New South Wales

Poisons and Therapeutic Goods Amendment (Cannabis Medicines) Regulation 2019

under the

Poisons and Therapeutic Goods Act 1966

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

BRADLEY HAZZARD, MP
Minister for Health and Medical Research

Explanatory note

The objects of this Regulation are as follows—

(a) to regulate cannabis and tetrahydrocannabinols (when included in Schedule 8 of the Poisons List), nabiximols and unregistered drugs of addiction that are not extemporaneously compounded for a particular person for therapeutic application to that person as type C drugs of addiction,

(b) to require medical practitioners to obtain an authority under Part 8 of the *Poisons and Therapeutic Goods Regulation 2008* prior to supplying or prescribing certain specified unregistered drugs of addiction for the purposes of a clinical trial,

(c) to make it clear that nurses and midwives, dentists and veterinarians are not permitted to supply or prescribe those specified unregistered drugs of addiction for the purposes of a clinical trial.

This Regulation is made under the *Poisons and Therapeutic Goods Act 1966*, including sections 24 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 Medicines) Regulation 2019*.

2 Commencement

This Regulation commences on 30 September 2019 and is required to be 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 C drug of addiction has the meaning given by section 28(6) of the Act.

type C unregistered drug of addiction means an unregistered drug of addiction other than an unregistered drug of addiction that is a type A drug of addiction.

[2] Clauses 84A and 84B

Insert after clause 84—

84A Authority required for prescriptions for clinical trials

A medical practitioner must not issue a prescription for a type C unregistered drug of addiction unless—

(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 type C unregistered drug of addiction for the purposes of a clinical trial, and

(b) the prescription is issued in accordance with the authority.

Maximum penalty—20 penalty units

84B Restriction on prescriptions for clinical trials

An authorised practitioner (other than a medical practitioner) must not issue a prescription for a type C unregistered drug of addiction for the purposes of a clinical trial.

Maximum penalty—20 penalty units

[3] Clauses 94AA and 94AB

Insert after clause 94—

94AA Authority required for supply for clinical trials

A medical practitioner must not supply a type C unregistered drug of addiction unless—

(a) the medical practitioner holds an authority under Division 4 of Part 8 of this Regulation that authorises the practitioner to supply that type C unregistered drug of addiction for the purposes of a clinical trial, and

(b) the supply of the unregistered drug is in accordance with the authority.

Maximum penalty—20 penalty units

94AB Restriction on supply for clinical trials

An authorised practitioner (other than a medical practitioner) must not supply a type C unregistered drug of addiction for the purposes of a clinical trial.

Maximum penalty—20 penalty units

[4] Clause 101 Possession and supply of drugs of addiction

Omit clause 101(5). Insert instead—

(5) This clause does not authorise a nurse practitioner, midwife practitioner, dentist or veterinary practitioner to have possession of, or to supply, a type A drug of addiction (other than methylphenidate in solid dosage form, in the case of a veterinary practitioner).

[5] Clause 122 Prescribed type A drugs of addiction

Omit clause 122(a1), (d1) and (g).

[6] Clause 122(h)

Insert "that is extemporaneously compounded for a particular person for therapeutic application to that person" after "addiction".