

Misuse of Drugs Amendment Regulations 2022

Cindy Kiro, Governor-General

Order in Council

At Wellington this 21st day of November 2022

Present:

Her Excellency the Governor-General in Council

These regulations are made under section 37 of the Misuse of Drugs Act 1975 on the advice and with the consent of the Executive Council.

Contents

		Page
1	Title	2
2	Commencement	2
3	Principal regulations	2 2 2 2
4	Regulation 13 amended (Manufacture and use in manufacture)	2
5	Regulation 15 amended (Hospitals and other institutions)	2
6	Regulation 20 amended (Supply and administration of controlled drugs without prescription)	2
7	Regulation 21 amended (Restrictions on application of section 8 of Act, etc)	2
8	Regulation 25 amended (Labelling of containers)	3
9	Regulation 29 amended (General requirements in relation to prescriptions)	3
10	Regulation 30 amended (Exemption for certain prescriptions)	4
11	Regulation 31 amended (Restrictions on supply on prescription)	4
12	Regulation 31A amended (Exceptions to restrictions in regulation 31(1))	4
13	Regulation 32 amended (Verification of prescriptions)	5
14	Regulation 33 amended (Retention of prescriptions)	6

r 1	Misuse of Drugs Amendment Regulations 2022	2022/303
15	Regulation 34 amended (Emergencies)	6
16	Regulation 36 amended (Special provisions for hospitals)	6
17	Regulation 48 amended (Exemptions from Part 6)	6
18	Schedule 1A amended	6
19	Schedule 1B amended	6

Regulations

1 Title

These regulations are the Misuse of Drugs Amendment Regulations 2022.

2 Commencement

(1) These regulations come into force on 22 December 2022, with some exceptions.

Exceptions

- (2) Regulations 18(1) and 19(2) come into force on 1 July 2023 (in relation to zolpidem and zopiclone).
- (3) Regulations 18(2) and 19(3) come into force on 1 October 2023 (in relation to tramadol).

3 Principal regulations

These regulations amend the Misuse of Drugs Regulations 1977.

4 Regulation 13 amended (Manufacture and use in manufacture)

In regulation 13(4), replace "section 8(2)(b)" with "section 8(1)(b)".

5 Regulation 15 amended (Hospitals and other institutions)

In regulation 15, replace "section 8(2)" with "section 8(1)".

- Regulation 20 amended (Supply and administration of controlled drugs without prescription)
- (1) In regulation 20(1), replace "Notwithstanding anything in section 8(2)(b)" with "Despite section 8(1)(b)".
- (2) In regulation 20(1)(c), replace "paragraph (g) or paragraph (i) of section 8(2)" with "section 8(1)(g) or (i)".
- 7 Regulation 21 amended (Restrictions on application of section 8 of Act, etc)
- (1) In regulation 21(2), replace "shall give" with "may issue".
- (2) In regulation 21(3), (4), (5), (5A), (5B), and (5C), replace "give" with "issue".
- (3) After regulation 21(5C), insert:

- (5D) Despite subclauses (4), (5), and (5B), if a designated prescriber nurse, designated prescriber pharmacist, or nurse practitioner issues an electronic prescription for a Class B controlled drug using an approved system under regulation 29, the supply must not be for any quantity greater than is reasonably required for the treatment of the patient for 3 months (see regulation 31A(6B)).
- (4) In regulation 21(6),—
 - (a) replace "Paragraph (c) of section 8(2) of the Act shall" with "Section 8(1)(c) of the Act does":
 - (b) replace "given" with "issued":
 - (c) replace "giving of the material" with "issuing of the".

8 Regulation 25 amended (Labelling of containers)

In regulation 25(3A), replace "signed" with "issued".

9 Regulation 29 amended (General requirements in relation to prescriptions)

- (1) Replace regulation 29(1)(a) and (b) with:
 - (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 that system.
- (2) In regulation 29(2),—
 - (a) replace "given" with "issued":
 - (b) after "any paper", insert "or electronic".
- (3) Replace regulation 29(3) with:
- (3) A prescription for the supply of a Class C controlled drug, other than a specified Class C controlled drug, must be—
 - (a) issued in a paper form; or
 - (b) issued in an electronic form that is completed by the controlled drug prescriber using an approved system and is transmitted through that system.
- (4) Revoke regulation 29(4)(a) and (b).
- (5) In regulation 29(4)(c), replace "signed" with "issued".
- (6) In regulation 29(4)(d), delete ", or be stamped with,".
- (7) In regulation 29(4)(g), (h), and (i),—
 - (a) replace "bear" with "include":
 - (b) replace "given" with "issued".
- (8) Replace regulation 29(4)(n) with:

- (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,—
 - (i) in a paper form, by being underlined, with the initials of the controlled drug prescriber set out in the margin opposite; or
 - (ii) in an electronic form, as required by the approved system.
- (9) After regulation 29(4), insert:
- (4A) In addition, every prescription for a controlled drug in paper form must—
 - (a) be legible and indelible; and
 - (b) be signed physically by the controlled drug prescriber in their own handwriting.
- (4B) Any reference in these regulations that relates to including or recording anything in or on a prescription means, for an electronic prescription, including or recording it in the electronic records for the electronic prescription.
- 10 Regulation 30 amended (Exemption for certain prescriptions) In regulation 30(2)(a), replace "(5C)" with "(5D)".

11 Regulation 31 amended (Restrictions on supply on prescription)

- (1) In regulation 31(3), delete "written".
- (2) In regulation 31(4), replace "written confirmation of that prescription, there must be written or stamped on the face of the prescription, above the signature of the controlled drug prescriber, in such manner and place that no part of the prescription is obliterated," with "confirmation of that prescription, there must be recorded in or on the prescription".
- (3) In regulation 31(5), replace "written or stamped on the face or back of the prescription, in such manner and place that no part of the prescription is obliterated," with "recorded in or on the prescription".
- (4) After regulation 31(5), insert:
- (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 a manner and place that does not obscure any details of the prescription:
 - (b) under subclause (5), it must be written or stamped on the face or back of the prescription, in a manner and place that does not obscure any details of the prescription.

12 Regulation 31A amended (Exceptions to restrictions in regulation 31(1))

(1) Before regulation 31A(1), insert:

Medical or nurse practitioners: prescriptions for Class A or Class B controlled drugs

- (2) In regulation 31A(1), (3), and (5),—
 - (a) replace "signs" with "issues":
 - (b) replace "direct on" with "direct in".
- (3) After regulation 31A(2), insert:

Medical or nurse practitioners: prescriptions for Class C controlled drugs

(4) After regulation 31A(4), insert:

Midwives: prescriptions for controlled drugs in Schedule 1C

(5) After regulation 31A(6), insert:

Certain controlled drug prescribers: electronic prescriptions for Class B controlled drugs

- (6A) Despite subclauses (1), (2), (5), and (6), if a controlled drug prescriber (other than a dentist or veterinarian) issues an electronic prescription for a Class B controlled drug using an approved system under regulation 29, they may direct in the prescription that the drug be supplied on 3 or more occasions, which must be at monthly or shorter intervals.
- (6B) The controlled drug covered by the direction must not be supplied in a total quantity greater than is sufficient for 3 months of use, having regard to the amount and frequency of the dose or the direction.

Certain controlled drug prescribers: prescriptions to protect patients or limit quantities in possession

- (6) In regulation 31A(7),—
 - (a) replace "signs" with "issues":
 - (b) replace "directs on" with "directs in":
 - (c) replace "1 month" with "3 months".
- (7) After regulation 31A(7), insert:

Supply by authorised persons to restricted persons

13 Regulation 32 amended (Verification of prescriptions)

- (1) In regulation 32(1), replace "prescription" with "paper prescription".
- (2) In regulation 32(2)(a) and (b), replace "prescription" with "paper or electronic prescription".
- (3) In regulation 32(2)(a), replace "signed" with "signed or issued".
- (4) In regulation 32(3), replace "signing a prescription" with "signing a paper prescription".
- (5) In regulation 32(4), replace "grounds" with "grounds,".

- (6) In regulation 32(4)(a), before "that any signature", insert "for a paper prescription,".
- (7) In regulation 32(4)(b), before "that the prescription", insert "for a paper or electronic prescription,".

14 Regulation 33 amended (Retention of prescriptions)

- (1) In the heading to regulation 33, replace "prescriptions" with "paper prescriptions".
- (2) In regulation 33(1), replace "written prescription" with "paper prescription".

15 Regulation 34 amended (Emergencies)

- (1) In regulation 34(3)(a), replace "prepare a prescription" with "issue a prescription in paper or electronic form".
- (2) In regulation 34(3)(b), replace "endorse the prescription with" with "include in the prescription".
- (3) In regulation 34(4), replace "deliver the prescription" with "deliver the paper prescription, or transmit the electronic prescription,".
- (4) In regulation 34(5), replace "delivery" with "delivery or transmission".

16 Regulation 36 amended (Special provisions for hospitals)

In regulation 36(1),—

- (a) replace "writing" with "issuing":
- (b) replace "paragraphs (a), (b), (k), and (n) of that subclause" with "regulation 29(4)(k) and (n) and (4A)(a) and (b)".

17 Regulation 48 amended (Exemptions from Part 6)

In regulation 48(1), replace "paragraphs (a), (b), and (f) of subsection (2) of section 8" with "section 8(1)(a), (b), and (f)".

18 Schedule 1A amended

- (1) In Schedule 1A, insert in its appropriate alphabetical order: Zopiclone
- (2) In Schedule 1A, insert in its appropriate alphabetical order: Tramadol

19 Schedule 1B amended

- (1) In the Schedule 1B heading, replace "pharmacist prescribers" with "prescriber pharmacists".
- (2) In Schedule 1B, insert in their appropriate numerical order:
 - 26 Zolpidem
 - 27 Zopiclone

(3) In Schedule 1B, insert in its appropriate numerical order:

24A Tramadol

Rachel Hayward, Clerk of the Executive Council.

Explanatory note

This note is not part of the regulations, but is intended to indicate their general effect. These regulations amend the Misuse of Drugs Regulations 1977 (the **principal regulations**) on 22 December 2022, except that they—

- add zolpidem and zopiclone to certain schedules for controlled drugs on 1 July 2023; and
- add tramadol to certain schedules for controlled drugs on 1 October 2023.

The other amendments—

- allow prescriptions to be issued electronically, not just on paper; and
- allow Class B controlled drugs to be prescribed for supply for up to 3 months
 of use (longer than usual) if prescribed electronically using an approved system; and
- change the maximum period during which a prescription may require a controlled drug to be supplied at intervals, in order to protect patients or limit quantities in possession, from 1 month to 3 months; and
- correct cross-references to provisions.

Issued under the authority of the Legislation Act 2019. Date of notification in *Gazette*: 24 November 2022.

These regulations are administered by the Ministry of Health.

Wellington, New Zealand: