
From: Sean Dougherty
Sent: Thursday, 13 October 2022 9:46 am
To: Suzanne Townsend
Subject: RE: Changes to prescription regs. and ADHD medicines.

Hi Suzanne,

The morning of the 27th is relatively free for me at the moment. Does this work for others?

Regards,

Sean

Sean Dougherty | Manager, Schedule Strategy and Development

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From: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>
Sent: Friday, 7 October 2022 2:17 pm
To: Sean Dougherty <sean.dougherty@pharmac.govt.nz>
Subject: Changes to prescription regs. and ADHD medicines.

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Hi Sean

I have been given your name by Trevor Lloyd. He suggested you may be the person to talk to. If not let me know who I should approach.

We would like to meet to discuss a couple of things. Cabinet has agreed to allow the issue of a prescription for up to 3 months for Class B Drugs. This was mostly aimed at allowing ADHD patients to get one prescription and avoid the costs of prescriber fees, etc. We understand that for this to happen there also needs to be changes to Pharmac rules. We would like to discuss how we can make that happen and if there are any other issues for other Class B Drugs.

Out of scope
Out of scope

Out of scope

The Ministry team who would like to meet with you are myself, Eddy Sommers, Diana Suggate (from the Mental Health and Addictions Team) and Trevor Lloyd (from Data and Digital).

Please let me know what time suits.

Ngā mihi

Suzanne Townsend
Manager, Regulatory Policy
Strategy, Policy and Legislation | Te Pou Rautaki
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Manatū Hauora, 133 Molesworth Street
Thorndon, Wellington 6011



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From: Sean Dougherty
Sent: Tuesday, 18 October 2022 1:46 pm
To: Belinda Ray-Johnson; Fiona Moscrop
Subject: FW: Consultation on DRAFT LEG paper - Misuse of Drugs Amendment Regulations 2022 and Medicines Amendment Regulations 2022 (No 2)
Attachments: DRAFT LEG paper - Misuse of Drugs Amendment Regulations 2022 and Medicines Amendment Regulations 2022.docx; Misuse of Drugs Regulations 1977 + Medicines Regul-v1.0.pdf

Sean Dougherty | Manager, Schedule Strategy and Development

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From: Eddy Sommers <Eddy.Sommers@health.govt.nz>
Sent: Tuesday, 18 October 2022 1:38 pm
To: WOOLLASTON, Sharon <Sharon.Woollaston@police.govt.nz>; MARSHALL Kirsty <kirsty.marshall@customs.govt.nz>; Matthew.McClennan@justice.govt.nz; Trevor Lloyd <Trevor.Lloyd@health.govt.nz>; Serena.Coxhead@treasury.govt.nz; ben.mcbride@dpmc.govt.nz; Sean Dougherty <sean.dougherty@pharmac.govt.nz>; Sara McFall <Sara.McFall@health.govt.nz>
Cc: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>; Jane Hubbard <Jane.Hubbard@health.govt.nz>
Subject: Consultation on DRAFT LEG paper - Misuse of Drugs Amendment Regulations 2022 and Medicines Amendment Regulations 2022 (No 2)

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Kia ora koutou

Please find attached 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**. These amendments will give effect to the following policy decisions made by Cabinet in August [CAB-22-MIN-0316]:

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

If there is someone in your organisation you think is more appropriate to review this draft please feel free to pass this on.

Also attached to this paper is the first draft of the amendments from PCO. These are quite technical changes but am providing this for reference. Please note that this is an early draft and the comments within have since been addressed.

Please provide any feedback by **COP Friday 21 October**.

Ngā mihi nui

Eddy Sommers (he/him)

Policy Analyst

Health System Settings

s 9(2)(a)

eddy.sommers@health.govt.nz

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Office of the Minister of Health

Chair, Cabinet Legislation Committee

Misuse of Drugs Amendment Regulations 2022 and Medicines Amendment Regulations 2022 (No 2)

Proposal

- 1 This paper seeks authorisation for submission to the Executive Council of the Misuse of Drugs Amendment Regulations 2022 and the Medicines Amendment Regulations 2022 (No 2).

Policy

- 2 These amendment regulations do not require any new policy decisions from the Cabinet Legislation Committee.

Improvements to electronic prescribing

- 3 The New Zealand ePrescription Service (NZePS) is a fast, secure system for the transmission and authentication of electronic prescriptions. It enables a prescription to be generated by the prescriber on an approved system, transmitted to the NZePS health information exchange broker and downloaded electronically at a community pharmacy.
- 4 The use of electronic prescriptions, instead of traditional hard-copy prescriptions, reduces costs for practices, provides flexibility for practitioners and improves the patient experience with fewer delays and less chance of prescriber error.
- 5 Transitioning prescriptions onto the NZePS will also enable regulators to more efficiently monitor and audit prescribing behaviour.
- 6 On 15 August 2022, Cabinet agreed to amend regulations to remove regulatory barriers to electronic prescribing and improve patient access to medicines by:
 - 6.1 enabling controlled drugs to be prescribed electronically
 - 6.2 reducing the frequency prescribers need to issue prescriptions for certain controlled drugs, when issued through the NZePS
 - 6.3 codifying the waiver issued by the Director-General that enables electronic prescribing
 - 6.4 ensuring designated pharmacist prescribers and designated prescriber nurses can continue to prescribe certain medicines when they become controlled drugs [CAB-22-MIN-0316].

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Minor correction to Misuse of Drugs Regulations

- 7 A minor printing error within the Misuse of Drugs Regulations was discovered through the drafting process of these amendments. Parliamentary Counsel Office have recommended using this opportunity to correct the error.

Timing and 28-day rule

- 8 I am not seeking a waiver of the 28-day rule.
- 9 The regulations will be notified in the *New Zealand Gazette* as soon as possible after officials are informed of the Executive Council's agreement. The regulations will come into force 28 days after they are notified in the *Gazette*.

Compliance

- 10 The regulations comply with:
- 10.1 the principles of the Treaty of Waitangi;
 - 10.2 advice from the Treaty Provisions Officials Group on any Treaty of Waitangi provisions;
 - 10.3 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 or the Human Rights Act 1993;
 - 10.4 the principles and guidelines set out in the Privacy Act 2020;
 - 10.5 relevant international standards and obligations;
 - 10.6 the Legislation Guidelines (2021 edition), which are maintained by the Legislation Design and Advisory Committee.
- 11 The Misuse of Drugs Amendment Regulations 2022 will be made under section 37 of the Misuse of Drugs Act 1975.
- 12 The Medicines Amendment Regulations 2022 (No 2) will be made under section 105 of the Medicines Act 1981. This section requires that I must be satisfied that consultation has occurred with 'such organisations or bodies as appear to the Minister to be representative of persons likely to be substantially affected by the regulations.' I am satisfied that Manatū Hauora has consulted with the appropriate organisations and bodies on my behalf.

Regulations Review Committee

- 13 The Parliamentary Counsel Office does not consider there are grounds for the Regulations Review Committee to draw this instrument or regulations to the attention of the House of Representatives under Standing Order 327.

Certification by Parliamentary Counsel

- 14 The draft regulations have been certified by the Parliamentary Counsel Office as being in order for submission to Cabinet.

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Impact Analysis

- 15 The Treasury's Regulatory Impact Analysis team has determined that the proposals are exempt from the requirement to provide a Regulatory Impact Statement on the grounds that they have no or only minor impacts on businesses, individuals, and not-for-profit entities.

Publicity

- 16 My office will issue a press release about these changes once they have been authorised by the Executive Council.
- 17 Once the regulations are notified in the *Gazette*, officials from Manatū Hauora and Te Whatu Ora will communicate directly with the impacted health practitioners to ensure they are aware of the new regulations and the implications.

Proactive release

- 18 This paper will be proactively released according to standard processes under the Cabinet Office circular CO (18) 4, subject to redactions as appropriate under the Official Information Act 1982.

Consultation

- 19 The following departments have been consulted on this paper: Pharmac, New Zealand Police, New Zealand Customs Service, Ministry of Justice, Te Whatu Ora, Te Aka Whai Ora, the Department of the Prime Minister and Cabinet and the Treasury.

Recommendations

I recommend that the Cabinet Legislation Committee:

- 1 note that on 15 August 2022 Cabinet agreed to:
 - 1.1 enable controlled drug medicines to be prescribed electronically
 - 1.2 reduce the frequency prescribers need to issue prescriptions for certain controlled drugs, when issued through the NZePS
 - 1.3 codify the waiver issued by the Director-General that enables electronic prescribing
 - 1.4 ensure designated pharmacist prescribers and designated prescriber nurses can continue to prescribe certain medicines when they become controlled drugs [CAB-22-MIN-0316 refers];
- 2 note that the Misuse of Drugs Amendment Regulations 2022 will give effect to the decision referred to in recommendation 1.1, 1.2 and 1.4 above;
- 3 note that the Medicines Amendment Regulations 2022 (No 2) will give effect to the decision referred to in recommendation 1.3 above;

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- 4 note that section 105 of the Medicines Act requires that I be satisfied that consultation has occurred with such organisations or bodies as appear to me to be representative of persons likely to be substantially affected by the regulations;
- 5 note my advice as Minister of Health that these requirements have been met;
- 6 authorise the submission to the Executive Council of the Misuse of Drugs Amendment Regulations 2022 and the Medicines Amendment Regulations 2022 (No 2);
- 7 note that the Misuse of Drugs Amendment Regulations 2022 and the Medicines Amendment Regulations 2022 (No 2) come into force on 22 December 2022;

Authorised for lodgement

Hon Andrew Little

Minister of Health

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PCO 25042/1.0

Drafted by Shane Williams

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**Misuse of Drugs Regulations 1977 + Medicines
Regulations 1984 [provs with consolidated amendments]**

Bill

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**Misuse of Drugs Regulations 1977 + Medicines
Regulations 1984 [provs with consolidated amendments]**

Bill

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Contents

	Page
Part 1	
Medicines Regulations 1984	
40A	2
41	2
42	3
43	5
Part 2	
Misuse of Drugs Regulations 1977	
21	5
25	7
29	9
30	11
31	11
31A	12
32	14
33	14
34	15
35	16
36	16
Schedule 1A	
Controlled drugs that designated prescriber nurses may prescribe in certain circumstances	
	18

Schedule 1B

19

Controlled drugs that designated ~~pharmacist prescribers~~
prescriber pharmacists may prescribe

Part 1

Medicines Regulations 1984

40A Urgently required prescriptions of prescription medicines may be communicated orally if later confirmed ~~in writing~~

- (1) Where an authorised prescriber or veterinarian finds it necessary to do so, he or she may communicate orally to a pharmacist to whom he or she is known personally (whether in the pharmacist's presence or by speaking to the pharmacist on the telephone) a prescription relating to a prescription medicine that the authorised prescriber or veterinarian requires urgently.
- (2) Within 7 days after a communication made by an authorised prescriber or veterinarian to a pharmacist under subclause (1), the authorised prescriber or veterinarian must ~~forward to the pharmacist a written prescription confirming the oral communication~~ issue a prescription in paper or electronic form that confirms the oral communication, and forward or transmit the prescription to the pharmacist.

Note

If we keep the amendments to reg 34 of the Misuse of Drugs Regs, we should probably amend this reg like this for consistency.

41 Form of prescription

- (1) A prescription given under these regulations must be in paper or electronic form.
- (2) ~~Every prescription given under these regulations shall~~ A paper prescription must—
 - (a) be legibly and indelibly printed; and
 - (b) be signed personally by the prescriber with his usual signature (not being a facsimile or other stamp), and dated; and
 - (c) set out the following information in relation to the prescriber:
 - (i) the prescriber's full name; and
 - (ii) the full street address of the prescriber's place of work or, in the absence of the prescriber having a place of work, the postal address of the prescriber; and
 - (iii) the prescriber's telephone number; and
 - (d) set out—
 - (i) the surname, each given name, and the address of the person for whose use the prescription is given; and

- (ii) in the case of a child under the age of 13 years, the date of birth of the child; and
 - (e) indicate by name the medicine and, where appropriate, the strength that is required to be dispensed; and
 - (f) indicate the total amount of medicine that may be sold or dispensed, or the total period of supply; and
 - (g) if the medicine is to be administered by injection, or by insertion into any cavity of the body, or by swallowing, indicate the dose and frequency of dose; and
 - (h) if the medicine is for application externally, indicate the method and frequency of use; and
 - (j) in the case of a prescription relating to the treatment of an animal,—
 - (i) set out the surname, each given name, and the address of the owner of the animal; and
 - (ii) contain the following statement, or words of similar meaning:
“Not for human use”.
- (3) [An electronic prescription must be completed using, and transmitted through, an approved system \(as defined by regulation 29\(5\) of the Misuse of Drugs Regulations 1977\).](#)

42 Dispensing of prescription medicines

- (1) Except as provided in subclause (2), no person other than an authorised prescriber, veterinarian, pharmacist, pharmacy graduate, a pharmacy technician, a student, or dispensary technician may dispense a prescription medicine.
- (1A) The following persons may not dispense prescription medicines unless under the direct personal supervision of a pharmacist:
 - (a) dispensary technicians:
 - (b) pharmacy graduates:
 - (c) pharmacy technicians:
 - (d) students.
- (2) An agent or employee of a veterinarian may, in any particular case, dispense any prescription medicine at the direction of the veterinarian for use in the treatment of any animal under the care of the veterinarian.
- (3) Every person dispensing a prescription relating to a prescription medicine must comply with the following requirements:
 - (a) if the prescription has been communicated orally under regulation 40A(1), the prescription must not be dispensed on more than 1 occasion before the pharmacist has received the ~~written~~ confirmation of the prescription, as required by regulation 40A(2):

**Misuse of Drugs Regulations 1977 + Medicines
Regulations 1984 [provs with consolidated amendments]
Bill**

Part 1 cl 42

- (b) the following information must be recorded [in or](#) on the prescription:
 - (i) the name and address of the proprietor of the business at which the prescription is dispensed; and
 - (ii) the date on which the prescription is dispensed; and
 - (iii) the quantity of medicine dispensed; and
 - (iv) a unique identifying number or code for the prescription:
 - (c) a prescription for a medicine other than an oral contraceptive must not be dispensed on any occasion after 6 months have elapsed from the date on which ~~it was printed~~ [the prescription was given](#) or, if given under regulation 40A(1), communicated orally:
 - (d) a prescription for a medicine that is an oral contraceptive must not be dispensed on any occasion after 9 months have elapsed from the date on which ~~it was printed~~ [the prescription was given](#) or, if given under regulation 40A(1), communicated orally:
 - (e) every [paper](#) prescription must be retained for a period of 3 years by the pharmacist on the premises on which it was dispensed or at a place approved by the Medical Officer of Health and must be kept in an orderly and consecutive manner so as to be readily available for inspection.
- (4) If an authorised prescriber or a veterinarian refers in a prescription to a medicine by its trade mark or trade name, or by reference to the name of its manufacturer, a pharmacist may supply an alternative brand of medicine, provided that—
- (a) the authorised prescriber or veterinarian has not marked the prescription “No brand substitution permitted” or with words of similar meaning; and
 - (b) the substituted brand contains the same active ingredient or active ingredients, and no other active ingredients; and
 - (c) the substituted brand is in the same dose form and strength as the prescribed brand; and
 - (d) there is no clinical reason why the substituted brand should not be supplied; and
 - (e) the pharmacist records the brand substitution [in or](#) on the prescription; and
 - (f) [for a paper prescription](#), the pharmacist signs and dates the prescription; and
 - (g) the pharmacist informs the patient of the brand substitution.
- (5) This regulation is subject to regulation 43.

43 Director-General may waive certain requirements

- (1) Despite the requirements in regulations 41 and 42, the Director-General may, at his or her discretion,—
 - (a) authorise a form of prescription that does not comply with all or any of the requirements in regulation 41, but that is subject to any other requirements that he or she thinks fit; and
 - (b) authorise the dispensing of prescription medicines in a manner that does not comply with all or any of the requirements in regulation 42, but that is subject to any other requirements that he or she thinks fit.
- (2) A form of prescription that may be authorised under subclause (1)(a) includes, but is not limited to, an electronic form of prescription.

Note

[I haven't amended reg 44\(h\) \("either verbally or in writing"\) to expressly cover electronic communication.](#)

Part 2

Misuse of Drugs Regulations 1977

21 Restrictions on application of section 8 of Act, etc

- (1) Nothing in section 8 of the Act or in these regulations, or in any licence granted under these regulations, shall authorise any dealing in a controlled drug contrary to any provision of these regulations or of section 20 or section 24 of the Medicines Act 1981.
- (2) No medical practitioner ~~shall give~~ [may issue](#) a prescription for the supply of a controlled drug otherwise than for the medical treatment of a patient under his or her care, unless the medical practitioner is acting in the course of his or her employment in the service of the Crown.
- (3) No dentist may ~~give~~ [issue](#) a prescription for the supply of a controlled drug—
 - (a) otherwise than for the treatment of a patient under the dentist's care; and
 - (b) in any quantity greater than the quantity reasonably required for the treatment of the patient for a period of 7 days.
- (4) No designated prescriber nurse may (within the authority given by regulation 12A(1)(a)) ~~give~~ [issue](#) a prescription for the supply of a controlled drug—
 - (a) otherwise than for the treatment of a patient under the designated prescriber nurse's care; and
 - (c) in any quantity greater than the quantity reasonably required for the treatment of the patient for a period of 7 days.
- (5) No designated prescriber pharmacist may (within the authority given by regulation 12A(1)(b)) ~~give~~ [issue](#) a prescription for the supply of a controlled drug—

**Misuse of Drugs Regulations 1977 + Medicines
Regulations 1984 [provs with consolidated amendments]
Bill**

Part 2 cl 21

- (a) otherwise than for the treatment of a patient under the designated prescriber pharmacist's care; and
 - (b) in any quantity greater than the quantity reasonably required for the treatment of the patient for a period of 3 days.
- (5A) No midwife may (within the authority given by regulation 12A(1)(c)) ~~give~~ issue a prescription for the supply of a controlled drug otherwise than for the treatment of a patient under the midwife's care.
- (5B) No nurse practitioner may (within the authority given by regulation 12A(1)(d)) ~~give~~ issue a prescription for the supply of a controlled drug—
- (a) otherwise than for the treatment of a patient under the nurse practitioner's care; and
 - (b) in any quantity greater than the quantity reasonably required for the treatment of the patient for—
 - (i) a period of 1 month, in the case of—
 - (A) a Class A controlled drug; or
 - (B) a Class B controlled drug where the prescription is not covered by regulation 31A(3) (generally paper prescriptions);
 - (ii) a period of 3 months, in the case of—
 - (A) a Class B controlled drug where the prescription is covered by regulation 31A(3) (electronic prescriptions using the approved system)
 - (B) a Class C controlled drug.
- (i) ~~a period of 1 month, in the case of a Class A controlled drug; or~~
 - (ii) ~~a period of 1 month, in the case of a Class B controlled drug; or~~
 - (iii) ~~a period of 3 months, in the case of a Class C controlled drug.~~
- (5C) No veterinarian may ~~give~~ issue a prescription for the supply of a controlled drug otherwise than for administration to an animal under the veterinarian's care.
- (6) ~~Paragraph (c) of section 8(2) of the Act shall~~ Section 8(1)(c) of the Act does not apply where the person for whose benefit the controlled drug is supplied or prescribed is in the course of being supplied with the same controlled drug for the same purpose by another practitioner, or pursuant to a prescription ~~given~~ issued by another practitioner, and does not disclose that fact to the practitioner referred to in that paragraph before the supply of the controlled drug, or the ~~giving of the material~~ issuing of the prescription, by that practitioner.

Note

I've assumed that (5B) should match the changes in reg 31A(3) & (4).

Re the first amendment in (6), s 8 was replaced on 31 Jan 2018 and former s 8(2)(c) became current s 8(1)(c).

25 Labelling of containers

- (1) Except in the case of a container to which subclause (3) applies, no person shall supply any controlled drug (other than an exempted drug) unless the container containing the controlled drug bears a label setting out, in letters of a colour contrasting clearly with the colour of the background, the following:
 - (a) in the upper part of the principal display panel, printed in conspicuous block capital letters, the words “CONTROLLED DRUG”, followed immediately by the appropriate designation specified in subclause (2); and
 - (b) the name of the controlled drug supplied; and
 - (c) directions for use, or, in the case of a drug for internal use, the recommended dose and frequency of the dose; and
 - (d) where the controlled drug is in the form of a preparation, mixture, or article, the name (if any) of the preparation, mixture, or article, together with a statement of the proportion that the controlled drug bears to the total ingredients of the preparation, mixture, or article, indicating (if the proportion is stated as a percentage) whether the percentage is calculated on the basis of weight in weight, or weight in volume, or volume in volume; and
 - (e) the name and address of the manufacturer, or the packer, or the seller by wholesale or by retail.
- (2) For the purposes of subclause (1), the appropriate designation, in relation to a controlled drug, is as follows:
- (3) Subclause (1) does not apply,—
 - (a) in respect of ephedrine or pseudoephedrine, if—
 - (i) the drug is enclosed in a primary container that complies with regulation 15(2) of the Medicines Regulations 1984; and
 - (ii) the larger container in which the strips of primary containers are contained complies with subclause (1); and
 - (b) in respect of all other controlled drugs, if—
 - (i) the drug is contained in a safety container within the meaning of regulation 2(1) of the Medicines Regulations 1984; and
 - (ii) the labelling of the safety container complies with the Medicines Regulations 1984.
- (3A) Subclause (1) does not apply in respect of any controlled drug supplied pursuant to a prescription ~~signed~~ issued by a controlled drug prescriber.
- (4) No person shall, in the course of any profession or business, supply any controlled drug (other than an exempted drug) as a medicine for human use, with reference to the needs of a particular patient, unless the container of the controlled drug bears a label setting out the following:

**Misuse of Drugs Regulations 1977 + Medicines
Regulations 1984 [provs with consolidated amendments]
Bill**

Part 2 cl 25

- (a) either—
 - (i) the general nature of the medicine, and a recognised code that indicates the precise nature of the contents or consists of a reference to a prescription book or similar record; or
 - (ii) the name or a description of the nature of the contents; and
 - (b) either—
 - (i) in the case of a medicine for internal use, the dose and frequency of the dose; or
 - (ii) in the case of a medicine for external use, the directions for use; and
 - (c) the name of the patient; and
 - (d) the name and address of the supplier.
- (5) No person shall, in the course of any profession or business, supply any controlled drug (other than an exempted drug) as a remedy for the treatment of an animal, unless the container of the controlled drug bears a label setting out the following:
- (a) either—
 - (i) the general nature of the remedy, and a recognised code that indicates the precise nature of the contents or consists of a reference to a prescription book or similar record; or
 - (ii) the name or a description of the nature of the contents; and
 - (b) the directions for use; and
 - (c) the name of the person in charge of the animal; and
 - (d) the words “Not for Human Use” or the words “For Veterinary Use Only”.
- (6) Notwithstanding anything in subclause (1), nothing in that subclause shall apply during the period of 12 months commencing with the date of the commencement of the Act with respect to any controlled drug that, immediately before that date, was a poison within the meaning of the Poisons Act 1960 and that, at that date, was part of the existing stock-in-trade in New Zealand of any person lawfully carrying on business there, if the controlled drug is contained in a container labelled in accordance with all of those requirements of the Poisons Regulations 1964 (SR 1964/64) that were applicable to it at the said date. For the purposes of this subclause any controlled drug purchased before the said date for importation into New Zealand shall be deemed to be part of the purchaser’s stock-in-trade in New Zealand.
- (7) In any proceedings in respect of an alleged contravention of subclause (1) in which subclause (6) is pleaded in defence, the burden of proving that the provisions of that subclause afford a defence to the particular charge shall lie on the person charged.

29 General requirements in relation to prescriptions

- (1) A prescription for the supply of a controlled drug that is intended for human use and that is a Class A controlled drug, a Class B controlled drug, or a specified Class C controlled drug must be—
 - (a) issued in a paper form that is provided by the Director-General and is completed in the handwriting of the controlled drug prescriber; or
 - (b) issued in an electronic form that is completed by the controlled drug prescriber using an approved system and is transmitted through the approved system.
 - ~~(a) on a paper form provided by the Director-General and completed in the handwriting of the controlled drug prescriber; or~~
 - ~~(b) on a paper form that is electronically generated by the controlled drug prescriber from an approved system.~~
- (2) Notwithstanding subclause (1), a prescription for the supply of methadone ~~given~~ issued by a medical practitioner, nurse practitioner, or designated prescriber nurse working in a place for the time being specified by the Minister under section 24(7)(b) of the Act may also be in any paper or electronic form approved by the Director-General.
- (3) [Every prescription for the supply of a Class C controlled drug, not being a specified Class C controlled drug, must be on paper and in handwriting, in print, or both.]
- (4) Every prescription for a controlled drug in paper form must—
 - (a) be signed physically by the controlled drug prescriber in his or her own handwriting; and
 - (b) be legible and indelible; and
 - (c) be dated with the date on which it was signed; and
 - (d) set out, or be stamped with, the address of the controlled drug prescriber; and
 - (e) set out the surname, initials of the first names, and address of—
 - (i) the person to whom the controlled drug is intended to be administered; or
 - (ii) the person who has custody of the animal to which the controlled drug is intended to be administered; and
 - (f) if it is for a person who is under the age of 12 years, set out in words the age in years and months of that person; and
 - (g) bear the words “for dental treatment only”, if ~~given~~ issued by a dentist; and
 - (h) bear the words “for midwifery use only”, if ~~given~~ issued by a midwife; and

**Misuse of Drugs Regulations 1977 + Medicines
Regulations 1984 [provs with consolidated amendments]
Bill**

Part 2 cl 29

- (i) bear the words “for animal treatment only”, if ~~given~~-issued by a veterinarian; and
 - (j) set out the name of the controlled drug to be supplied; and
 - (k) not be in cipher, or abbreviated, otherwise than by abbreviations recognised in the British Pharmacopoeia, the British Pharmaceutical Codex, or other standard reference books on materia medica or pharmacy; and
 - (l) indicate the total amount of the controlled drug that may be sold or dispensed on the 1 occasion, or on each of the several occasions, authorised by that prescription; and
 - (m) set out the dose and frequency of the dose, or, in the case of a controlled drug for external use, directions for use; and
 - (n) where it prescribes an unusual dose, or what may be regarded as a dangerous dose, of any controlled drug, have the amount of the dose emphasised by being underlined, with the initials of the controlled drug prescriber set out in the margin opposite.
- (5) In this regulation,—
- approved system** means a system approved by the Director-General by notice in the *Gazette*
- [specified Class C controlled drug—**
- (a) means—
 - (i) a drug that is amobarbital, amobarbital sodium, buprenorphine, butobarbitone, glutethimide, ketamine, secobarbital, or secobarbital sodium; or
 - (ii) a combination of 2 or more of the substances specified in subparagraph (i); but
 - (b) does not include any substance referred to in paragraph (a)(i), or any combination of substances referred to in paragraph (a)(ii), if that substance or combination of substances is combined with any other pharmacologically active substance or substances that are not listed in clause 1 of Part 4 of Schedule 3 of the Act.]
- (6) This regulation does not apply—
- (a) to a prescription for a controlled drug communicated under regulation 34(1); or
 - (b) in respect of an exempted drug or partially exempted drug.

Note

We can't simply revoke (3). Sub (1) only says how a specified Class C controlled drug must be prescribed. So (3) says how other Class C controlled drugs (excluding specified Class C controlled drugs) are prescribed. If you want the drugs covered by (3) to now follow the same rules as in (1), I'll expand (1) to cover all Class C controlled drug. The definition of specified Class C controlled drug in (5) would then be redundant. Otherwise, please tell me the new rules for drugs covered by (3).

I've ensured that (4) applies to all prescriptions for controlled drugs in paper form, so that it also covers a paper form under (2).

Excluding electronic prescriptions from (4) means you're leaving all requirements to whatever the approved system happens to require, which seems questionable. Even then, are you certain that the approved system will ensure that all electronic prescriptions meet your requirements, in the same way that (3) ensures that all paper prescriptions meet your requirements?

And what if the DG approves an electronic form under (3)? There's no requirement for it to be done in the approved system.

30 Exemption for certain prescriptions

- (1) This regulation applies if there is imposed on a licence a condition prohibiting the acquisition of controlled drugs otherwise than pursuant to the prescription of—
 - (a) a controlled drug prescriber; or
 - (b) a named controlled drug prescriber; or
 - (c) a controlled drug prescriber belonging to a particular class of controlled drug prescribers.
- (2) The following regulations do not apply to the extent that they are inconsistent with the terms of the licence in respect of anything done for the purpose of enabling compliance with the condition imposed on the licence:
 - (a) regulation 21(2) to (5C);
 - (b) regulation 29(4)(e), (f), (g), (h), (i), (m), and (n).

31 Restrictions on supply on prescription

- (1) A person may not supply a controlled drug on a prescription—
 - (a) more than once on that same prescription; or
 - (b) more than 7 days after the date of the prescription, in the case of a Class A controlled drug or a Class B controlled drug; or
 - (c) more than 6 months after the date of the prescription, in the case of a Class C controlled drug; or
 - (d) in a quantity that, having regard to the dose and frequency of dose or the directions given by the controlled drug prescriber, is greater than a quantity sufficient for use for a period of 1 month.
- (2) Subclause (1) is subject to regulation 31A.
- (3) A person may not supply a controlled drug on an oral prescription more than once before receiving the ~~written~~ confirmation of that prescription under regulation 34(4).
- (4) On the first occasion of dispensing a prescription or, in the case of an oral prescription, on receipt of the ~~written~~ confirmation of that prescription, there must be ~~written or stamped on the face of the prescription, above the signature of the~~

**Misuse of Drugs Regulations 1977 + Medicines
Regulations 1984 [provs with consolidated amendments]
Bill**

Part 2 cl 31A

~~controlled drug prescriber, in such manner and place that no part of the prescription is obliterated,~~ recorded in or on the prescription—

- (a) the name of the proprietor of the business at which the prescription is dispensed; and
 - (b) the address of the premises from which the prescription is dispensed; and
 - (c) the date on which the prescription is dispensed.
- (5) On every subsequent occasion of dispensing a prescription, there must be ~~written or stamped on the face or back of the prescription, in such manner and place that no part of the prescription is obliterated,~~ recorded in or on the prescription—
- (a) the name of the proprietor of the business at which the prescription is dispensed; and
 - (b) the address of the premises from which the prescription is dispensed; and
 - (c) the date on which the prescription, or any indicated part or portion of the prescription, is dispensed.

(5A) If information is recorded on a paper prescription—

- (a) under subclause (4), it must be written or stamped on the face or back of the prescription, above the signature of the controlled drug prescriber, in such manner and place that no part of the prescription is obliterated;
- (b) under subclause (5), it must be written or stamped on the face or back of the prescription, in such manner and place that no part of the prescription is obliterated.

- (6) In this regulation, **oral prescription** means a prescription communicated under regulation 34(1).

Note

Does the approved system allow the info in (4) and (5) to be “recorded in” an electronic prescription? I based this wording on reg 42(3)(b) of the Medicines Regs.

Do we need to keep the distinct requirements of (5A)(a) and (b) (taken from (4) and (5)) or can we just apply the requirements in (5)(b) to both situations?

31A Exceptions to restrictions in regulation 31(1)

Medical or nurse practitioner: any prescription for Class A, or generally paper prescriptions for Class B, controlled drugs

- (1) A medical practitioner or nurse practitioner who ~~signs a prescription for a Class A controlled drug or a Class B controlled drug may direct or~~ issues a prescription for a Class A controlled drug, or a prescription that is for a Class B controlled drug and is not covered by subclause (3) (generally paper prescriptions), may direct in the prescription that the drug be supplied on 2 occasions at a specified interval, with—

- (a) the first occasion being not more than 7 days after the date of prescription; and
- (b) the second occasion being not more than 7 days after the termination of that interval.
- (2) In the case of a controlled drug supplied pursuant to a direction under subclause (1), the total quantity supplied, having regard to the dose and frequency of dose or the directions of the medical practitioner or nurse practitioner, must not be greater than a quantity sufficient for use for a period of 1 month.
- Medical or nurse practitioner: generally electronic prescriptions for Class B, or any prescription for Class C, controlled drugs*
- (3) A medical practitioner or nurse practitioner who ~~signs a prescription for a Class C controlled drug may direct on~~ issues an electronic prescription for a Class B controlled drug using the approved system under regulation 29(1)(b), or any prescription for a Class C controlled drug, may direct in the prescription that the drug be supplied on not more than 3 occasions, which, unless specified otherwise, are to be at monthly intervals.
- (4) In the case of a controlled drug supplied pursuant to a direction under subclause (3), the total quantity supplied, having regard to the dose and frequency of dose or the directions of the medical practitioner or nurse practitioner, must not be greater than a quantity sufficient for use for a period of 3 months.
- Midwife: prescription for controlled drugs in Schedule 1C*
- (5) A midwife who ~~signs~~ issues a prescription for a controlled drug specified in Schedule 1C may direct ~~on~~ in the prescription that the drug be supplied on 2 occasions at a specified interval, with—
- (a) the first occasion being not more than 4 days after the date of the prescription; and
- (b) the second occasion being not more than 4 days after the termination of that interval.
- (6) In the case of a controlled drug supplied pursuant to a direction under subclause (5), the total quantity supplied, having regard to the dose and frequency of dose or the directions of the midwife, must not be greater than a quantity sufficient for use for a period of 1 month.
- Prescription to protect patient or limit quantity in possession*
- (7) If, for special reasons relating to the protection of the patient, or for the purpose of limiting the quantity of any controlled drug in the possession of any person, the controlled drug prescriber (not being a dentist or veterinarian) who ~~signs~~ issues a prescription directs ~~on~~ in the prescription that the controlled drug is to be dispensed daily or at such other regular intervals as the controlled drug prescriber considers necessary for a specified period not exceeding 1 month, the controlled drug may be supplied on not more than the number of occasions indicated, and not more frequently than the intervals directed.

Supply to restricted person

- (8) If a Medical Officer of Health has issued to a person a notice under section 25 of the Act that authorises him or her to supply a controlled drug for a restricted person on more than 2 occasions on any prescription, that person may supply the controlled drug in such quantity, at such frequency, and for such period as the notice specifies.

Note

Please confirm that Class B controlled drugs can only be prescribed by a medical practitioner or nurse practitioner, as I've assumed in my amendments to (3).

Reg 29(2) currently envisages an electronic prescription issued outside of the approved system. If we end up changing reg 29 so that all electronic prescriptions must be done by the approved system, this reg can just refer to any electronic prescription (without referring to the approved system).

32 Verification of paper prescriptions

- (1) No person may supply a controlled drug pursuant to a paper prescription purporting to be signed by a controlled drug prescriber, with whose signature the person is not acquainted, until the person has satisfied himself or herself that the signature is genuine.
- (2) No person may—
- (a) alter any paper prescription appearing to be signed by a controlled drug prescriber that purports to authorise the supply of any controlled drug; or
 - (b) alter any paper prescription in such a manner that it purports to authorise the supply of any controlled drug.
- (3) However, subclause (2) does not apply to a controlled drug prescriber who, after signing a prescription, alters that prescription in his or her own handwriting and then signs the prescription again beside the alteration.
- (4) A person authorised to deal in controlled drugs must keep a paper prescription purporting to authorise the supply of a controlled drug and notify immediately the officer in charge of the nearest Police station or the Medical Officer of Health if the person believes on reasonable grounds—
- (a) that any signature purporting to be that of a controlled drug prescriber, and appearing on the prescription, is not genuine; or
 - (b) that the prescription has been altered by an unauthorised person.

33 Retention of paper prescriptions

- (1) No person shall supply any controlled drug (other than a Class C controlled drug) pursuant to any ~~written~~ paper prescription except on condition that the prescription is retained by him or her.
- (2) Every person so supplying any such controlled drug shall retain the prescription for a period of 4 years from the date on which the controlled drug is supplied, or, if the controlled drug is supplied pursuant to the same prescription on

more than 1 occasion, from the last of the dates on which it is so supplied. All such prescriptions shall be retained on the premises in an orderly and consecutive manner, and shall at all times be available to any constable or any officer, who may inspect them and make copies thereof:

provided that, if the proprietor of the business from which the controlled drug was supplied vacates those premises, the prescriptions shall be stored at such place as is approved in writing by the Medical Officer of Health for the purpose.

34 Emergencies

- (1) In the case of an emergency, a prescriber may communicate orally or by telephone a prescription for a controlled drug to a pharmacist who personally knows the prescriber (an **oral prescription**).
- (2) A pharmacist may supply a controlled drug to any person on an oral prescription.
- (3) Immediately after communicating an oral prescription, a prescriber must—
 - (a) ~~prepare a prescription~~ issue a prescription in paper or electronic form in accordance with the requirements of regulation 29 confirming the oral prescription; and
 - (b) ~~endorse the prescription with~~ include in the prescription—
 - (i) a statement to the effect that the prescription is intended only as confirmation of the oral prescription; and
 - (ii) the date of the oral prescription.
- (4) Not later than 2 business days after the date of the oral prescription, the prescriber must ~~deliver the prescription~~ deliver the paper prescription, or transmit the electronic prescription, to the pharmacist to whom the oral prescription was communicated.
- (5) After delivery or transmission of the prescription in accordance with subclause (4), the prescription and the pharmacist are subject to all provisions in these regulations relating to prescriptions for the supply of controlled drugs and to the duties of persons in respect of such prescriptions.
- (6) In this regulation, **prescriber** means any of the following persons:
 - (a) a medical practitioner;
 - (b) a nurse practitioner;
 - (c) a midwife;
 - (d) a designated prescriber nurse;
 - (e) a designated prescriber pharmacist.

Note

These emergency prescriptions are an exception under reg 29(6)(a). But “endorse” (write on the back of) and “deliver” (transfer possession) in this reg, and “written” in

[reg 31\(3\) & \(4\), suggest only paper documents. So I've widened these to also allow electronic prescriptions to confirm an oral prescription.](#)

35 Duty to supply information

- (1) Every controlled drug prescriber must answer in writing, to the best of his or her knowledge and belief, any questions addressed to him or her by the Medical Officer of Health with respect to his or her prescribing, administering, or supplying controlled drugs and in respect of the identification of the person for whom they were prescribed or to whom they were administered or supplied.
- (2) Every person who supplies a controlled drug (not being a Class C controlled drug) on the prescription of a controlled drug prescriber must ensure that the Medical Officer of Health is advised, within 1 month after the date of the supply, of—
 - (a) the name and address of the person for whom the controlled drug is supplied;
 - (b) the name and address of the controlled drug prescriber;
 - (c) the date of the prescription;
 - (d) the name or description of the controlled drug supplied;
 - (e) the amount of the controlled drug supplied on the occasion or on each of the occasions of supply;
 - (f) each date on which the controlled drug is supplied.
- (3) It shall be sufficient compliance with the requirements of subclause (2) if the person supplying the controlled drug provides the Medical Officer of Health, within 1 month after the date of the supply or, if the prescription authorises the supply of a controlled drug on more occasions than 1, the date of the first supply, with a copy of the prescription to which the supply relates.
- (4) In this regulation, **prescription** includes any written authority, order, or request for the supply of controlled drugs signed by a controlled drug prescriber, not being an authority, order, or request relating to a disposal by wholesale within the meaning of regulation 47; and **prescribing** has a corresponding meaning: provided that subclause (2)(a) shall not apply to any such authority, order, or request not having reference to a particular patient.

Note

[Sub \(4\) merely ensures certain written & signed things are included \(eg, an entry under reg 36\(2\)?\). It's not exhaustive, so we don't strictly need to widen it to cover electronic prescriptions, unless you prefer to.](#)

36 Special provisions for hospitals

- (1) Where a controlled drug is required for the treatment of a patient for the time being maintained in a hospital or other institution, the medical practitioner, nurse practitioner, midwife, designated prescriber nurse, or designated prescriber pharmacist attending the patient may, instead of ~~writing~~ [issuing](#) a pre-

scription, enter on the patient's chart, or other clinical record appertaining to the patient, the particulars required by regulation 29(4)(c), (j), and (m), in the manner required and subject to the limitations imposed by paragraphs (a), (b), (k), and (n) of that subclause, and such entry shall have the same effect as a prescription.

- (2) In the case of a maternity hospital, the medical superintendent, if any, may generally, and any medical practitioner, nurse practitioner, midwife, designated prescriber nurse, or designated prescriber pharmacist attending a patient may in relation to any patient or patients attended by him or her, by an instruction in writing recorded in a book set aside for the purpose containing the same particulars and written in the like manner as are required in the case of an entry under subclause (1), authorise the administration, in the absence of complications requiring the presence of a medical practitioner or midwife, of a controlled drug (being a controlled drug that, if there is no medical superintendent of the hospital, the manager of the hospital is authorised to possess) to a maternity patient between the commencement and the termination of labour.
- (3) Every instruction given under subclause (2) shall cease to have effect on the expiration of 6 months from the date on which it is given or renewed, as the case may require.

Misuse of Drugs Regulations 1977 [Schedules]

Schedule 1A
**Controlled drugs that designated prescriber nurses may prescribe in
certain circumstances**

r 12A(1)(a)

Alprazolam
Buprenorphine, transdermal only
Buprenorphine with naloxone, sublingual only
Clonazepam, for anxiety and panic disorder only
Codeine
Diazepam, oral only
Dihydrocodeine
Fentanyl, transdermal only
Lorazepam
Lormetazepam
Methadone, oral only
Morphine
Nitrazepam
Oxazepam
Temazepam
[Tramadol](#)
Triazolam
[Zopiclone](#)

Note

Do you know when the Misuse of Drugs (Classification and Presumption of Supply) Order 2022 will commence? It's only then that these drugs added to Schedules 1A and 1B of the Misuse of Drugs Regs actually become controlled drugs. So if that order hasn't commenced before you want these regs to commence, we'll need to separately commence these amendments to Schedules 1A and 1B (at the same time the order commences). For the rest of the amendments, if the regs are approved by LEG on Thu 20 Oct, made on Tue 25 Oct (after Labour Day), and gazetted on Thu 27 Oct, they could commence 28 days later on Thu 24 Nov.

Schedule 1B

Controlled drugs that designated ~~pharmacist prescribers~~ prescriber pharmacists may prescribe

r 12A(1)(b)

A reference in this schedule to a substance is a reference to the substance in every compound, form, mixture, or preparation that is declared to be a controlled drug under the Act.

- 1 Alprazolam
- 2 Buprenorphine
- 3 Clobazam
- 4 Clonazepam
- 5 Codeine
- 6 Diazepam
- 7 Dihydrocodeine
- 8 Diphenoxylate
- 9 Fentanyl
- 10 Hydromorphone
- 11 Lorazepam
- 12 Lormetazepam
- 13 Methadone
- 14 Midazolam
- 15 Morphine
- 16 Nitrazepam
- 17 Oxazepam
- 18 Oxycodone
- 19 Pethidine
- 20 Phenobarbital
- 21 Phentermine
- 22 Pholcodine
- 23 Temazepam
- 24 Tetrahydrocannabinol when a Class B1 controlled drug
- 24A Tramadol
- 25 Triazolam
- 26 Zolpidem
- 27 Zopiclone

From: Sean Dougherty
Sent: Tuesday, 18 October 2022 1:46 pm
To: Belinda Ray-Johnson; Fiona Moscrop
Subject: FW: Consultation on DRAFT LEG paper - Misuse of Drugs Amendment Regulations 2022 and Medicines Amendment Regulations 2022 (No 2)
Attachments: DRAFT LEG paper - Misuse of Drugs Amendment Regulations 2022 and Medicines Amendment Regulations 2022.docx; Misuse of Drugs Regulations 1977 + Medicines Regul-v1.0.pdf

Sean Dougherty | Manager, Schedule Strategy and Development

Pharmac | Level 9, 40 Mercer Street, Wellington

P: **s 9(2)(a)** | F: +64 4 460 4995 | www.pharmac.govt.nz

From: Eddy Sommers <Eddy.Sommers@health.govt.nz>
Sent: Tuesday, 18 October 2022 1:38 pm
To: WOOLLASTON, Sharon <Sharon.Woollaston@police.govt.nz>; MARSHALL Kirsty <kirsty.marshall@customs.govt.nz>; Matthew.McClennan@justice.govt.nz; Trevor Lloyd <Trevor.Lloyd@health.govt.nz>; Serena.Coxhead@treasury.govt.nz; ben.mcbride@dpmc.govt.nz; Sean Dougherty <sean.dougherty@pharmac.govt.nz>; Sara McFall <Sara.McFall@health.govt.nz>
Cc: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>; Jane Hubbard <Jane.Hubbard@health.govt.nz>
Subject: Consultation on DRAFT LEG paper - Misuse of Drugs Amendment Regulations 2022 and Medicines Amendment Regulations 2022 (No 2)

You don't often get email from eddy.sommers@health.govt.nz. [Learn why this is important](#)

Kia ora koutou

Please find attached 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**. These amendments will give effect to the following policy decisions made by Cabinet in August [CAB-22-MIN-0316]:

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

If there is someone in your organisation you think is more appropriate to review this draft please feel free to pass this on.

Also attached to this paper is the first draft of the amendments from PCO. These are quite technical changes but am providing this for reference. Please note that this is an early draft and the comments within have since been addressed.

Please provide any feedback by **COP Friday 21 October**.

Ngā mihi nui

Eddy Sommers (he/him)

Policy Analyst

Health System Settings

s 9(2)(a)

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Office of the Minister of Health
Chair, Cabinet Legislation Committee

Misuse of Drugs Amendment Regulations 2022 and Medicines Amendment Regulations 2022 (No 2)

Proposal

- 1 This paper seeks authorisation for submission to the Executive Council of the Misuse of Drugs Amendment Regulations 2022 and the Medicines Amendment Regulations 2022 (No 2).

Policy

- 2 These amendment regulations do not require any new policy decisions from the Cabinet Legislation Committee.

Improvements to electronic prescribing

- 3 The New Zealand ePrescription Service (NZePS) is a fast, secure system for the transmission and authentication of electronic prescriptions. It enables a prescription to be generated by the prescriber on an approved system, transmitted to the NZePS health information exchange broker and downloaded electronically at a community pharmacy.
- 4 The use of electronic prescriptions, instead of traditional hard-copy prescriptions, reduces costs for practices, provides flexibility for practitioners and improves the patient experience with fewer delays and less chance of prescriber error.
- 5 Transitioning prescriptions onto the NZePS will also enable regulators to more efficiently monitor and audit prescribing behaviour.
- 6 On 15 August 2022, Cabinet agreed to amend regulations to remove regulatory barriers to electronic prescribing and improve patient access to medicines by:
 - 6.1 enabling controlled drugs to be prescribed electronically
 - 6.2 reducing the frequency prescribers need to issue prescriptions for certain controlled drugs, when issued through the NZePS
 - 6.3 codifying the waiver issued by the Director-General that enables electronic prescribing
 - 6.4 ensuring designated pharmacist prescribers and designated prescriber nurses can continue to prescribe certain medicines when they become controlled drugs [CAB-22-MIN-0316].

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Minor correction to Misuse of Drugs Regulations

- 7 A minor printing error within the Misuse of Drugs Regulations was discovered through the drafting process of these amendments. Parliamentary Counsel Office have recommended using this opportunity to correct the error.

Timing and 28-day rule

- 8 I am not seeking a waiver of the 28-day rule.
- 9 The regulations will be notified in the *New Zealand Gazette* as soon as possible after officials are informed of the Executive Council's agreement. The regulations will come into force 28 days after they are notified in the *Gazette*.

Compliance

- 10 The regulations comply with:
- 10.1 the principles of the Treaty of Waitangi;
 - 10.2 advice from the Treaty Provisions Officials Group on any Treaty of Waitangi provisions;
 - 10.3 the rights and freedoms contained in the New Zealand Bill of Rights Act 1990 or the Human Rights Act 1993;
 - 10.4 the principles and guidelines set out in the Privacy Act 2020;
 - 10.5 relevant international standards and obligations;
 - 10.6 the Legislation Guidelines (2021 edition), which are maintained by the Legislation Design and Advisory Committee.
- 11 The Misuse of Drugs Amendment Regulations 2022 will be made under section 37 of the Misuse of Drugs Act 1975.
- 12 The Medicines Amendment Regulations 2022 (No 2) will be made under section 105 of the Medicines Act 1981. This section requires that I must be satisfied that consultation has occurred with 'such organisations or bodies as appear to the Minister to be representative of persons likely to be substantially affected by the regulations.' I am satisfied that Manatū Hauora has consulted with the appropriate organisations and bodies on my behalf.

Regulations Review Committee

- 13 The Parliamentary Counsel Office does not consider there are grounds for the Regulations Review Committee to draw this instrument or regulations to the attention of the House of Representatives under Standing Order 327.

Certification by Parliamentary Counsel

- 14 The draft regulations have been certified by the Parliamentary Counsel Office as being in order for submission to Cabinet.

IN CONFIDENCE

Impact Analysis

- 15 The Treasury's Regulatory Impact Analysis team has determined that the proposals are exempt from the requirement to provide a Regulatory Impact Statement on the grounds that they have no or only minor impacts on businesses, individuals, and not-for-profit entities.

Publicity

- 16 My office will issue a press release about these changes once they have been authorised by the Executive Council.
- 17 Once the regulations are notified in the *Gazette*, officials from Manatū Hauora and Te Whatu Ora will communicate directly with the impacted health practitioners to ensure they are aware of the new regulations and the implications.

Proactive release

- 18 This paper will be proactively released according to standard processes under the Cabinet Office circular CO (18) 4, subject to redactions as appropriate under the Official Information Act 1982.

Consultation

- 19 The following departments have been consulted on this paper: Pharmac, New Zealand Police, New Zealand Customs Service, Ministry of Justice, Te Whatu Ora, Te Aka Whai Ora, the Department of the Prime Minister and Cabinet and the Treasury.

Recommendations

I recommend that the Cabinet Legislation Committee:

- 1 note that on 15 August 2022 Cabinet agreed to:
- 1.1 enable controlled drug medicines to be prescribed electronically
 - 1.2 reduce the frequency prescribers need to issue prescriptions for certain controlled drugs, when issued through the NZePS
 - 1.3 codify the waiver issued by the Director-General that enables electronic prescribing
 - 1.4 ensure designated pharmacist prescribers and designated prescriber nurses can continue to prescribe certain medicines when they become controlled drugs [CAB-22-MIN-0316 refers];
- 2 note that the Misuse of Drugs Amendment Regulations 2022 will give effect to the decision referred to in recommendation 1.1, 1.2 and 1.4 above;
- 3 note that the Medicines Amendment Regulations 2022 (No 2) will give effect to the decision referred to in recommendation 1.3 above;

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- 4 note that section 105 of the Medicines Act requires that I be satisfied that consultation has occurred with such organisations or bodies as appear to me to be representative of persons likely to be substantially affected by the regulations;
- 5 note my advice as Minister of Health that these requirements have been met;
- 6 authorise the submission to the Executive Council of the Misuse of Drugs Amendment Regulations 2022 and the Medicines Amendment Regulations 2022 (No 2);
- 7 note that the Misuse of Drugs Amendment Regulations 2022 and the Medicines Amendment Regulations 2022 (No 2) come into force on 22 December 2022;

Authorised for lodgement

Hon Andrew Little

Minister of Health

released under the
Official Information Act