse. We intend to work with Manatū Hauora to provide stakeholders with key messages and implementation support.

Ngā mihi, nā

Allanah Andrews (she/her) | Manager, Policy and Government Services
P: s 9(2)(a) | M: s 9(2)(a) | www.pharmac.govt.nz
Te Pātaka Whaioranga | Pharmac | PO Box 10-254, Wellington 6140 | Level 9, 40 Mercer Street, Wellington 6011

PHARMAC
TE PĀTAKA WHAIORANGA

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

Stakeholder group	Theme	Pharmac comment
	General feedback (opioids)	
National Medication Safety Advisory Group (NMSAG)	The change in regulations re: Class B opioids is an opportunity for a more nuanced approach to both manage risk and ensure equity of access. Stakeholders not identified in Pharmac consultation who may wish to contribute include Police and public health	MoH advised these parties were consulted with as part of changes to regulations
	Support for the proposal (general)	
(Patient, supplier, clinician, government etc. note can be more than one per theme) Consumer Pharmacists PSNZ Clinicians Analgesic stewardship Consumer	We received supportive feedback regarding E-prescriptions being provided for a 3 month period with monthly dispensings: • Patients not picking up repeats frequently enough so being denied repeats **(opioids)** • Monthly dispensing has worked well for ADHD medicines and should be expanded for all chronic use Class B **(opioids)** • It would be difficult to have the legal duration not match the funded duration **(opioids**) • increased access for patients requiring these medicines, at a time when they may already be struggling with their underlying conditions **(opioids and ADHD)** • Reduced treatment burden and costs for patients on class B medicines **(ADHD and opioids)** • changes to bring Rules into line with the Regulations are welcome. This represents a small but useful reduction in the excessive bureaucratic overhead associated with being neurodiverse in Aotearoa **(ADHD only)**	We are grateful to the people who shared their personal experiences of whānau members with ADHD, chronic conditions and the terminally ill and the barriers for access to medicines.

PSNZ RNZCGP RNZCGP RANZCP	• in favour of rationalizing prescribing through electronic prescribing • Support improving equity of access to these medications by a) supporting access to care b) reducing barriers faced by those living rurally/ those with mobility issues/ in circumstances where frequent Rx renewals and collections are difficult to manage, including medical (GP visit, pharmacy co-payment) and transport costs.	
	Support for the proposal (opioids)	
Consumer GPs Hospice setting Child health Addiction medicine NMSAG	We received supportive feedback regarding E-prescriptions for opioids being provided for a 3 month period with monthly dispensings: • Some patients may benefit from improved access to opioids (cancer, COPD) • Reducing stress for patients and whanāu experienced with more regular prescriptions and dispensings • Noted ability of prescriber to endorse an electronic Rx for more frequent prescribing if concerns re: abuse/diversion • Support prescribing duration and electronic prescribing for methadone • Less dosing errors, better tracking and monitoring of scripts, reduced forged Rxs	• Noted safeguards and standards and regulatory framework in place with the Opioid substitution treatment (OST) supporting 90 day methadone Rxs.
	Support for the proposal (ADHD)	
Consumer Child pschiatrist Child psychiatrist	We received supportive feedback regarding E-prescriptions for methylphenidate and stimulants being provided for a 3 month period with monthly dispensings:	

Consumer Advocacy Paediatrician NP- psychiatry NP – mental health GP Pharmacist	• Reduced costs (GP and prescriptions) for patients on ADHD medicines • Patients with ADHD should have Rx length the same as for other conditions • Stability of patients on methylphenidate dosing allows for 3/12 Rxs • Supports efficient use of small ADHD workforce (reduced admin etc) • Support for reduced barriers to collection of Rx and therefore treatment for people with ADHD • Safety mechanisms in place include stimulants being commenced and approved by a specialist psychiatrist • Good evidence for long term use of stitimulants	
	Timeframe (ADHD)	
Consumer advocacy	• Negative impact on patients of implementation date later than 22 Dec not justifiable	
	Legislation	
RNZCGP Multiple stakeholders Pharmacists, Pharmacy Guild, Clinicians (RNZCGP, NZ Pain Society), Pharmacist	• Support E-prescribing but do not consider this a rationale for lifting the system time limits on opioid use for pain management • Much of the feedback we received was on the legislative changes that necessitated changes to the Schedule General Rules in order to give effect to these • Disagree with proposal (to align with legislation) • Inadequate legislation consultation process • Regulatory changes were considered and approved without adequate consultation with medical experts of peak medical	Gazetted 24 Nov 2022. Pharmac seeking to ensure funding is in line with legislative change.

Mental health SAC RNZCGP	bodies which is highly unusual for such a sensitive area. • Concerns no adequate risk assessment has been done of the potential for increasing opioid addiction, diversion or other opioid related harms in NZ, or adequate examination of ways to mitigate the risk of this happening • Concerns subsequent changes to funding rules to support legislation changes were not discussed at SAC meetings • The regulatory changes go against international best practice guidelines, undermines professionalism and clinical judgement – a maximum of four weeks (prescription) is workable, often much less – 3 months is inappropriate and dangerous – prescriber responsibilities include i) avud creating dependance ii) to see that the patient does not gradually increase the dose of a drug to a point where dependance becomes likely iii) to avoid being used as an unwitting source of supply for addicts and being vigilant to methods for obtaining medicines. • the inconvenience of monthly prescriptions for those small number of opioid recipients that could benefit from a three-monthly script is very slight in comparison to the risks of providing more.	
	ADHD medications versus opioids	

Pharmacists, clinicians, consumers Pharmacists, Pharmacy Guild, Clinicians Pharmacists, Clinicians	• General support for changes to prescribing and dispensing of ADHD medicines • ADHD medicines (Methadone as part of OST) and opioids should be treated differently with tighter controls on opioids, although some support for monthly dispensing for long term, stable patients on opioids • 10 day dispensing (or suggestions for other intervals e.g. 15 days, two weeks) should remain on **opioids** (feedback in relation to patient safety, safe size, pharmacy safety), although some support for three month prescriptions) – noted 10/7 dispensing awkward as often falls on weekend	
	Patient stability	
Clinicians Pharmacists Analgesic stewardship Clinicians	• Many patients on stable doses **(ADHD and chronic use opioids)** • Opioid dose requirements change rapidly and often. • Opioid prescribing for non-cancer pain should be of short duration • Opioid Rx's should be presented for dispensing within 7/7 of Rx/g when the dose and quantity are clinically appropriate	Under this proposal, prescribers have flexibility to prescribe more or less frequently to meet the requirements of their patients. Key message for Implementaton
	Patient safety	
RNZCGP Analgesic stewardship RNZCGP Pharmacists Anaesthetist GPs RANZCP	• Strongly opposed to move away from monthly dispensing of opiates and opioids with 10/7 dispensing, especially in clinical situation of non-cancer pain. • Increased risk of opioid related harm outweighs benefit of this proposal • Considers controls to date on opioid dispensing has (in part) led to NZ's avoidance to date of opioid excess and harm (as in eg USA)	

Addiction medicine Pharmacist Analgesic stewardship NMSAG Clinician Analgesic stewardship	• Increased stockpiling of opioids (prn meds often given on repeat in addition to regular medicine) • • Concern that patient with supplies of these medicines will be targeted **(opioids)** • Risk of misuse, overdose/ diversion, unintended harm and increase in addiction issues that will likely disproportionately affect those with high needs, Māori and Pacific peoples • The quantity of opioids in a long-term Rx has high street value • Reduced visibility of drug seeking Behaviour and diversion direct health sector impact • Potential to increase the quantity of controlled drugs within the community by 300% • Risks reducing interactions, review opportunities and informal checkpoints between patients and their healthcare team • Noted convenience factor important for people who live rurally and consider an exception to better accommodate for this by enabling >10/7 dispensing (concerns extending to 30/7 dispensing) • Greater responsibility for prescribers to think about and manage dispensing intervals and qualities of opioids • Risk of prescriber not over-riding default 30/7 dispensing in patient management system to smaller dispensing amount • Suggesting Pharmac can be more nuanced than regulations allow. Suggest keeping 10/7 dispensing as the default for opioids (and longer periods of supply	

Child psychiatrist Addiction medicine	being available via special authority (for specific justifiable situations eg cancer pain) Suggest keeping 1/12 prescriptions for opioids • Support wider consultation before this proposal is progressed • Considers concerns about abuse and misappropriation won't be any different under proposed new funding framework (ADHD) • Considers guidance should support lesser amounts of stimulants being dispensed at prescribers discretion where risks are identified.	
	Inappropriate prescribing and abuse potential	
RACP RNZCGP FPN Faculty of Pain management Anaethetist Pain medicine Community mental health and addictions Clinicians Analgesic stewardship Pharmacists Clinicians	diverse opinions among the members of the RACP who responded on Pharmac's proposal. • Risks potential opioid overuse particularly in the treatment of non-cancer acute or chronic pain where there is little evidence of benefit for long-term pain. • Facilitates long term use of opioids • Rx'g opioids for longer periods of time reduces the opportunity for the prescriber to review • Concerns of errant CD prescribing by a minority of GPs • Concern GPs will be pressured for 3/12Rx's for opioids where there are not clinically indicated • Provide education (to GPs) on avoidance of prescribing long term opioids for pain and limiting supply to 7 days	We acknowledge the way services have safely adapted for prescribing Class B CDs during the COVID-19 lockdowns. We intend to work with Manatū Hauora to provide stakeholders with key messages and implementation support

Clinician RNZCGP	• Prescribing controlled drugs for opioid dependence or ADHD uses risk assessment approach - not concerned about increased prescription length • Increasing the length of prescription creates greater potential for opioid diversion, unintended harm and addiction • Misuse mostly occurs when medication is taken at a higher dose, increased frequency or for a longer duration than indicated • Strong evidence largest opioid prescription size substantially increases the risk of people becoming new and persistent opioid users after surgery and other medical procedures •	
	Implementation timeframe	
Pharmacists Suppliers Pharmacy software vendors PSNZ RANCZP Pharmacist	• Concerns about consultation timing and feedback window • Insufficient time to plan and address storage requirements • Implementation date too soon to ensure sufficient stock (increase in initial demand) including relevant import permits (? controlled by Medsafe) • Insufficient time to make software changes • concern about the gap and inconsistency in practice, in between legislation in force and funding change • difficulty faced by Pharmac in effecting changes to legislation	Tight timeframes created by legislative changes Communication with sector, stakeholders, patients and carers Work with Medsafe to ensure clarity in communication to support import permits for Class B CDs
	Implementation	
National Medication Safety Advisory Group (NMSAG)	• Public health and quality use of medicines issues with proposed change for prescribing and dispensing of opioids - Consideration	

RNZCGP	of a monitoring plan by Pharmac or Medsafe • Suggest need for accompanying education campaign and addition of restrictions to daily oral morphine equivalent dose that can be prescribed without specialist review and supervision (as per Australian model) • We suggest that opioids should not be started without a clear exit plan for stopping these medications. • Interventions to reduce inappropriate opioid prescribing should be focused on improving patient care, management of patients with complex pain, and reducing comorbidities rather than seeking to enforce a threshold for prescribing. • Given current data, we want to see safeguards put in place such as a special authority, and auditing to highlight inappropriate prescribing against best practice guidelines and give the ability to provide governance over the supply of opioids. • The maximum of one month prescribing and dispensing already in place is not robust enough.	
RNZCGP	• more focus should be placed on opioid prescribing and supporting the integration of the National Medication Safety Programme • It has a key leadership role in improving overall medication safety, harm from medication errors and addressing unwarranted variation and clinical leadership • Support improving safety of opioid prescribing practices at system level to support	

	prescribers with evidence, bets practice and establish systems to include i) standards for best practice prescribing and dispensing ii) auditing and reconciliation of medicines that have a known potential for misuse iii) setting boundaries for prescribing iv) dispensing pharmacists should reiterate information to patients	

break	Call for legislative change to Class Bs – they are not all the same	
RNZCGP	• Distinct clinical situations have not been considered or outlined for separate feedback • Methylphenidate and Dexamfetamine are used in a stable long term treatment regime with continuity of prescriber, there may be a benefit to three-monthly prescription with monthly dispensing. • For methadone in an opiate substitution programme where the patient is in a • regular pharmacy dispensing situation likewise there may be a benefit for three monthly scripts. • non-cancer pain is where the main risk lies for diversion and increased potential for addiction and this scenario should not move away from monthly scripts with 10-day dispensing. • a patient who is diagnosed with ADHD and is stable with continuous follow up, methadone in an addiction substitution program and opioids for the treatment of cancer pain are very different clinical scenarios to prescribing opiates for non-cancer pain. • Opioids outside of methadone should continue to be prescribed monthly and dispensed at 10-day intervals	
	Pharmacist adjustment of dispensing	
Pharmacists	• Pharmacists should be able to adjust supply periods to provide smaller quantities for long term conditions patients	The legislation only allows prescribers to specify dispensing frequency - we are unable to override the legislation with subsidy rules
	Safe storage of CDs at community pharmacy	
Pharmacists, Pharmacy Guild	• Lack of CD safes within NZ • Storing increased volume of CDs • Increased “owes” to patients • Dispensed CDs need to be stored in safe until patient collects	

PSNZ	• Pharmacy and staff safety – concerns about pharmacies being targeted • Aware that there is no additional funding from Te Whatu Ora to help manage any future safe requirements. This is outside of Pharmac's control and should not affect the outcome of the consultation. •	
	Co-payments	
Pharmacists	• Should now be applied to all (opioids as well as ADHD meds) • Clarity on what co-payments will apply	Copayments is MoH policy – not within Pharmac's remit Current copayment rules apply
	Impact on the supply chain	
Pharmacists	• Risk of out of stocks	more across supply chain (end to end, including patients) increases resilience
	Workload	
Clinicians Pharmacists,Pharmacy Guild	• Reduced GP and pharmacy admin and workload **(mostly in relation to OST and ADHD prescribing)** • Increased pharmacy workload **(mostly opioids)**	
	Wastage and disposal/destruction of CDs	
Analgesic stewardship Pharmacists, Pharmacy Guild	• Increased wastage of opioids with dose changes • Financial and social cost of increased wastage (prn meds often given on repeats in addition to regular medicine, when not required) • Environmental hazard with increased wastage of CDs • Increased workload for safe disposal of CDs	
	Cost burden to pharmacies	
Pharmacists	• Cost of safes • Greater financial losses if holding short-dated stock • Reduction in dispensing fees	

	• Pharmac should provide financial support	
	Call for	
RANZCP	•	
	• Strongly opposed to move away from monthly dispensing of opiates and opioids with 10/7 dispensing, especially in clinical situation of non-cancer pain. • Increased risk of opioid related harm outweighs benefit of this proposal • Considers controls to date on opioid dispensing has (in part) led to NZ's avoidance to date of opioid excess and harm (as in eg USA) • Increased stockpiling of opioids (prn meds often given on repeat in addition to regular medicine) • • Concern that patient with supplies of these medicines will be targeted **(opioids)** • Risk of misuse, overdose/ diversion, unintended harm and increase in addiction issues that will likely disproportionately affect those with high needs, Māori and Pacific peoples • The quantity of opioids in a long-term Rx has high street value • Reduced visibility of drug seeking Behaviour and diversion direct health sector impact • Potential to increase the quantity of controlled drugs within the community by 300% (stimulants changing from 30/7 to 90/7 supply), remaining class B s changing from 10/7 to 30/7 supply) • Risks reducing interactions, review opportunities and informal checkpoints between patients and their healthcare team	

	• Noted convenience factor important for people who live rurally and consider an exception to better accommodate for this by enabling >10/7 dispensing (concerns extending to 30/7 dispensing) • Greater responsibility for prescribers to think about and manage dispensing intervals and qualities of opioids • Risk of prescriber not over-riding default 30/7 dispensing in patient management system to smaller dispensing amount • Suggesting Pharmac can be more nuanced than regulations allow. Suggest keeping 10/7 dispensing as the default for opioids (and longer periods of supply being available via special authority (for specific justifiable situations eg cancer pain) Suggest keeping 1/12 prescriptions for opioids • Support wider consultation before this proposal is progressed • Considers concerns about abuse and misappropriation won't be any different under proposed new funding framework (ADHD) Considers guidance should support lesser amounts of stimulants being dispensed at prescribers discretion where risks are identified.	
Consumer advocacy	• Feedback that Special Authority criteria for methylphenidate hydrochloride require diagnosis according to DSM-IV or ICD 10 criteria which does not encompass a te ao Māori worldview.	
Multiple stakeholders	• Specialist approval/ SA applicant type for methylphenidate and	SA prescriber type reflects the legislation

Consumer advocacy NPs GP	dexamfetamine is a barrier to access (ADHD) • Feedback requesting nurse practitioners be able to initiate a special authority for methylphenidate hydrochloride • Feedback asking for review of specialist approval for initiating methylphenidate described as causing inequity due to difficulty of getting adult patients with ADHD assessed in the public system and the cost of seeing a psychiatrist privately.	From 1 November 2020, the methylphenidate SA was amended to enable applications from nurse practitioners (in addition to medical practitioners) on the recommendation of a paediatrician or psychiatrist in writing. https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/2020-10-23-decision-to-widen-access-to-long-acting-methylphenidate/ This is in line with prescribing restrictions under regulation 22 of the Misuse of Drugs Regulations 1977 https://www.medsafe.govt.nz/profs/riss/restrict.asp#Methylphenidate
Addiction medicine	• Feedback for benefits of funding a long-acting injectable buprenorphine (LAIB)	Buprenorphine depot injection is under assessment as a funding proposal. It has been recommended with a high priority by the Mental Health Specialist Advisory Committee https://pharmac.govt.nz/assets/2021-09-Mental-Health-Subcommittee-record.pdf

Unknown category at this stage

- The only downside I can see is that there may need to be a limit on the amount that is prescribed in the sense that if a medication is prescribed PRN to hourly, as it often is in palliative care, a month's supply if the doctor has no specified an amount, could be excessive (perhaps need to state that an actual amount of medication is prescribed in these circumstances e.g "mitte: 100" rather than "one month's supply". (Alana Wilson) [response – prescribers can do this]

- "Is there any change proposed to how long a class B CD script is valid for, ie will it still be only 7 days from writing" (Milton Pharmacy) [*Note this is legislative and hasn't changed – BRJ has responded to enquirer]*

- feedback on the difficulties we are having running effectively 2 systems – electronic and paper based. (Tasmin Willis – hospital, receiving barcoded prescriptions for initiating patients) *[is about NZePS implementation?]*
- Why was suboxone not included – oversight? (GP/CADS prescriber) [response - Buprenorphine naloxone – is C4 so already less restricted]
- plea for the requirement of hard copy prescription for class B medications to be disbanded (Tony Farrell) *[not Pharmac but we might be able to answer – need to check but I think the new leg does remove this]*

- could there be special circumstances in which a patient could collect the entire 3 months script for dexamphetamine or methylphenidate hydrochloride (young adults who travel) (child/adolescent prescriber) *[I don't think the legislation contemplates this. Can't override leg with subsidy rules]*
- Patient admin systems will need updating - timing of the change is of concern. Many organisations enforce an IT change freeze over the Christmas holidays. Please delay implementation until January (Te Whatu Ora IT service provider) [*refer this to Te Whatu Ora/MoH – even though it has come from someone in Te Whatu Ora - as it is about timing implementation of the leg change, not Schedule rules?]*
- The dispensing date should be within one month of being written, the seven day rule is outdated (pharmacist) *[this is legislative so we are unable to override with subsidy rules]*
- The period of supply should never be greater than 1 month with repeats (pharmacist) [*proposal has no provision for stat as leg does not allow it]*
- The period of supply should be able to be annotated by the pharmacist based on discussion with the patient and their whanau due to safety/security concerns and in palliative and end of life care *[as above]*
- Greater use must be made of the electronic data that is received each week through Health Benefits when the pharmacy sends in their "claim" (pharmacist)
- Medicines Control needs to rigorously look for over use/ multiple prescribers/ and inappropriate prescribing, There is no national drug seeker list and this change has the potential to greatly increase the misuse of controlled drugs (pharmacist)
- Prescribers should take full responsibility for patients prescribed an extended supply (exceeding the usual 10-days per single dispensing) of class B controlled drugs, by clearly endorsing the NZePS prescription. This endorsement should take the form of "please supply 30 days at once" or similar and must be electronically recorded via NZePS. Note, this should occur infrequently, based on an individual patient's unique needs. (Pharmacy Guild) [*the legislation sets out prescriber responsibilities in relation to period of supply]*

……

References

186-3.2.3-Opioid.pdf (medsafe.govt.nz)

Stakeholder group	Theme	Pharmac comment
	Support for the proposal	
(Patient, supplier, clinician, government etc. note can be more than one per theme) Consumer Pharmacists PSNZ Consumer PSNZ	We received supportive feedback regarding E-prescriptions being provided for a 3 month period with monthly dispensings: • Reducing stress for patients and whanāu for more regular prescriptions and dispensings **(opioids)** • Patients not picking up repeats frequently enough so being denied repeats **(opioids)** • Monthly dispensing has worked well for ADHD medicines and should be expanded for all chronic use Class B **(opioids)** • It would be difficult to have the legal duration not match the funded duration **(opioids**) • increased access for patients requiring these medicines, at a time when they may already be struggling with their underlying conditions **(opioids and ADHD)** • Reduced costs for patients on ADHD medicines **(ADHD only)** • changes to bring Rules into line with the Regulations are welcome. This represents a small but useful reduction in the excessive bureaucratic overhead associated with being neurodiverse in Aotearoa **(ADHD only)**	We are grateful to the people who shared their personal experiences of whānau members with ADHD, chronic conditions and the terminally ill and the barriers for access to medicines.
	Legislation	
Multiple stakeholders	• Much of the feedback we received was on the legislative changes that necessitated changes to the Schedule General Rules in order to give effect to these	Gazetted 24 Nov 2022. Pharmac seeking to ensure funding is in line with legislative change.

Pharmacists, Pharmacy Guild, Clinicians (RNZCGP, NZ Pain Society)	• Specialist approval/ SA applicant type for methylphenidate and dexamfetamine is a barrier to access **(ADHD)** • Disagree with proposal (to align with legislation) • Inadequate legislation consultation process	SA prescriber type reflects the legislation
	ADHD medications versus opioids	
Pharmacists, clinicians, consumers Pharmacists, Pharmacy Guild, Clinicians Pharmacists, Clinicians	• General support for changes to prescribing and dispensing of ADHD medicines • ADHD medicines and opioids should be treated differently with tighter controls on opioids, although some support for monthly dispensing for long term, stable patients on opioids • 10 day dispensing (or suggestions for other intervals e.g. 15 days, two weeks) should remain on **opioids** (feedback in relation to patient safety, safe size, pharmacy safety), although some support for three month prescriptions)	
	Patient stability	
Clinicians Pharmacists	• Many patients on stable doses **(ADHD and chronic use opioids)** • Some patients have frequently changing doses	Under this proposal, prescribers have flexibility to prescribe more or less frequently to meet the requirements of their patients. Key message for Implementaton
	Patient safety	
Pharmacists	• Concern that patient with supplies of these medicines will be targeted **(opioids)** •	
	Inappropriate prescribing and abuse potential	
Pharmacists Clinicians	• Provide education to GPs on avoidance of prescribing long term opioids for pain and limiting supply to 7 days • Prescribing controlled drugs	We acknowledge the way services have safely adapted for prescribing Class B CDs during the COVID-19 lockdowns.

Clinician	for opioid dependence or ADHD uses risk assessment approach - not concerned about increased prescription length	We intend to work with Manatū Hauora to provide stakeholders with key messages and implementation support
	Implementation timeframe	
Pharmacists Suppliers Pharmacy software vendors Consumer advocacy PSNZ	• Concerns about consultation timing and feedback window • Insufficient time to plan and address storage requirements • Implementation date too soon to ensure sufficient stock • Insufficient time to make software changes • Impact on patients of implementation date later than 22 Dec not justifiable **(ADHD)** • concern about the gap between legislation in force and funding change	Tight timeframes created by legislative changes Communication with sector and patients
	Pharmacist adjustment of dispensing	
Pharmacists	• Pharmacists should be able to adjust supply periods to provide smaller quantities for long term conditions patients	The legislation only allows prescribers to specify dispensing frequency - we are unable to override the legislation with subsidy rules
	Safe storage of CDs at community pharmacy	
Pharmacists, Pharmacy Guild PSNZ	• Lack of CD safes within NZ • Storing increased volume of CDs • Increased “owes” to patients • Dispensed CDs need to be stored in safe until patient collects • Pharmacy and staff safety – concerns about pharmacies being targeted • Aware that there is no additional funding from Te Whatu Ora to help manage any future safe requirements.This is outside of Pharmac’s control and should not affect the outcome of the consultation. •	

	Co-payments	
Pharmacists	• Should now be applied to all (opioids as well as ADHD meds) • Clarity on what co-payments will apply	Copayments is MoH policy – not within Pharmac's remit Current copayment rules apply
	Impact on the supply chain	
Pharmacists	• Risk of out of stocks	more across supply chain (end to end, including patients) increases resilience
	Workload	
Clinicians Pharmacists,Pharmacy Guild	• Reduced GP and pharmacy admin and workload **(mostly in relation to OST and ADHD prescribing)** • Increased pharmacy workload **(mostly opioids)**	
	Wastage and disposal/destruction of CDs	
Pharmacists, Pharmacy Guild	• Environmental hazard with increased wastage of CDs • Increased workload for safe disposal of CDs	
	Cost burden to pharmacies	
Pharmacists	• Cost of safes • Reduction in dispensing fees • Pharmac should provide financial support	

Unknown category at this stage

- The only downside I can see is that there may need to be a limit on the amount that is prescribed in the sense that if a medication is prescribed PRN to hourly, as it often is in palliative care, a month's supply if the doctor has no specified an amount, could be excessive (perhaps need to state that an actual amount of medication is prescribed in these circumstances e.g "mitte: 100" rather than "one month's supply". (Alana Wilson) [response – prescribers can do this]

- "Is there any change proposed to how long a class B CD script is valid for, ie will it still be only 7 days from writing" (Milton Pharmacy) [*Note this is legislative and hasn't changed – BRJ has responded to enquirer]*

- feedback on the difficulties we are having running effectively 2 systems – electronic and paper based. (Tasmin Willis – hospital, receiving barcoded prescriptions for initiating patients) *[is about NZePS implementation?]*
- Why was suboxone not included – oversight? (GP/CADS prescriber) [response - Buprenorphine naloxone – is C4 so already less restricted]
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Update: 20 December 2022

Pharmac would like to thank everybody for their feedback to this proposal. We appreciate the time taken to share your support for, or concerns about, changes to the prescribing and dispensing of Class B controlled drugs.

In light of this feedback, Manatū Hauora, the Ministry of Health, has indicated that it would like to revisit the regulatory arrangements for opioids, and has asked Pharmac to delay making a decision on the proposed changes to the Schedule Rules in order 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 you updated as this work progresses.

From: Sean Dougherty
Sent: Monday, 5 December 2022 4:56 pm
To: David Hughes; Lisa Williams; Sarah Fitt
Cc: Belinda Ray-Johnson
Subject: Re: Controlled drugs

Hi David,

The origin of the 10 day rule is unknown, but it seems to predate Pharmac.

It has no basis in legislation.

SD.

From: David Hughes <david.hughes@pharmac.govt.nz>
Sent: Monday, December 5, 2022 4:45:54 PM
To: Sean Dougherty <sean.dougherty@pharmac.govt.nz>; Lisa Williams <lisa.williams@pharmac.govt.nz>; Sarah Fitt <sarah.fitt@pharmac.govt.nz>
Cc: Belinda Ray-Johnson <belinda.ray-johnson@pharmac.govt.nz>
Subject: RE: Controlled drugs

Kia ora Sean,
Could I just check the current situation? Is the current 7 day dispensing restriction for opioids in the schedule based on previous regulations? I asked Scott M and he has no recollection of where they came from. They appear at odds with the current regulations.

Ngā mihi,
David

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

From: Sean Dougherty <sean.dougherty@pharmac.govt.nz>
Sent: Monday, 5 December 2022 2:59 pm
To: Lisa Williams <lisa.williams@pharmac.govt.nz>; David Hughes <david.hughes@pharmac.govt.nz>; Sarah Fitt <sarah.fitt@pharmac.govt.nz>
Cc: Belinda Ray-Johnson <belinda.ray-johnson@pharmac.govt.nz>
Subject: RE: Controlled drugs

Further to this…

Our proposal at this stage (subject to consultation feedback of course) is that we:

> Make a decision in the next month or so to implement the Schedule changes, but slightly modified to accommodate future MODR changes. So essentially: dispensing frequency as on the prescription, and prescription lengths in line with the regs (without necessarily stating what they are, which we don't actually need to do).
>
> Defer implementation of that decision until the MoH either confirms the current change or implements a replacement (this would likely be at least a few months). And be clear to everyone what we're doing.
>
> This would both (a) give us time to sort out the implementation package (for dispensing frequency, which seems increasingly important), and (b) give the MoH the proper incentives to sort out opiates quickly.

SD.

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: Sean Dougherty
Sent: Monday, 5 December 2022 11:49 am
To: Lisa Williams <lisa.williams@pharmac.govt.nz>; David Hughes <david.hughes@pharmac.govt.nz>; Sarah Fitt <Sarah.Fitt@pharmac.govt.nz>
Cc: Belinda Ray-Johnson <Belinda.Ray-Johnson@pharmac.govt.nz>
Subject: Controlled drugs

Hi,

We've just had a catch-up with the MoH about the controlled drugs issue.

> They're very aware of the strong feedback (mostly in relation to opioids). They noted that they did consult earlier, but it was predominantly framed as a consultation on allowing CDs to be prescribed within the NZePS, which they realise now probably buried the lede.
>
> They are keen to explore how they can treat opioids differently from ADHD treatments. However they have no way to do this right now.
>
> They're not intending to stop the new regs coming into force as planned.
>
> SO, I said that we would buy them some time to sort through this all, which means delaying the Schedule changes. Longer scripts would still be legal, but not funded. BUT, we'll need to have some good messaging to support that, which will (as I see it) mean a statement from the Ministry that they're actually going to use the time to relook at the issue. Unfortunately the people that I'm dealing with aren't really able to make that commitment. We don't need to say anything immediately, so we've got time to coordinate something over the coming days.

SD.

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: Belinda Ray-Johnson
Sent: Monday, 5 December 2022 12:37 pm
To: David Hughes
Cc: Lisa Williams
Subject: Controlled drugs consult - new close date 21 Dec

Kia ora David

We've extended the consultation period for the controlled drugs consult.
Lisa mentioned you plan to send something out to RNZCGP tomorrow – here's the link with updated close date.

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

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.

From: Belinda Ray-Johnson
Sent: Friday, 9 December 2022 3:08 pm
To: Adam McRae
Subject: RE: Consultation on Class B controlled drugs

Thanks Adam. I think that's where it's heading.

Talk next week, have a good w/e.

Cheers
Belinda

From: Adam McRae <adam.mcrae@pharmac.govt.nz>
Sent: Friday, 9 December 2022 2:59 pm
To: Belinda Ray-Johnson <belinda.ray-johnson@pharmac.govt.nz>
Subject: FW: Consultation on Class B controlled drugs

Hi Belinda
Have this from Pfizer and a question from Sandoz and concern from AFT.
Will work to collate for you next week but would recommend we delay (as suggested in the supply issues meeting).
Cheers
Adam

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

Dear Adam,

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

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

Please see the specific feedback below on the products we supply into New Zealand:

- Morphine hydrochloride – RA Morph solution (1mg/mL, 2mg/mL, 5mg/mL, 10mg/mL) – these products are to be discontinued as previously communicated to Pharmac. We have received our final shipment of all 4 presentations which extends supply of all until Q4 2023, so will not be affected by Pharmac's proposed changes. The only potential impact would be that last supply dates could be brought forward.
- Morphine sulphate – DBL Morphine injection (5mg/mL, 10mg/mL, 15mg/mL, 30mg/mL) – these products are being delisted on 1 March 2023 so Pfizer does not see an issue with the proposed change for these presentations.
- Pethidine hydrochloride – 50mg/mL (1mL & 2mL) amps – we have adequate inventory to accommodate the proposed change on 1 Feb 2023.

Regards,
Andy

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

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

Kia ora

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

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

Ngā mihi
Adam

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

From: Belinda Ray-Johnson
Sent: Friday, 9 December 2022 11:44 am
To: Sarah Fitt; Lisa Williams; David Hughes
Cc: Sean Dougherty
Subject: FW: New Zealand Pain Society - Class B controlled drugs
Attachments: Letter to Pharmac_Class B opioid dispensing changes.pdf

Kia ora koutou

Flagging this consultation response with you as also cc'd to Minister of Health.

Ngā mihi

Belinda

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

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

Kia ora,

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

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

The attached letter outlines our concerns in more detail.

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

Ngā mihi
David

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

P 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

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.

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

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

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

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

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

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

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

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

Yours sincerely,

Associate Professor David Rice

President, New Zealand Pain Society

References

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From: Lisa Williams
Sent: Tuesday, 13 December 2022 12:31 pm
To: David Hughes; Sean Dougherty; Belinda Ray-Johnson
Cc: Sarah Fitt; Peter Alsop; Trevor Simpson; Michael Johnson; Kathryn McInteer; Allanah Andrews
Subject: RE: Class B drug regulations changes and Pharmac consultation
Attachments: Re: Controlled drugs

Thanks David,

As you know, Sean and Belinda are leading this work, so I have shared your view below with them.

Consultation is open until 21 December so we will keep an open mind as we read all the consultation feedback and work collaboratively with the MOH on the way forward.

I think Pharmac has done a really good job so far in terms of escalating and voicing the concerns we are hearing in response to our feedback to the Ministry of Health (Sarah F to Di S) – which is responsible for the regulations - and to the Minis office (No surprises briefing and engagement from the Chair). Thank goodness we actually consulted on this proposed change in order to highlight it to prescribers.

I do not agree that a joint statement making any recommendations is advisable (Peter and I have discussed this, and he agrees). We have our process to go through, which is assessing consultation feedback and making a decision in January. The MOH needs to run theirs.

Attached is Sean's email of last week that shows the team is thinking carefully about the way forward. They will of course continue collaborating with the CPs within Pharmac as well, as with the MOH, when coming up with a proposed recommendation to a decision-maker. It seems this matter is pretty contentious, so we may need to consider taking it to the Board for a decision.

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
DDI: s 9(2)(a) | M: s 9(2)(a) | P: 0800 660 050 | www.pharmac.govt.nz

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From: David Hughes <david.hughes@pharmac.govt.nz>
Sent: Tuesday, 13 December 2022 12:14 PM
To: Lisa Williams <lisa.williams@pharmac.govt.nz>; Sarah Fitt <sarah.fitt@pharmac.govt.nz>; Peter Alsop <peter.alsop@pharmac.govt.nz>; Trevor Simpson <trevor.simpson@pharmac.govt.nz>; Michael Johnson <michael.johnson@pharmac.govt.nz>; Kathryn McInteer <kathryn.mcinteer@pharmac.govt.nz>
Subject: Class B drug regulations changes and Pharmac consultation

Kia ora tatou,
In light of the feedback received from Pain Medicine and RNZCGP, I propose that:

- we make no change to our schedule rules pending an urgent review by the ministry of its decision.
- we work with the ministry to develop a joint statement prior to 22 December 2022 acknowledging the feedback received and strongly recommending no change to prescribing or dispensing behaviour.
- engage with key stakeholders to disseminate message to prescribers and pharmacies.

I would note that I have heard second hand that s 9(2)(g)(i) s 9(2)(g)(i).

Ngā mihi,
David

David Hughes (he/him)

Tumu Whakarae Haumanu | Chief Medical Officer

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

From: Belinda Ray-Johnson
Sent: Friday, 20 January 2023 9:07 am
To: David Hughes; Melissa Copland; Craig MacKenzie
Cc: Fiona Moscrop; Sean Dougherty
Subject: RE: Themed consultation responses - Class B controlled drugs
Attachments: 2023-01 Themed feedback Pharmac CD consultation - for working group.obr

Have completed changes to the attached document as below.

Ngā mihi

Belinda

From: Belinda Ray-Johnson
Sent: Wednesday, 18 January 2023 4:34 pm
To: David Hughes <david.hughes@pharmac.govt.nz>; Melissa Copland <melissa.copland@pharmac.govt.nz>; Craig MacKenzie <craig.mackenzie@pharmac.govt.nz>
Cc: Fiona Moscrop <fiona.moscrop@pharmac.govt.nz>; Sean Dougherty <Sean.Dougherty@Pharmac.govt.nz>
Subject: Themed consultation responses - Class B controlled drugs

Kia ora koutou

Thanks for your time earlier in the week and for your review of the themed consultation feedback.

I'm planning to go into the document in the next day or so and:

1. Remove all the Pharmac comment boxes

These now seem redundant/inappropriate, noting your review comments Craig, and the complicated nature of the issues as we discussed. It may be better to tease those issues out through the working group discussion and limit the scope of this document to being a themed summary of the feedback.

2. Attempt some dispensing and prescribing feedback differentiation as discussed (and address other points from the review process as needed)

3. Do a final clean up

I hope that sounds reasonable. I'll let you know when this is done – it will be well ahead of the working group meeting next week.

Ngā mihi

Belinda

Belinda Ray-Johnson | Schedule Development Manager

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

Contents

1: Introduction

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

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

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

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

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

- indicated it would like to revisit the regulatory arrangements for opioids and have convened a working group to support this work.

- asked Pharmac to delay making a decision on the proposed changes to the Schedule Rules (which Pharmac has agreed to) until this work is completed.

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

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

2: Consumer voice

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

i) *For opioids, consumers noted this proposal would:*

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

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

ii) *Stimulant specific feedback from consumers noted:*

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

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

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

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

3: Legislation changes

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

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

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

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

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

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

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

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

Stakeholders noted the following concerns:

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

i) General feedback included:

- Inadequate legislation consultation process (multiple stakeholders)

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

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

ii) Opioid specific feedback:

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

4: Prescribing periods and dispensing frequency

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

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

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

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

5: Timing of proposed funding change

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

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

Feedback relating to timeframe concerns included:

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

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

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

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

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

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

The ADHD community told us that:

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

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

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

They noted:

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

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

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

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

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

- Stimulants
- Methadone
- Other Class B opioids

7: Stimulants (Methylphenidate and Dexamfetamine)

i) Supportive feedback

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

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

Specific supportive feedback included:

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

ii) Patient safety

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

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

8: Methadone

i) Supportive feedback

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

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

Specific supportive feedback included:

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

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

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

i) Supportive feedback

We received supportive feedback from multiple stakeholders) regarding

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

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

Specific supportive feedback included:

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

ii) Patient safety, Inappropriate prescribing and abuse potential

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

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

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

These stakeholders supported wider consultation before this proposal is progressed.

Specific patient safety feedback included:

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

iii) Patient stability

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

Specific feedback included:

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

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

10: Operational process considerations

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

i) Safe storage of CDs in a community pharmacy

Specific feedback included:

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

ii) Wastage and disposal/destruction of CDs

Specific feedback included:

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

iii) Financial and workload impact on pharmacies

Specific feedback included:

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

iv) Impact on the supply chain

Specific feedback included:

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

11: Implementation

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

Specific feedback included:

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

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

Specific feedback included:

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

11: Other feedback

Other feedback received included

i) *Prescription co-payments*

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

ii) *Specialist applicant type for Special Authorities*

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

Specific feedback included:

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

Pharmac Consultation Groups

Please use the checkbox ☐ in the left column to indicate which groups you would like your consultation to be sent to below, any additional emails to be sent out please list separately on page 2.

Before communicating below need to:

1. Communicate via chair of subcommittees (via David)
    a. Analgesic Advisory Committee
    b. Mental Health Advisory Committee.

	Below Therapeutic Group are sent via MailChimp:
☐	Alimentary Tract & Metabolism
☐	Allergies
☐	Blood & Blood Forming Organs
☐	Cardiovascular System
☐	Cardiovascular System – Renal
☒	Colleges & Professional Societies
☐	Consumer Group
☐	Dermatological
☐	Diabetes
☐	Genito-Urinary System
☐	Hormone Preparations
☐	Immunisation
☐	Immunology
☐	Immunosuppressant
☐	Infections
☐	Infections – Antiretroviral
☐	Musculoskeletal Anti- inflammatory Rheumatology
☐	Musculoskeletal – Osteoporosis
☐	Nephrology
☒	Nervous System – Anaesthetics/Analgesics
☒	Nervous System – Mental Health
☒	Nervous System - Drug and Alcohol Dependency
☐	Nervous System – Neurology
☐	Oncology Agents *(includes MoH Cancer Team, Medical Oncology Work Group, INCOM membership, Cancer Society, BCAC, Breast Cancer Foundation, and CANGO – please do not note these groups as additional groups/emails to be sent out)*
☐	Respiratory
☐	Sensory organs
☐	Special Foods
☐	Tender
	Subcommittees
☒	Analgestic Advisory Committee
☐	Anti-Infective Advisory committee
☐	Cancer Treatments Advisory Committee
☐	Cardiovascular Advisory Committee
☐	Dermatology Advisory Committee

☐	Diabetes Advisory Committee
☐	Endocrinology Advisory Committee
☐	Gastrointestinal Advisory Committee
☐	Haematology Advisory Committee
☐	Immunisation Advisory Committee
☐	Interventional Cardiology Advisory Committee
☒	Mental Health Advisory Committee
☐	Nephrology Advisory Committee
☐	Neurological Advisory Committee
☐	Ophthalmology Advisory Committee
☐	PTAC Members
☐	Rare Disorders Advisory Committee
☐	Reproductive and Sexual Health Advisory Committee
☐	Respiratory Advisory Committee
☐	Rheumatology Advisory Committee
☐	Special Foods Advisory Committee
☐	Tender Clinical Advisory Committee
☐	Transplant Immunosuppressant Advisory Committee
	Other Mailchimp
☒	Updates for Pharmacist (Includes Pharmac Internal)* - formally community pharmacy
☒	Suppliers and wholesalers
	Below groups are sent via Outlook:
☒	Other – GP's (Which is sent by an MD/ Medical Directorate TA)
☒	DHB Chief Pharmacists (List received from EA to Medical Director) *

**All consultation & notifications are to be sent to the following groups unless otherwise stated*

Additional Groups/emails to be sent out:

Please list additional emails/groups here without bullet points

RNZCGP (if not covered by other GPs) rnzcgp@rnzcgp.org.nz

Software vendors –Toniq s 9(2)(a) s 9(2)(a)

Software vendors – RxOne s 9(2)(a) support@rxone.co.nz

s 9(2)(a)

Not in MailChimp

~~Pharmaceutical Society NZ p.society@psnz.org.nz~~

Already in Mailchimp

Updates for Pharmacist

Pharmacy Guild

Green Cross

TAS- Te Whatu Ora pharmacy@tas.health.nz

Toniq LTD

E-mail details

Subject: Ministry of Health consultation on the safe use of opioids

Body:

Kia ora

Manatū Hauora, the Ministry of Health, is re-consulting on the safe use of opioids following the recent changes to the Misuse of Drugs Regulations and subsequent concerns which were raised over the effectiveness of the controls intended to manage people's safe access to opioids.

Full details of the consultation and how to make a submission can be found on the Ministry of Health Website

Please note this is not a Pharmac consultation, however, we are keen to ensure everybody who is interested in this consultation has the opportunity to make a submission.

Please circulate this e-mail to others who may be interested.

Ngā mihi

Fiona Moscrop (she/her) | Clinical Lead, Schedule Development

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

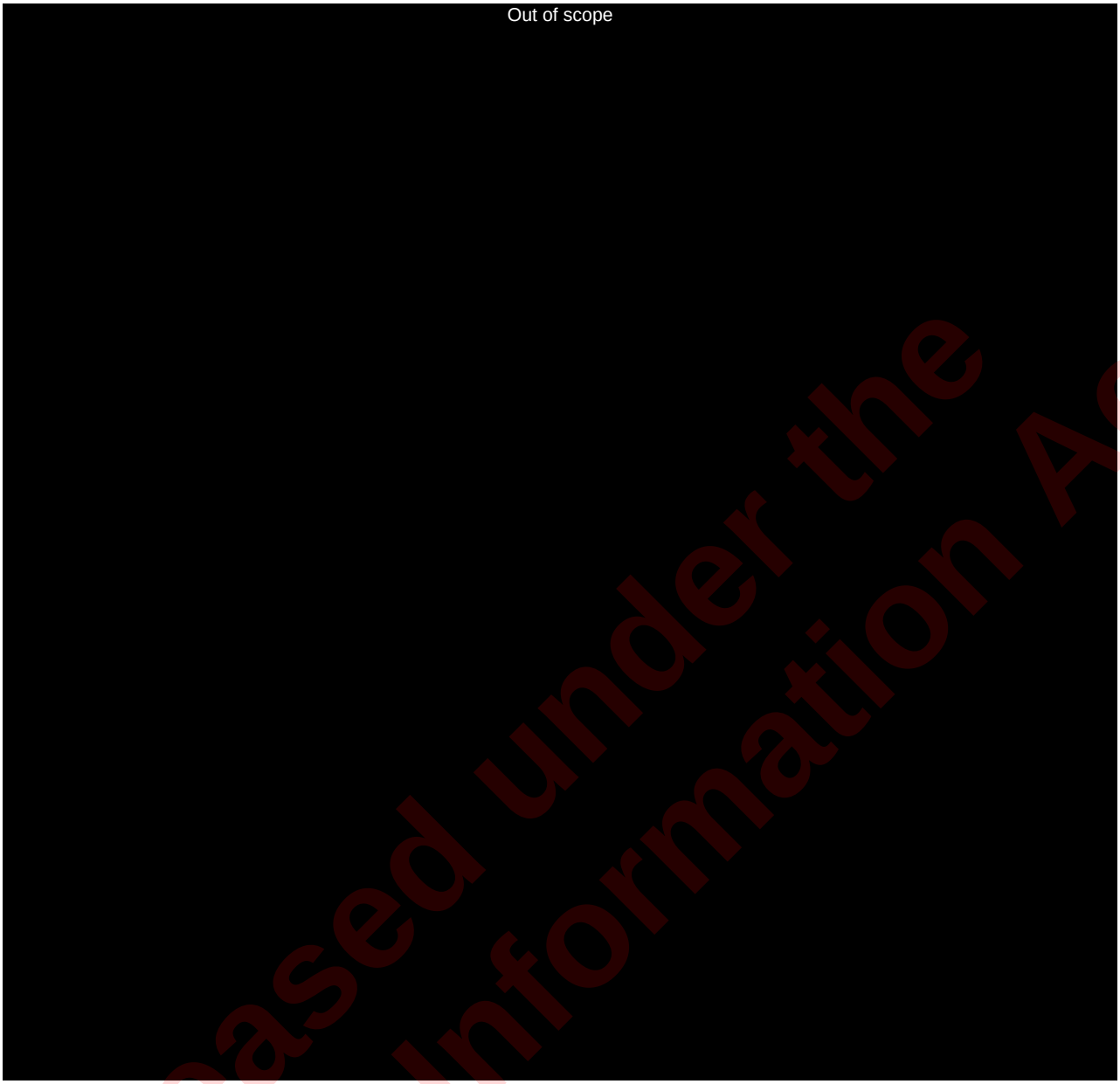
PHARMAC
TE PĀTAKA WHAIORANGA

MEMORANDUM FOR BOARD MEETING 24 FEBRUARY 2023

To: Pharmac Directors
From: Chief Executive
Date: February 2023

Pharmaceutical Transactions Report

Out of scope



Class B controlled drugs consultation

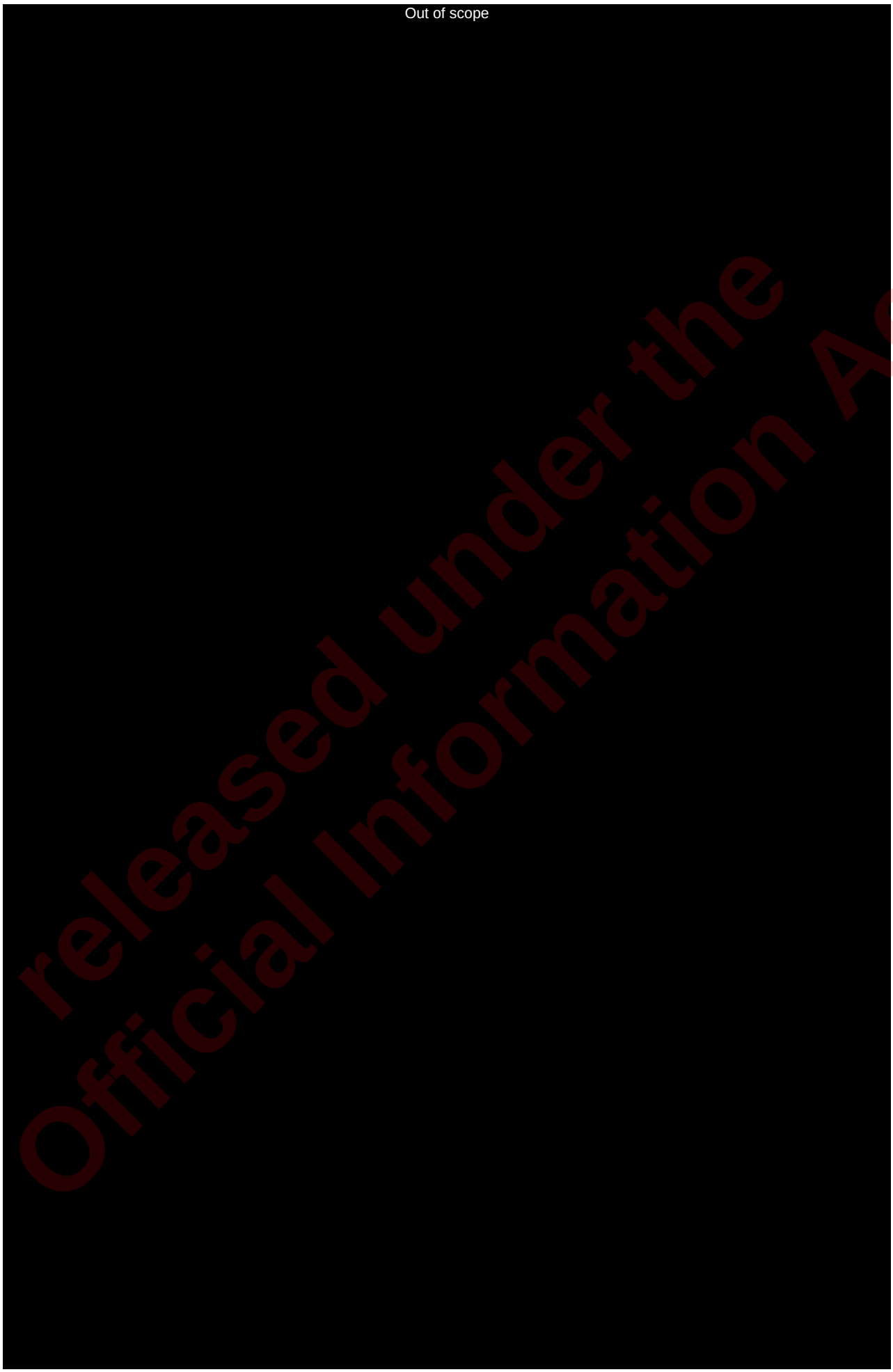
Late last year, we consulted on a proposal to update the General Rules of the Pharmaceutical Schedule to reflect changes to the Misuse of Drugs Regulations, which:

- Enable controlled drugs to be prescribed electronically via the New Zealand Electronic Prescribing System (NZePS)
- Allow prescriptions for Class B controlled drugs to be prescribed for three months (instead of one month) with monthly dispensing if the prescription is issued electronically via the NZePS
- Allow prescribers to direct shorter prescriptions or more frequent dispensing when they issue a prescription
- Reduce the number of times people need to visit a prescriber for repeat prescriptions of Class B controlled drugs for some chronic conditions, like ADHD.

Our consultation process was the first information that many stakeholders received about the regulatory changes, and we received a large amount of feedback (both in support of, and raising concerns about, these changes). As a result of this feedback, the Ministry of Health has decided to revisit the issue and requested that Pharmac delay making a decision on the proposed Schedule rule changes, which we have agreed to do.

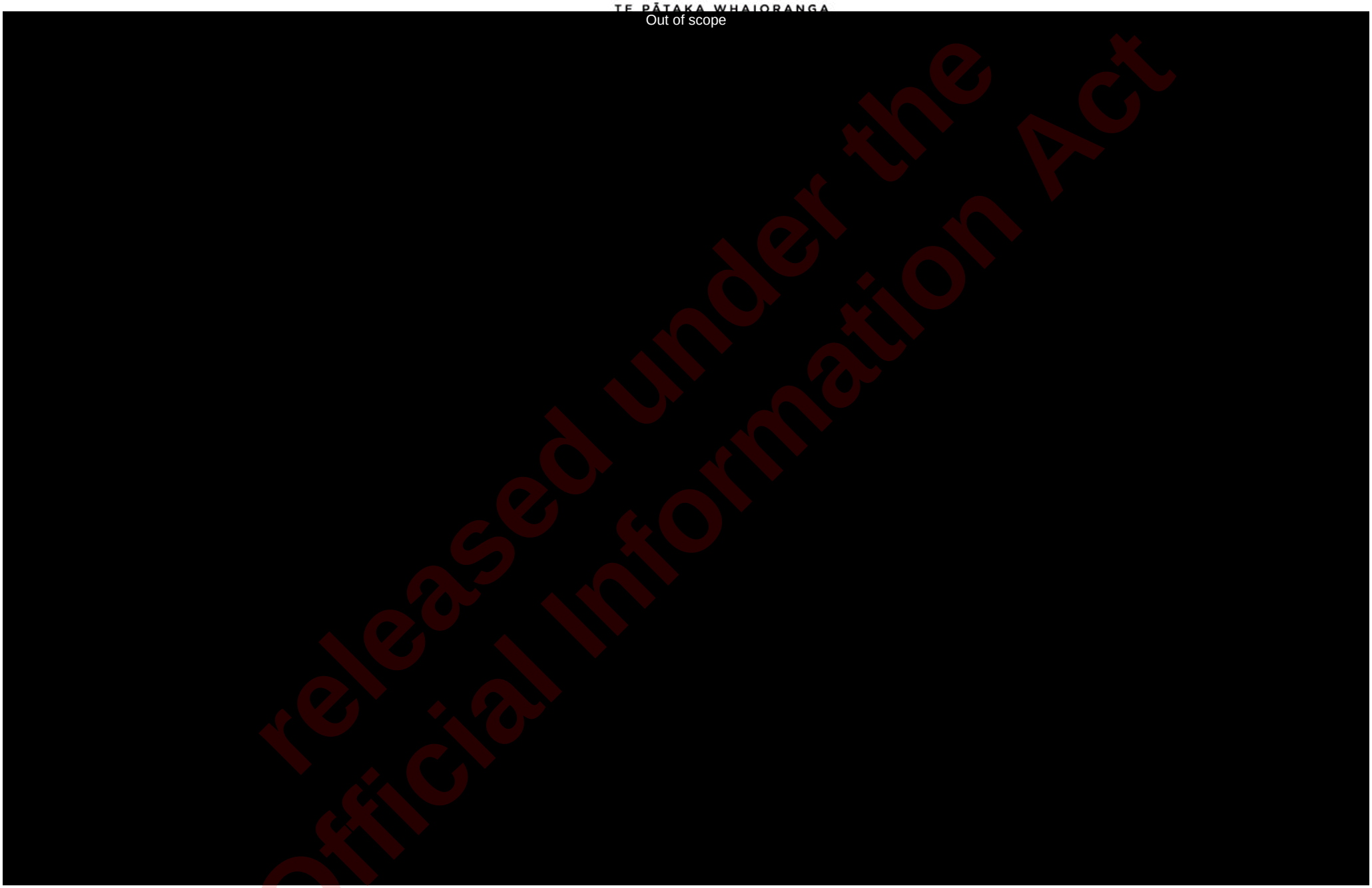
The Ministry of Health has established a cross-agency working group (which includes Pharmac) to examine the existing system settings relating to controlled drugs. These include, but are not limited to, oversight of prescribing behaviour, appropriate regulation, and training and clinical guidance for prescribers and dispensers of opioids. This working group will be meeting over the course of the next few months, and we will keep the Board updated as this progresses.

Out of scope



PHARMAC
TE PĀTAKA WHAIORANGA

Out of scope



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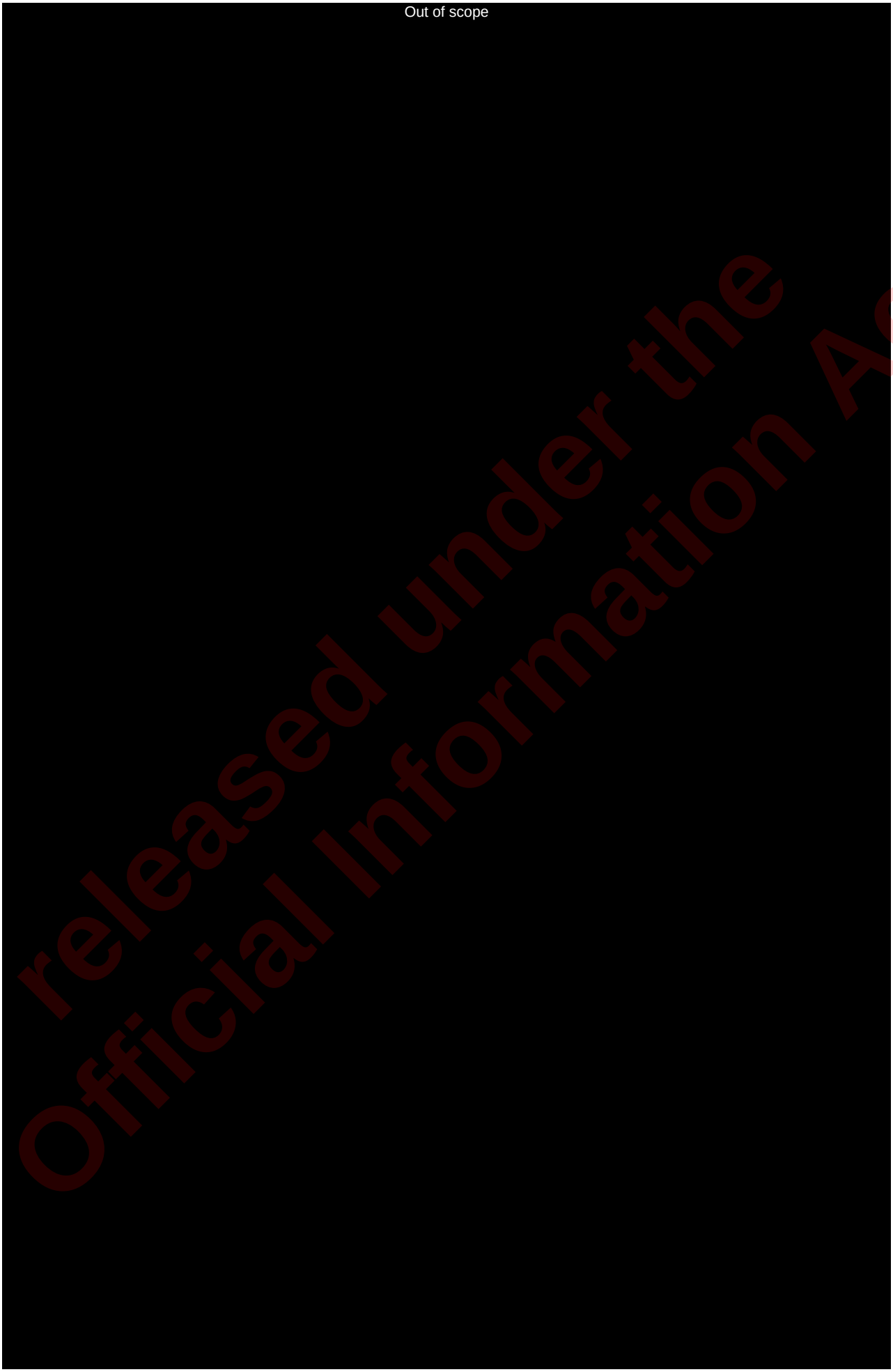

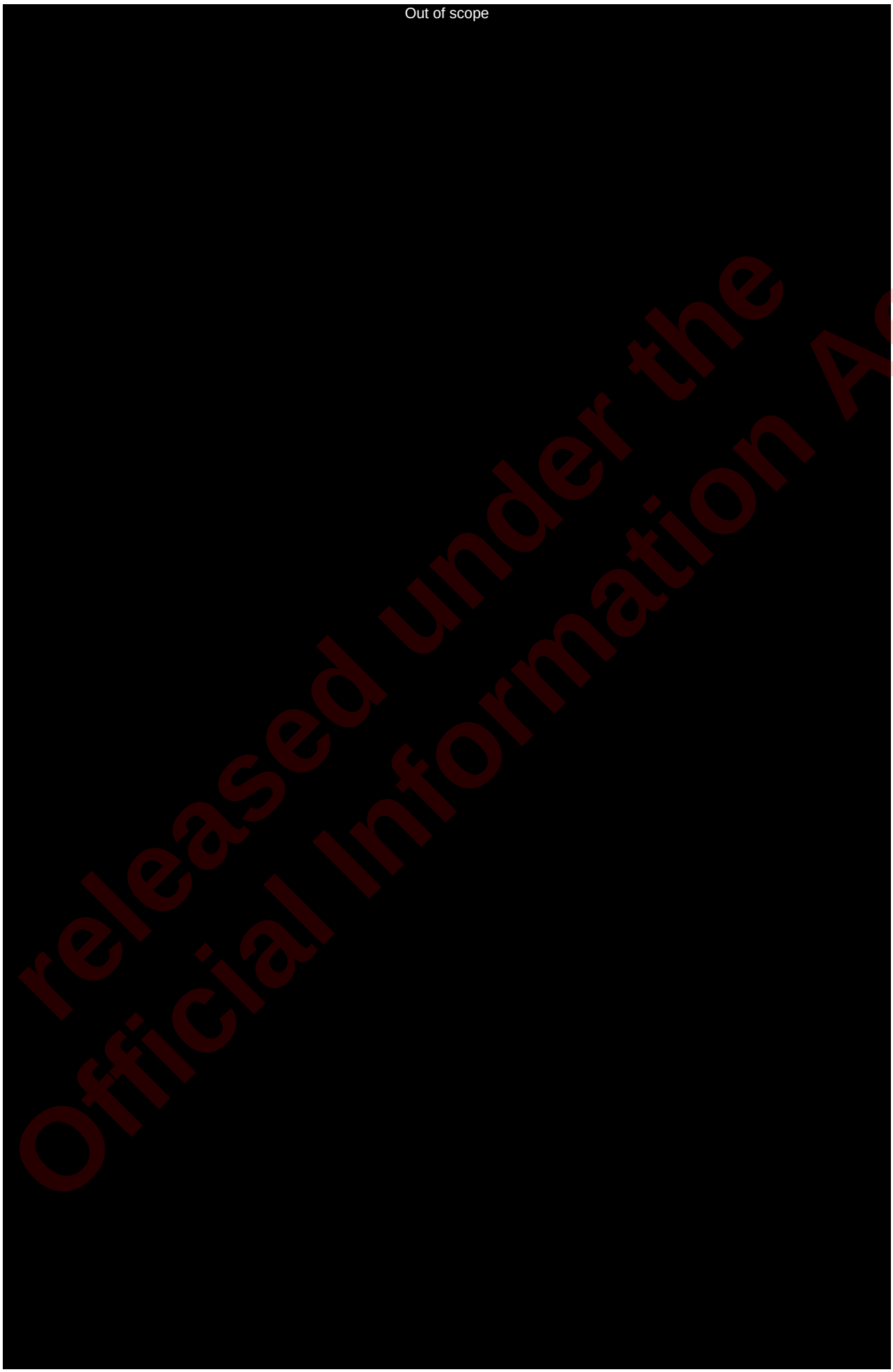

From: Jessica Birch
Sent: Thursday, 16 March 2023 8:24 am
Subject: Ministry of Health consultation on the safe use of opioids

Kia ora

Manat Hauora, the Ministry of Health, is re-consulting on the safe use of opioids following the recent changes to the Misuse of Drugs Regulations and subsequent concerns which were raised over the effectiveness of the controls intended to manage people s safe access to opioids.

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Please note this is not a Pharmac consultation, however, we are keen to ensure everybody who is interested in this consultation has the opportunity to make a submission.

Please circulate this e-mail to others who may be interested.

Ng mihi

Fiona Moscrop (she/her) | Clinical Lead, Schedule Development
_____
Te P taka Whaioranga | Pharmac | PO Box 10 254 | Level 9, 40 Mercer Street, Wellington |
P: 0800 660 050 | www.pharmac.govt.nz

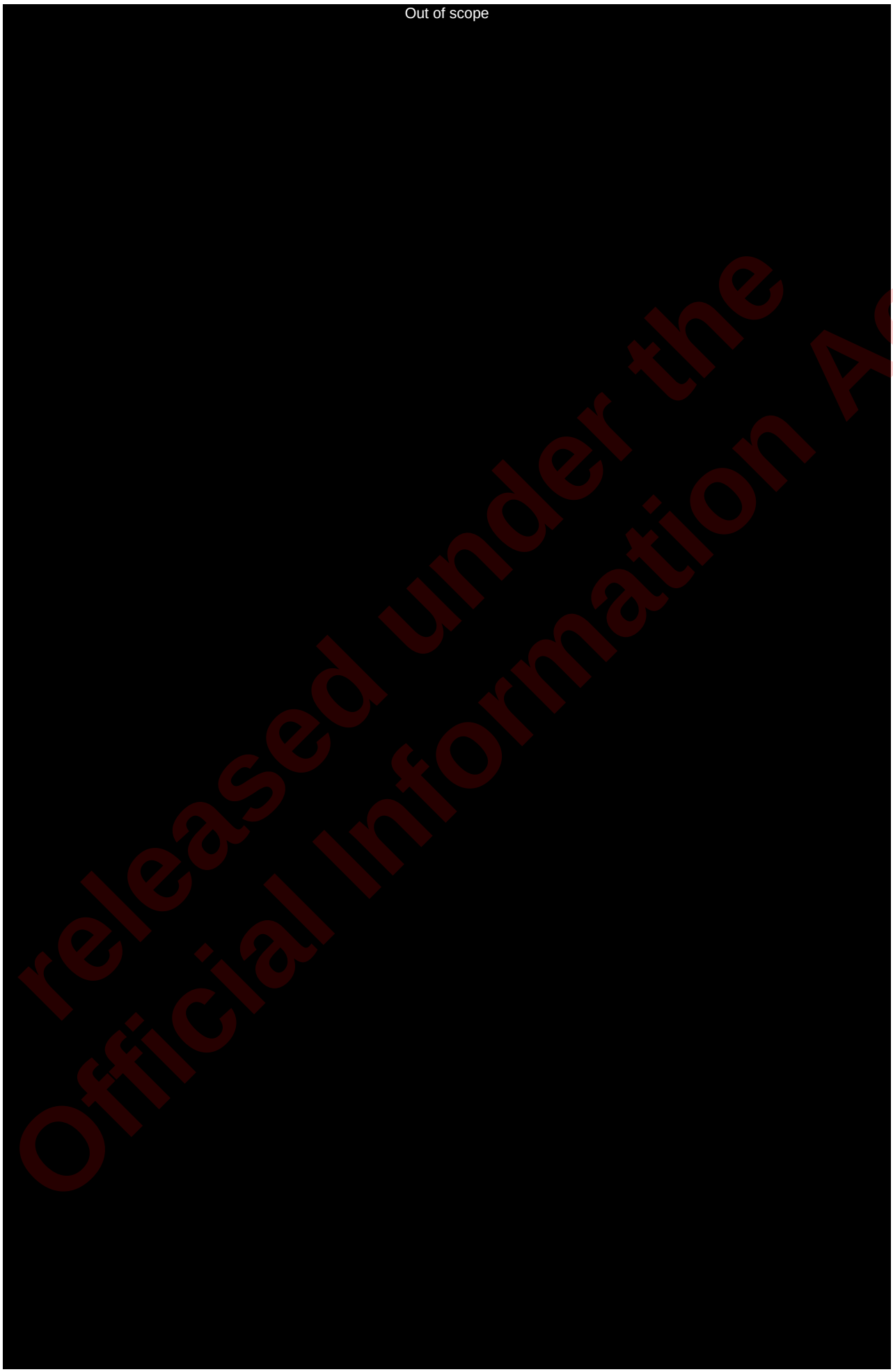
PHARMAC
TE PĀTAKA WHAIORANGA

MEMORANDUM FOR BOARD MEETING 31 MARCH 2023

To: Pharmac Directors
From: Chief Executive
Date: March 2023
Item: 7.1

Chief Executive's Report

Out of scope



Update on Class B opioid regulations and schedule changes

In December 2022, the Misuse of Drugs Amendment Regulations 2022 came into effect. These amendments made several changes to controlled drug prescribing regulations. One of these changes allowed Class B controlled drugs to be prescribed for up to three months with up to one month's dispensing, when prescribed electronically through the NZ ePrescription Service (NZePS) by any prescriber with authority to prescribe them. In response to these amendments, Pharmac consulted on changes to the schedule rules that would enable these changes and remove the default 10 day dispensing rule.

In response to our consultation, clinicians raised concerns that this prescription length might increase the quantity of opioids being prescribed and could increase the risk of opioids being accessed inappropriately. Pharmac and Manatū Hauora worked collaboratively to consider clinician concerns and placed a pause on schedule changes while matters were addressed.

Manatū Hauora is now consulting on what controls and safeguards are needed for the prescribing of opioids to enable all those who need prescription opioids to have reasonable access to them, while maintaining appropriate controls to mitigate their risk of harm to the public.

Manatū Hauora is seeking feedback on the following options:

- Option 1: no regulatory change
- Option 2: strengthen guidance to encourage good prescribing practice
- Option 3: strengthen guidance and change regulations

Submissions are due before 31 March. The consultation has been circulated to our committees and to all those who provided feedback to the previous consultation on this matter.