PCO 25042/1.0 Drafted by Shane Williams

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

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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.

<u>Note</u>

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) <u>A prescription given under these regulations must be in paper or electronic form.</u>
- (2) Every prescription given under these regulations shall<u>A</u> 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

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- (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) <u>An electronic prescription must be completed using, and transmitted through,</u> an approved system (as defined by regulation 29(5) of the Misuse of Drugs <u>Regulations 1977).</u>

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):

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	(b)	the fo	ollowing 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)	be di on w	escription for a medicine other than an oral contraceptive must not spensed on any occasion after 6 months have elapsed from the date which it was printed the prescription was given or, if given under lation 40A(1), communicated orally:
	(d)	dispe whic	escription for a medicine that is an oral contraceptive must not be ensed on any occasion after 9 months have elapsed from the date on h it was printed the prescription was given or, if given under regula- 40A(1), communicated orally:
	(e)	phari appro	y <u>paper</u> prescription must be retained for a period of 3 years by the macist on the premises on which it was dispensed or at a place oved by the Medical Officer of Health and must be kept in an ely and consecutive manner so as to be readily available for inspec-
4)	cine	by its rer, a j	rised prescriber or a veterinarian refers in a prescription to a medi- trade mark or trade name, or by reference to the name of its manu- pharmacist may supply an alternative brand of medicine, provided
	(a)		uthorised prescriber or veterinarian has not marked the prescription brand substitution permitted" or with words of similar meaning; and
	(b)		ubstituted brand contains the same active ingredient or active ingre- s, and no other active ingredients; and
	(c)		ubstituted brand is in the same dose form and strength as the pre- ed brand; and
	(d)	there plied	is no clinical reason why the substituted brand should not be sup; and
	(e)	the p and	harmacist records the brand substitution in or on the prescription;
	(f)	<u>for a</u> and	paper prescription, the pharmacist signs and dates the prescription;
	(g)	the p	harmacist informs the patient of the brand substitution.
(5)	This	regula	tion is subject to regulation 43.

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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.

<u>Note</u>

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—

- (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) <u>a Class A controlled drug; or</u>
 - (B) <u>a Class B controlled drug where the prescription is not</u> <u>covered by regulation 31A(3) (generally paper prescrip-</u> <u>tions):</u>
 - (ii) <u>a period of 3 months, in the case of</u>
 - (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.

<u>Note</u>

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:

(a) either—

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- 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—
 - 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

- 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 <u>in paper form</u> 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 <u>given issued</u> by a dentist; and
 - (h) bear the words "for midwifery use only", if <u>given-issued</u> by a midwife; and

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(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
- 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 pharma-cologically 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).

Part 2 cl 31

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 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

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		rolled drug prescriber, in such manner and place that no part of the pre- tion 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)	ten o	very subsequent occasion of dispensing a prescription, there must be writ- or stamped on the face or back of the prescription, in such manner and that no part of the prescription is obliterated, recorded in or on the pre-	

scription-

- (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).

<u>Note</u>

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 on 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.

<u>Medical or nurse practitioner: generally electronic prescriptions for Class B,</u> 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.

<u>Note</u>

Part 2 cl 32

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 <u>paper</u> 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 <u>paper</u> prescription appearing to be signed by a controlled drug prescriber that purports to authorise the supply of any controlled drug; or
 - (b) alter any <u>paper</u> 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

Part 2 cl 35

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

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-

(1)

Part 2 cl 36

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

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

<u>Tramadol</u>

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.

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

Schedule 1B

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
- <u>24A</u> <u>Tramadol</u>
- 25 Triazolam
- 26 Zolpidem
- 27 Zopiclone

From: Sent: To: Subject: Sean Dougherty Friday, 21 October 2022 11:43 am Suzanne Townsend Re: Controlled drugs and Pharmac rules

Hi Suzanne,

9:30 is problematic for me. I can do 10:30, 12 or 2-4pm that day.

Sean

From: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>
Sent: Friday, October 21, 2022 11:39:48 AM
To: Eddy Sommers <Eddy.Sommers@health.govt.nz>; Diana Suggate <Diana.Suggate@health.govt.nz>; Sean
Dougherty <sean.dougherty@pharmac.govt.nz>; Trevor Lloyd <Trevor.Lloyd@health.govt.nz>
Subject: Controlled drugs and Pharmac rules
When: Thursday, 27 October 2022 9:30 AM-10:00 AM.
Where: Microsoft Teams Meeting

Diana Can't make 10 does this still work

Microsoft Teams meeting

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754254586@t.plcm.vc Video Conference ID: 135 773 575 4 Alternate VTC instructions

Or call in (audio only)

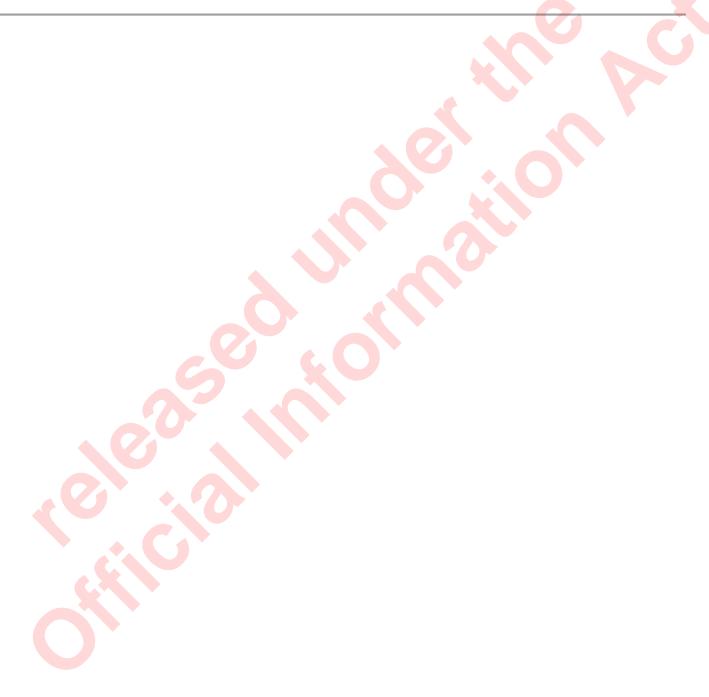
+64 4-280 2674,,841242654# New Zealand, Wellington Phone Conference ID: 841 242 654# Find a local number | Reset PIN



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Subject: Location:

Start: End: Show Time As:

Recurrence:

(none)

Tentative

Organizer:

Suzanne Townsend

Controlled drugs and Pharmac rules

Microsoft Teams Meeting

Thu 27/10/2022 10:00 am

Thu 27/10/2022 10:30 am

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

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Subject: Location:

Start: End: Show Time As: Controlled drugs and Pharmac rules Microsoft Teams Meeting

Thu 27/10/2022 2:00 pm Thu 27/10/2022 2:30 pm Tentative

Recurrence:

Organizer:

Suzanne Townsend

(none)

Lets try this

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Join with a video conferencing device

754254586@t.plcm.vc Video Conference ID: 135 773 575 4 <u>Alternate VTC instructions</u>

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From:	Sean Dougherty
Sent:	Friday, 25 November 2022 10:51 am
То:	Eddy Sommers
Subject:	RE: Controlled drugs regulations changes

Perfect. We should only need 15 mins.

Sean

From: Eddy Sommers <Eddy.Sommers@health.govt.nz>
Sent: Friday, 25 November 2022 10:48 am
To: Sean Dougherty <sean.dougherty@pharmac.govt.nz>
Subject: Re: Controlled drugs regulations changes

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Hi Sean

Would 1230 work for you?

From: Sean Dougherty <<u>sean.dougherty@pharmac.govt.nz</u>> Sent: Friday, November 25, 2022 10:37:11 AM To: Eddy Sommers <<u>Eddy.Sommers@health.govt.nz</u>> Subject: RE: Controlled drugs regulations changes

Hi Eddy,

What times today would suit for a quick catch-up? We've mostly sorted out the confusion at our end, but it would be good to give you a heads-up on our consultation process.

Sean

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 <<u>Eddy.Sommers@health.govt.nz</u>>
Sent: Thursday, 24 November 2022 12:35 pm
To: Sean Dougherty <<u>sean.dougherty@pharmac.govt.nz</u>>
Subject: RE: Controlled drugs regulations changes

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Hi Sean

Had a look through and unfortunately the last marked up version doesn't quite capture the final changes. So instead of risking more confusion lets catchup tomorrow to go over in detail.

Cheers

Eddy Sommers (he/him)

Policy Analyst Health System Settings s 9(2)(a)

eddy.sommers@health.govt.nz Manatū Hauora, 133 Molesworth Street Thorndon, Wellington 6011





From: Eddy Sommers
Sent: Thursday, 24 November 2022 11:58 am
To: Sean Dougherty <<u>sean.dougherty@pharmac.govt.nz</u>>
Cc: Suzanne Townsend <<u>Suzanne.Townsend@health.govt.nz</u>>
Subject: RE: Controlled drugs regulations changes

Hi Sean

Both sets of amendment regulations to come into force on 22 December are attached. Misuse of Drugs amendment is the one relevant to schedule changes.

We're happy to discuss re practical implications, Suzanne is off today so tomorrow might be best.

Cheers

Eddy Sommers (he/him) Policy Analyst Health System Settings s 9(2)(a)

eddy.sommers@health.govt.nz Manatū Hauora, 133 Molesworth Street Thorndon, Wellington 6011



From: Sean Dougherty <<u>sean.dougherty@pharmac.govt.nz</u>>
Sent: Thursday, November 24, 2022 10:40:37 AM

To: Suzanne Townsend <<u>Suzanne.Townsend@health.govt.nz</u>> Subject: RE: Controlled drugs regulations changes

Hi Suzanne,

We are hoping to consult on Schedule rule changes next week.

Do you have a copy of the new Regulations (as at 22 December) that we could reference? It's quite easy to get lost in jumping back and forth between documents.

I suspect that I might also have some further questions for you later today or tomorrow, just to make sure that we're clear on the practical impacts of the new Regs.

Thanks,

Sean

Sean Dougherty | Manager, Schedule Strategy and Development

Pharmac | Level 9, 40 Mercer Street, Wellington P: **s 9(2)(a)** | F: +64 4 460 4995 | <u>www.pharmac.govt.nz</u>

From: Suzanne Townsend <<u>Suzanne.Townsend@health.govt.nz</u>>
Sent: Monday, 21 November 2022 3:05 pm
To: Sean Dougherty <<u>sean.dougherty@pharmac.govt.nz</u>>
Subject: Re: Controlled drugs regulations changes

Hi Sean

They are being signed today. They will be gazetted on Thursday and will come into force on 22 December

From: Sean Dougherty <<u>sean.dougherty@pharmac.govt.nz</u>> Sent: Monday, November 21, 2022 2:04:00 PM To: Suzanne Townsend <<u>Suzanne.Townsend@health.govt.nz</u>> Subject: Controlled drugs regulations changes

Hi Suzanne,

It has been a few weeks since we discussed upcoming changes to controlled drugs regulations. Are you able to give me any updates on expected timings of the change being approved and/or the actual implementation date? We are trying to plan our own consultation on the Schedule rules, and any guidance that you can give us would be greatly appreciated.

Kind regards,

Sean

Sean Dougherty | Manager, Schedule Strategy and Development

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From: Sent: To: Subject: Belinda Ray-Johnson Friday, 25 November 2022 4:08 pm Eddy Sommers; Suzanne Townsend RE: Pharmac controlled drugs consultation letter

Thanks very much. Have a great weekend.

From: Eddy Sommers <Eddy.Sommers@health.govt.nz>
Sent: Friday, 25 November 2022 4:05 pm
To: Belinda Ray-Johnson <belinda.ray-johnson@pharmac.govt.nz>; Suzanne Townsend
<Suzanne.Townsend@health.govt.nz>
Cc: Sean Dougherty <sean.dougherty@pharmac.govt.nz>
Subject: RE: Pharmac controlled drugs consultation letter

Kia ora Belinda and Sean

Thanks for sending this through, looks great to us.

Cheers

Eddy Sommers (he/him) Policy Analyst Health System Settings s 9(2)(a)

eddy.sommers@health.govt.nz Manatū Hauora, 133 Molesworth Street Thorndon, Wellington 6011





From: Belinda Ray-Johnson <<u>belinda.ray-johnson@pharmac.govt.nz</u>>
Sent: Friday, 25 November 2022 12:54 pm
To: Eddy Sommers <<u>Eddy.Sommers@health.govt.nz</u>>; Suzanne Townsend <<u>Suzanne.Townsend@health.govt.nz</u>>
Cc: Sean Dougherty <<u>sean.dougherty@pharmac.govt.nz</u>>
Subject: Pharmac controlled drugs consultation letter

Kia ora Suzanne and Eddy

Thanks for your time earlier.

I've attached the entire consultation letter that we intend to release on Monday – please keep this version within team until then.

If there's anything in there that you'd like us to revise, please let me know by 4pm today.

Thanks

Belinda

Belinda Ray-Johnson | Schedule Development Manager

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

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

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From: Sent: To: Cc: Subject: Sean Dougherty Monday, 28 November 2022 5:00 pm Trevor Lloyd Billy Allan RE: MODR Changes

Hi Trevor,

We've been working with Suzanne Townsend and Eddy Sommers.

My understanding is that the messaging from the Ministry to the sector has been that behaviour change should wait until the Schedule changes happen.

I can appreciate your concerns. However, it would seem to be inappropriate to change the Schedule rules midconsultation. Unfortunately, these sorts of issues will always happen when we're unable to properly coordinate timing.

Regards,

Sean

Sean Dougherty | Manager, Schedule Strategy and Development

Te Pātaka Whaioranga | Pharmac

PO Box 10-254, Wellington 6140 | Level 9, 40 Mercer Street, Wellington 6011

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

From: Trevor Lloyd <Trevor.Lloyd@health.govt.nz> Sent: Monday, 28 November 2022 4:42 pm To: Sean Dougherty <sean.dougherty@pharmac.govt.nz> Cc: Billy Allan <Billy.Allan@health.govt.nz> Subject: RE: MODR Changes

Hi Sean

When you say MoH policy team who are you referring to, Billy and co?

I note your response but I assume that you can see the issue and how the timing of the legislation changes and people being holiday has the potential to lead to chaos? I don't want to

I do agree with holding off on any other possible changes that may flow from the consultation.

Nga mihi

Trevor Lloyd B.Pharm | \$ 9(2)(a)

From: Sean Dougherty <<u>sean.dougherty@pharmac.govt.nz</u>> Sent: Monday, 28 November 2022 4:01 pm To: Trevor Lloyd <<u>Trevor.Lloyd@health.govt.nz</u>> Cc: Lisa Williams <<u>\$9(2)(a)</u> Subject: RE: MODR Changes

Hi Trevor,

As you'll see, the proposal is to make all of the changes from the 1st of February. This approach has been discussed with the MoH policy team, and this lines up with their expectations.

Regards,

Sean

Sean Dougherty | Manager, Schedule Strategy and Development

Te Pātaka Whaioranga | Pharmac PO Box 10-254, Wellington 6140 | Level 9, 40 Mercer Street, Wellington 601

DDI: s 9(2)(a)

| P: 0800 660 050 | www.pharmac.govt.nz

From: Trevor Lloyd <<u>Trevor.Lloyd@health.govt.nz</u>> Sent: Monday, 28 November 2022 3:52 pm To: Sean Dougherty <<u>sean.dougherty@pharmac.govt.nz</u>> Cc: Lisa Williams <<u>\$ 9(2)(a)</u> Subject: MODR Changes

Kia Ora Sean

I am getting a lot of anxious questions about the funding of CD scripts post 22 December mainly around supplies beyond one month. The issue is 1.2.1 which restricts funding in total to one month for Class B CDs. I didn't expect the 30 day lots of dexamfetamine and methylphenidate or the 10 day lots for the rest of the Class B CDs to change but it is imperative that 1.2.1 should change to allow the repeats to be processed prior to the 19th of Jan 2023 if a patient is getting weekly supplies. I see from your consultation that there will no changes implemented before 1 Feb which will too late for the repeats that extend beyond the first month.

What are your thoughts? My preference is obviously to remove 1.2.1 b with the next schedule update as we not technically altering the amount of drug supplied on any one occasion all it changes is how often the patient has to see the prescriber.

Ngā mihi

Trevor Lloyd B.Pharm NZePS Change Manager Data and Digital

waea pūkoro: \$9(2)(a) | īmēra: <u>Trevor.Lloyd@health.govt.nz</u> 133 Molesworth Street, Wellington



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From:	Media
Sent:	Tuesday, 29 November 2022 9:46 am
То:	Media Health; Media
Subject:	Fwd: Controlled drug legislation and Schedule rules changes

Hi health media, see below! An fyi and happy to discuss if any queries come in!

Jane

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From: Jane Wright <jane.wright@pharmac.govt.nz>
Sent: Tuesday, November 29, 2022 8:26 AM
To: Jannel Fisher <jannel.fisher@pharmac.govt.nz>; Belinda Ray-Johnson <belinda.ray-johnson@pharmac.govt.nz>; Cameron Webb <cameron.webb@pharmac.govt.nz>; Media <media@pharmac.govt.nz>
Cc: Sean Dougherty <sean.dougherty@pharmac.govt.nz>
Subject: Re: Controlled drug legislation and Schedule rules changes

Thanks Belinda, Rosa and I have a great relationship with MoH media so we can touch base with them, and they will work with their people on messages.

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From: Jannel Fisher <jannel.fisher@pharmac.govt.nz>
Sent: Tuesday, November 29, 2022 8:24:42 AM
To: Belinda Ray-Johnson <belinda.ray-johnson@pharmac.govt.nz>; Cameron Webb
<cameron.webb@pharmac.govt.nz>; Jane Wright <jane.wright@pharmac.govt.nz>
Cc: Sean Dougherty <sean.dougherty@pharmac.govt.nz>
Subject: Re: Controlled drug legislation and Schedule rules changes

Thanks for the heads up Belinda. Much appreciated.

Get Outlook for iOS

From: Belinda Ray-Johnson <belinda.ray-johnson@pharmac.govt.nz>
Sent: Tuesday, November 29, 2022 8:12:16 AM
To: Cameron Webb <cameron.webb@pharmac.govt.nz>; Jane Wright <jane.wright@pharmac.govt.nz>

Cc: Jannel Fisher <jannel.fisher@pharmac.govt.nz>; Sean Dougherty <sean.dougherty@pharmac.govt.nz> **Subject:** RE: Controlled drug legislation and Schedule rules changes

Mōrena

I suspect we might get some media interest in this as we've already had a bit of reaction to this consult:

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

I will contact the Ministry team responsible for the legislative changes that would be implemented by this proposal to see if they can give us a contact person in case we need to do any joint messaging.

Also, I noted in the cabinet paper that the Ministry intended to communicate directly with impacted practitioners but it might be useful to understand if they have any other implementation support plans for this legislation.

Shout out if you have any questions.

Thanks

Belinda

From: Belinda Ray-Johnson

Sent: Wednesday, 9 November 2022 10:05 am

To: Sandy Bhawan <sandy.bhawan@pharmac.govt.nz>; Jannel Fisher <jannel.fisher@pharmac.govt.nz>; Cameron Webb <cameron.webb@pharmac.govt.nz>; Jane Wright <jane.wright@pharmac.govt.nz> Subject: Controlled drug legislation and Schedule rules changes

Kia ora Sandy and Jannel

@Cameron Webb @Jane Wright – FYI noting Jannel is on leave.

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 within your teams as appropriate.

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 in greater amounts 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 has 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 – soon!

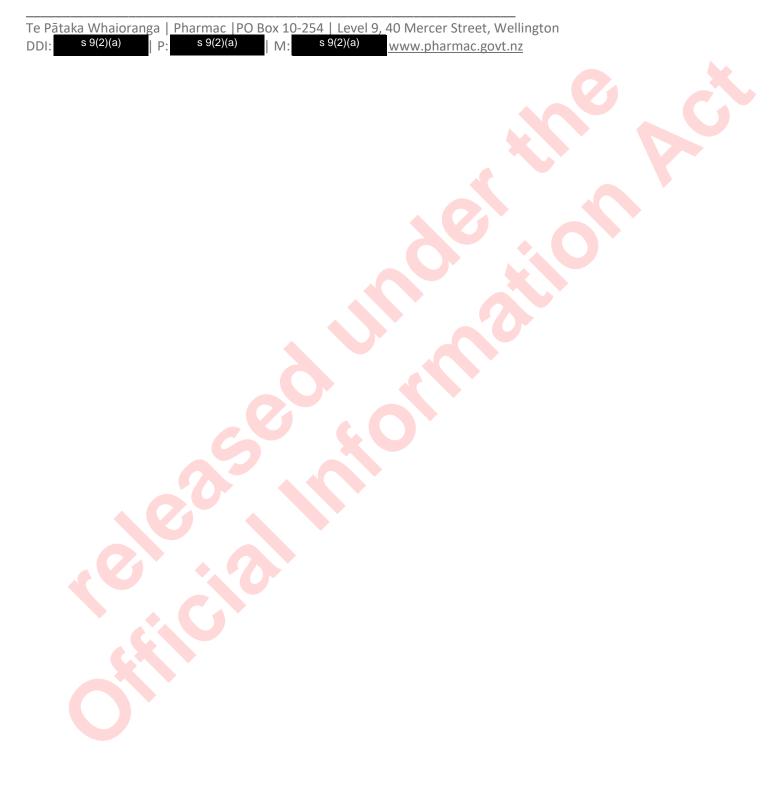
- Tight timeframes
- The Ministry are planning for this come into force on 22nd Dec
- Ideally we would want proposed subsidy rule changes to come into force as soon as possible after the legislation to avoid there being a period when there's gap between what the legislation and the subsidy rules allow
- 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



From: Sent: To: Subject: Belinda Ray-Johnson Tuesday, 29 November 2022 8:24 am Suzanne Townsend; Eddy Sommers RE: Pharmac controlled drugs consultation letter

Mōrena

I think there's a reasonable chance that we will get some media enquiries and I was wondering if I could give our Comms Team a contact person from your end in case in the event that some joint messaging might be useful?

Apologies for the daily emails 😊

Thanks

Belinda

From: Sean Dougherty <sean.dougherty@pharmac.govt.nz>
Sent: Monday, 28 November 2022 4:25 pm
To: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>
Cc: Belinda Ray-Johnson <belinda.ray-johnson@pharmac.govt.nz>; Eddy Sommers <Eddy.Sommers@health.govt.nz>
Subject: RE: Pharmac controlled drugs consultation letter

Hi Suzanne,

As was a bit expected, this consultation has made a lot more people aware of the Reg changes.

I've had a discussion with Dr Jane Thomas, the Chair of PTAC (our main clinical advisory committee). Dr Thomas is a pain medicine specialist, and was not aware of the Regs changes before today, and doesn't seem to know anyone who was aware, so has raised the question as to how extensively the medical community was consulted in the preparation of the Reg changes.

Would it be possible for someone to make contact with Dr Thomas to explain the consultation process, and discuss her concerns? She has concerns about the changes vis-à-vis inappropriate prescribing and abuse.

Her details are: s 9(2)(a)
Thanks,
Sean
Sean Dougherty Manager, Schedule Strategy and Development

Te Pātaka Whajoranga | Pharmac PO Box 10-254, Wellington 6140 | Level 9, 40 Mercer Street, Wellington 6011 DDI: s 9(2)(a) | P: 0800 660 050 | www.pharmac.govt.nz From: Suzanne Townsend <<u>Suzanne.Townsend@health.govt.nz</u>>
Sent: Monday, 28 November 2022 9:14 am
To: Belinda Ray-Johnson <<u>belinda.ray-johnson@pharmac.govt.nz</u>>; Eddy Sommers
<<u>Eddy.Sommers@health.govt.nz</u>>
Cc: Sean Dougherty <<u>sean.dougherty@pharmac.govt.nz</u>>
Subject: RE: Pharmac controlled drugs consultation letter

Thank you Belinda

From: Belinda Ray-Johnson <<u>belinda.ray-johnson@pharmac.govt.nz</u>>
Sent: Monday, 28 November 2022 9:12 am
To: Eddy Sommers <<u>Eddy.Sommers@health.govt.nz</u>>; Suzanne Townsend <<u>Suzanne.Townsend@health.govt.nz</u>>;
Cc: Sean Dougherty <<u>sean.dougherty@pharmac.govt.nz</u>>
Subject: RE: Pharmac controlled drugs consultation letter

Morning

This consultation is now live – here's the link <u>Proposal to amend Pharmaceutical Schedule Rules on prescribing and</u> <u>dispensing of Class B controlled drugs</u>

Cheers

Belinda

From: Eddy Sommers <<u>Eddy.Sommers@health.govt.nz</u>>
Sent: Friday, 25 November 2022 4:05 pm
To: Belinda Ray-Johnson <<u>belinda.ray-johnson@pharmac.govt.nz</u>>; Suzanne Townsend
<<u>Suzanne.Townsend@health.govt.nz</u>>
Cc: Sean Dougherty <<u>sean.dougherty@pharmac.govt.nz</u>>
Subject: RE: Pharmac controlled drugs consultation letter

Kia ora Belinda and Sean

Thanks for sending this through, looks great to us.

Cheers

Eddy Sommers (he/him)

Policy Analyst Health System Settings s 9(2)(a)

eddy.sommers@health.govt.nz Manatū Hauora, 133 Molesworth Street Thorndon, Wellington 6011





From: Belinda Ray-Johnson <<u>belinda.ray-johnson@pharmac.govt.nz</u>>
Sent: Friday, 25 November 2022 12:54 pm
To: Eddy Sommers <<u>Eddy.Sommers@health.govt.nz</u>>; Suzanne Townsend <<u>Suzanne.Townsend@health.govt.nz</u>>
Cc: Sean Dougherty <<u>sean.dougherty@pharmac.govt.nz</u>>
Subject: Pharmac controlled drugs consultation letter

Kia ora Suzanne and Eddy

Thanks for your time earlier.

I've attached the entire consultation letter that we intend to release on Monday please keep this version within team until then.

If there's anything in there that you'd like us to revise, please let me know by 4pm today.

Thanks

Belinda

Belinda Ray-Johnson | Schedule Development Manager

 Te Pātaka Whaioranga | Pharmac | PO Box 10-254 | Level 9, 40 Mercer Street, Wellington

 DDI:
 \$ 9(2)(a)

 P: +0800 660 050 | M:
 \$ 9(2)(a)

 www.pharmac.govt.nz

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From:Allanah AndrewsSent:Wednesday, 30 November 2022 9:37 amTo:Senior Leadership TeamCc:Sean Dougherty; Belinda Ray-JohnsonSubject: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: <u>Proposal to amend Pharmaceutical Schedule Rules on prescribing and dispensing of Class B controlled drugs -</u> <u>Pharmac | New Zealand Government</u>

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.

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The effects of the legislative changes will be to:

- enable controlled drugs to be prescribed electronically via the New Zealand Electronic Prescribing System (NZePS)
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 otherwise specified by the prescriber
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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: \$9(2)(a) | M: \$9(2)(a) | www.pharmac.govt.nz Te Pātaka Whaioranga | Pharmac |PO Box 10-254, Wellington 6140 | Level 9, 40 Mercer Street, Wellington 6011



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

From: Sent:	Peter Jane <peter.jane@health.govt.nz> Wednesday, 30 November 2022 9:10 am</peter.jane@health.govt.nz>
То:	Chris James
Cc:	Adelia Hallett-Ext; Andi Shirtcliffe; Allison Bennett; Therese Egan; Carol Morris
Subject:	RE: No Surprises - Proposal to amend Pharmaceutical Schedule Rules

Hi Chris. Is this something you have been involved in?

Peter Jane Principal Advisor System Performance and Monitoring s 9(2)(a)

<u>Peter.Jane@health.govt.nz</u> Manatū Hauora, 133 Molesworth Street

Thorndon, Wellington 6011





From: Allanah Andrews <allanah.andrews@pharmac.govt.nz> Sent: Wednesday, 30 November 2022 8:40 am To: anna.gillies@parliament.govt.nz

Cc: Adelia Hallett-Ext <Adelia.Hallett@parliament.govt.nz>; Talisa Kupenga-EXT <talisa.kupenga@parliament.govt.nz>; Peter Jane <Peter.Jane@health.govt.nz>; Andi Shirtcliffe <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,

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Ngā mihi, nā

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

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From: Sent: To: Cc: Subject: Sean Dougherty Friday, 2 December 2022 3:03 pm Suzanne Townsend; Belinda Ray-Johnson Eddy Sommers; Laurence Holding RE: Class B Drugs

11:00 on Monday looks good for us. Shall we aim for that?

Sean

From: Suzanne Townsend <Suzanne.Townsend@health.govt.nz>
Sent: Friday, 2 December 2022 2:04 pm
To: Sean Dougherty <sean.dougherty@pharmac.govt.nz>; Belinda Ray-Johnson <belinda.ray-johnson@pharmac.govt.nz>
Cc: Eddy Sommers <Eddy.Sommers@health.govt.nz>; Laurence Holding <Laurence.Holding@health.govt.nz>
Subject: RE: Class B Drugs

Eddy and I can do anytime between 10.30 and 1.

Suzanne

From: Sean Dougherty <<u>sean.dougherty@pharmac.govt.nz</u>>
Sent: Friday, 2 December 2022 2:00 pm
To: Suzanne Townsend <<u>Suzanne.Townsend@health.govt.nz</u>>; Belinda Ray-Johnson <<u>belinda.ray-johnson@pharmac.govt.nz</u>>
Cc: Eddy Sommers <<u>Eddy.Sommers@health.govt.nz</u>>; Laurence Holding <<u>Laurence.Holding@health.govt.nz</u>>
Subject: RE: Class B Drugs

Hi Suzanne,

Happy to talk. What times work for you on Monday / Tuesday?

Sean

Sean Dougherty | Manager, Schedule Strategy and Development

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

From: Suzanne Townsend <<u>Suzanne.Townsend@health.govt.nz</u>>
Sent: Friday, 2 December 2022 1:53 pm
To: Sean Dougherty <<u>sean.dougherty@pharmac.govt.nz</u>>; Belinda Ray-Johnson <<u>belinda.ray-</u>
johnson@pharmac.govt.nz>
Cc: Eddy Sommers <<u>Eddy.Sommers@health.govt.nz</u>>; Laurence Holding <<u>Laurence.Holding@health.govt.nz</u>>
Subject: Class B Drugs

Can Eddy and I have a catch up in regards to you proposed rule changes early next week. As you know there has been a lot of noise this week.

We would like to talk through the issues raised at our end.

Suzanne Townsend Manager, Regulatory Policy Strategy, Policy and Legislation | Te Pou Rautaki M \$ 9(2)(a)

E suzanne.townsend@health.govt.nz

Manatū Hauora, 133 Molesworth Street Thorndon, Wellington 6011







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From: Sent: To: Subject: Sarah Fitt Sunday, 4 December 2022 1:51 pm Di Sarfati Fwd: No Surprises - Proposal to amend Pharmaceutical Schedule Rules

FYI

Sarah Fitt **Chief Executive** PHARMAC

From: Allanah Andrews <allanah.andrews@pharmac.govt.nz>

Sent: Wednesday, November 30, 2022 09:37 s 9(2)(a)

To: Senior Leadership Team <

Cc: Sean Dougherty <sean.dougherty@pharmac.govt.nz>; Belinda Ray-Johnson <belinda.ray johnson@pharmac.govt.nz>

Subject: FW: No Surprises - Proposal to amend Pharmaceutical Schedule Rules

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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

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Ngā mihi, nā

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



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