



New South Wales

Poisons and Therapeutic Goods Amendment (Cannabis and Unregistered Drugs of Addiction) Regulation 2018

under the

Poisons and Therapeutic Goods Act 1966

His Excellency the Governor, with the advice of the Executive Council, has made the following Regulation under the *Poisons and Therapeutic Goods Act 1966*.

BRAD HAZZARD, MP
Minister for Health

Explanatory note

The objects of this Regulation are as follows:

- (a) to regulate cannabis and tetrahydrocannabinols for therapeutic use as type A drugs of addiction,
- (b) to regulate unregistered drugs of addiction (defined as any therapeutic good that consists of a Schedule 8 substance and that is not a registered good or a substance or good that has been excluded from the definition by an order made by the Secretary) as type A drugs of addiction, subject to certain additional restrictions,
- (c) to set out storage requirements for pharmacies in relation to drugs of addiction that require refrigeration,
- (d) to omit existing provisions about designated non-ARTG products, which are instead to be regulated as unregistered drugs of addiction.

This Regulation is made under the *Poisons and Therapeutic Goods Act 1966*, including sections 24, 28 and 45C (the general regulation-making power).

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1 Name of Regulation

This Regulation is the *Poisons and Therapeutic Goods Amendment (Cannabis and Unregistered Drugs of Addiction) Regulation 2018*.

2 Commencement

This Regulation commences on the day on which it is published on the NSW legislation website.

Schedule 1 Amendment of Poisons and Therapeutic Goods Regulation 2008

[1] Clause 3 Definitions

Insert in alphabetical order in clause 3 (1):

type A drug of addiction means a drug of addiction prescribed by clause 122.

unregistered drug of addiction means any therapeutic good that consists of a Schedule 8 substance and that is not:

- (a) a registered good, or
- (b) a substance or good that has been excluded from this definition by an order made by the Secretary and published in the Gazette.

[2] Clause 76 Storage in pharmacies

Insert after clause 76 (3):

- (3A) Despite subclause (1), a drug of addiction that requires refrigeration may be kept in a refrigerator rather than a safe if all of the following requirements are met:
 - (a) the refrigerator must be in a *room* (which includes a part of a room or an enclosure) to which the public does not have access,
 - (b) the refrigerator, or any cupboard or receptacle in which the refrigerator is kept, must be securely attached to a part of the premises,
 - (c) the refrigerator, or the room, cupboard or receptacle in which the refrigerator is kept, must be kept securely locked when not in immediate use,
 - (d) a device (including a key) that is used to securely lock anything under this subclause must:
 - (i) be kept on the person of a pharmacist who is at the premises, or
 - (ii) be securely locked in a safe that can be unlocked only by a pharmacist,
 - (e) a code or combination that is used to securely lock anything under this subclause must not be disclosed to any person who is not a pharmacist,
 - (f) the refrigerator must not be used to store any other item that is not a substance listed in Schedule 2, 3, 4 or 8 of the Poisons List or is not a therapeutic good.

[3] Clause 78 Prescriptions may be issued for certain purposes only

Insert “(including in a clinical trial)” after “treatment” in clause 78 (1).

[4] Clause 80 Form of prescription

Insert after clause 80 (1) (h):

- (i) if the drug of addiction is a type A drug of addiction and the person holds an authority to issue the prescription under section 29 of the Act or Part 8 of this Regulation, the reference number of the authority.

[5] Clause 81 Emergency prescriptions may be given by telephone or otherwise

Insert “, other than an unregistered drug of addiction,” after “drug of addiction” in clause 81 (1).

[6] Clause 83 Exceptions to section 28—prescriptions generally

Insert “, other than an unregistered drug of addiction,” after “drug of addiction” in clause 83 (1).

[7] Clause 83 (4) and (5)

Insert after clause 83 (3):

- (4) A medical practitioner is authorised to issue a prescription for a drug of addiction for a person without an authority under section 29 of the Act if:
 - (a) the prescription is issued for an in-patient in a public hospital or private health facility who was, immediately before the person’s admission to that hospital or facility, being treated with that drug of addiction, which was prescribed or supplied in accordance with the Act or this Regulation, and
 - (b) the prescription is issued for the purpose of continuing the person’s treatment with that drug of addiction following the person’s admission.
- (5) A medical practitioner is authorised to issue a prescription for a drug of addiction for a person without an authority under section 29 of the Act if:
 - (a) the medical practitioner holds an authority under Division 4 of Part 8 of this Regulation that authorises the practitioner to issue a prescription for that drug of addiction for the purposes of a clinical trial, and
 - (b) the prescription is issued in accordance with the authority.

[8] Clause 84 Exceptions to section 28—prescriptions for type A drugs of addiction

Omit clause 84 (1).

[9] Clause 84 (3)

Omit “a substance to which this clause applies”.

Insert instead “a type A drug of addiction”.

[10] Clause 90

Omit the clause. Insert instead:

90 Supply by pharmacists of type A drugs of addiction

A pharmacist must not supply a type A drug of addiction on prescription unless:

- (a) the reference number of the authority to issue the prescription (whether given under section 29 of the Act or Part 8 of this Regulation) is shown on the prescription, or
- (b) the medical practitioner who issued the prescription was authorised to do so under clause 83 (1)–(4).

Maximum penalty: 20 penalty units.

[11] Clause 94 Exceptions to section 28—supply

Insert “, other than an unregistered drug of addiction,” after “drug of addiction” in clause 94 (1).

[12] Clause 94 (4) and (5)

Insert after clause 94 (3):

- (4) A medical practitioner is authorised to supply a drug of addiction for a person without an authority under section 29 of the Act if:
 - (a) the person is an in-patient in a public hospital or private health facility who was, immediately before the person's admission to that hospital or facility, being treated with that drug of addiction, which was prescribed or supplied in accordance with the Act or this Regulation, and
 - (b) the drug of addiction is supplied for the purpose of continuing the person's treatment with that drug of addiction following the person's admission.
- (5) A medical practitioner is authorised to supply a drug of addiction to a person without an authority under section 29 of the Act if:
 - (a) the medical practitioner holds an authority under Division 4 of Part 8 of this Regulation that authorises the practitioner to supply that drug of addiction for the purposes of a clinical trial, and
 - (b) the supply of the drug of addiction is in accordance with the authority.

[13] Clause 96 Emergency supply by pharmacists

Insert “, other than an unregistered drug of addiction,” after “drug of addiction” in clause 96 (1).

[14] Clause 97 Supply by pharmacists for emergency purposes

Insert “, other than an unregistered drug of addiction,” after “drug of addiction”.

[15] Clause 98 Supply of type A drugs of addiction

Omit clause 98 (1).

[16] Clause 98 (3)

Omit “any substance to which this clause applies”.

Insert instead “a type A drug of addiction”.

[17] Clause 121 Self-administration by medical practitioners and dentists

Insert after clause 121 (3):

- (4) This clause does not authorise a medical practitioner or dentist to self-administer an unregistered drug of addiction.

[18] Clause 122 Prescribed type A drugs of addiction

Insert after clause 122 (a):

- (a1) cannabis (when included in Schedule 8 of the Poisons List),

[19] Clause 122 (g) and (h)

Insert after clause 122 (f):

- (g) tetrahydrocannabinols (when included in Schedule 8 of the Poisons List),
- (h) any unregistered drug of addiction.

[20] Clause 128A Exclusion of designated non-ARTG product

Omit the clause.

[21] Part 4A Designated non-ARTG products

Omit the Part.

[22] Clause 182

Insert after clause 181:

182 Licences and authorities for substance reclassified as type A drug of addiction

- (1) The reclassification of a substance from a designated non-ARTG product to a type A drug of addiction by the amending regulation does not affect any licence or authority under Part 8 of this Regulation that relates to the substance and that was in force immediately before that reclassification.
- (2) Despite subclause (1), an authority referred to in that subsection that authorises the prescription or supply of a substance by a medical practitioner to treat a particular person, is taken, on the commencement of the amending regulation to be an authority of the Secretary issued under section 29 of the Act.
- (3) In this clause:
amending regulation means the *Poisons and Therapeutic Goods Amendment (Cannabis and Unregistered Drugs of Addiction) Regulation 2018*.