



New South Wales

Poisons and Therapeutic Goods Amendment (Designated Non-ARTG Products) Regulation 2016

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*.

JILLIAN SKINNER, MP
Minister for Health

Explanatory note

The objects of this Regulation are:

- (a) to regulate the manufacture, supply and use of medicinal cannabis products and other therapeutic goods that consist of Schedule 8 substances that are not on the Australian Register of Therapeutic Goods as registered goods, and
- (b) to regulate the supply and use of the veterinary product, etorphine, and
- (c) to prohibit the manufacture, supply and use of Schedule 10 substances without an authority, and
- (d) to allow the Secretary to grant exemptions from storage requirements on the grounds that compliance is not reasonably practicable because the particular goods concerned require refrigeration.

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

Poisons and Therapeutic Goods Amendment (Designated Non-ARTG Products) Regulation 2016

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Poisons and Therapeutic Goods Act 1966

1 Name of Regulation

This Regulation is the *Poisons and Therapeutic Goods Amendment (Designated Non-ARTG Products) Regulation 2016*.

2 Commencement

This Regulation commences on 1 August 2016 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

Omit the definition of *hallucinogen* from clause 3 (1).

[2] Clause 3 (2) (c)

Omit “or 8”. Insert instead “, 8 or 9”.

[3] Clause 20 Certain Schedule 7 substances to be supplied and used only under an authority

Omit “any Schedule 7 substance that is listed in Appendix C of the current Poisons Standard” from clause 20 (9).

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

Omit clause 101 (4).

[5] Clause 102 Possession and manufacture of drugs of addiction by retail pharmacists

Omit clause 102 (2) (but not the penalty provision at the end of the clause).

[6] Clause 104 Possession of drugs of addiction by masters of ships

Omit clause 104 (5) (but not the penalty provision at the end of the clause).

[7] Clause 105 Possession of hallucinogens

Omit the clause.

[8] Clause 128A

Insert after clause 128:

128A Exclusion of designated non-ARTG product

- (1) Subject to clause 128K, this Part does not apply to a designated non-ARTG product.
- (2) For the purposes of section 28 (5) of the Act, a medical practitioner is authorised to prescribe or supply a designated non-ARTG product that is a drug of addiction for the treatment of a person if the practitioner holds an authority as referred to in clause 128G.
- (3) In this clause:
designated non-ARTG product has the same meaning as in Part 4A.

[9] Parts 4A, 4B and 4C

Insert after Part 4:

Part 4A Designated non-ARTG products

128B Definitions

- (1) In this Part:
designated non-ARTG product means:
 - (a) a medicinal cannabis product, or
 - (b) other therapeutic goods that:

- (i) consist of a Schedule 8 substance, and
- (ii) are not registered goods, and
- (iii) have not been excluded from this paragraph under subclause (3).

Note. Registered goods are therapeutic goods included in the part of the Australian Register of Therapeutic Goods for goods known as registered goods.

manufacture includes compound.

medicinal cannabis product—see clause 128C.

prescribe and **issue a prescription** includes make an entry on a patient's medication chart for treatment of the patient.

- (2) A reference in this Part to a licence or authority under Part 8, or under the *Drug Misuse and Trafficking Act 1985*, includes a reference to a licence or authority issued before the commencement of this Part and, in the case of an authority under Part 8, to an authority under section 29 of the Act.
- (3) The Secretary may, by order published in the Gazette, exclude a substance from paragraph (b) of the definition of **designated non-ARTG product**.

128C Meaning of medicinal cannabis products

- (1) Subject to subclause (2), in this Part, **medicinal cannabis products** are therapeutic goods that:
 - (a) comprise or contain:
 - (i) cannabis, or
 - (ii) tetrahydrocannabinols extracted from cannabis or derived from an extract of cannabis, or
 - (iii) any other extract, or derivative of an extract, of cannabis, and
 - (b) are not registered goods.

Note. Medicinal cannabis products are prohibited goods under the *Customs Act 1901* of the Commonwealth and may only be imported in accordance with regulations made under that Act. Cannabis plants may only be cultivated, and medicinal cannabis products may only be manufactured, under a licence under the *Narcotic Drugs Act 1967* of the Commonwealth.

- (2) The following are not medicinal cannabis products:
 - (a) a Schedule 4 substance,
 - (b) a Schedule 8 substance comprising Nabiximols (as defined in the Poisons List),
 - (c) hemp seed oil containing 50 mg/kg or less of tetrahydrocannabinols extracted from cannabis or derived from an extract of cannabis, when labelled with a warning statement “Not for internal use” or “Not to be taken”,
 - (d) other products for purposes other than internal human use containing 50 mg/kg or less of tetrahydrocannabinols extracted from cannabis or derived from an extract of cannabis.
- (3) In this clause:
cannabis means any part of a plant of the genus *Cannabis*, including its seeds.

128D Manufacture of designated non-ARTG product

- (1) A person must not manufacture a designated non-ARTG product unless the person holds a licence or authority under Part 8, or under the *Drug Misuse and Trafficking Act 1985*, authorising the manufacture of the product.
Maximum penalty: 20 penalty units.
- (2) This clause does not apply to a medical practitioner or pharmacist manufacturing a designated non-ARTG product for the treatment of a person.

128E Supply of medicinal cannabis product

A person must not supply a medicinal cannabis product to another person unless the product has been lawfully imported into or manufactured in Australia and:

- (a) the person to whom the product is supplied is a medical practitioner and the product is supplied for the treatment of patients of the medical practitioner (including patients in a clinical trial), or
- (b) the person supplying the product is a medical practitioner and the product is supplied for the treatment of a patient of the practitioner (including a patient in a clinical trial), or
- (c) the person to whom the product is supplied is a pharmacist and the product is supplied for the purposes of the pharmacist supplying the product on the prescription of a medical practitioner, or
- (d) the person supplying the product is a pharmacist and the product is supplied on the prescription of a medical practitioner, or
- (e) the product is supplied for the purposes of a clinical trial and the person responsible for the conduct of the trial holds a licence or authority under Part 8, or under the *Drug Misuse and Trafficking Act 1985*, authorising the use of the product in the trial, or
- (f) the product is supplied for the treatment of a particular patient and the supply is authorised by a licence or authority under Part 8.

Maximum penalty: 20 penalty units.

128F Prescribing designated non-ARTG product

A person must not issue a prescription for a designated non-ARTG product unless the person is a medical practitioner.

Maximum penalty: 20 penalty units.

128G Medical practitioners

- (1) A medical practitioner must not prescribe, supply or manufacture a designated non-ARTG product for the treatment of a person unless:
 - (a) the medical practitioner holds an authority under Part 8 authorising the practitioner to treat the particular person with the product, or
 - (b) the medical practitioner holds an authority under Part 8, or under the *Drug Misuse and Trafficking Act 1985*, authorising the practitioner to treat any person participating in a clinical trial identified in the authority with the product and the person is participating in that clinical trial.

Maximum penalty: 20 penalty units.

- (2) The Secretary may refer an application for an authority under Part 8 authorising a medical practitioner to treat a person with a designated non-ARTG product to the Medical Committee and, if an application is referred, the Secretary must consider any recommendations of the Committee.

- (3) A medical practitioner must ensure that a prescription for a designated non-ARTG product:
- (a) specifies the number of the practitioner's authority, and
 - (b) if the prescription is issued for the purposes of a clinical trial—identifies the clinical trial, and
 - (c) if the product is a medicinal cannabis product (whether or not it is prescribed for the purposes of a clinical trial)—identifies a particular place at which the product is to be supplied for the person, being a place approved for that purpose by the Secretary.

Maximum penalty: 10 penalty units.

Note. These requirements are in addition to those that apply to a prescription for a designated non-ARTG product under clause 128K.

128H Pharmacists

A pharmacist must not supply or manufacture a designated non-ARTG product for the treatment of a person unless:

- (a) the product is supplied, or manufactured and supplied, for the person on the prescription of a medical practitioner who holds an authority under Part 8, or under the *Drug Misuse and Trafficking Act 1985*, authorising the practitioner to treat a person with the product, and
- (b) the prescription complies with the requirements of clause 128G (3), and
- (c) in the case of the supply of a medicinal cannabis product—the product is supplied at the place identified in the prescription.

Maximum penalty: 20 penalty units.

128I Clinical trials

It is a condition of a licence or authority under Part 8 authorising the use of a designated non-ARTG product in a clinical trial that the holder of the licence or authority must ensure that:

- (a) the product is not supplied for the treatment of a person in the clinical trial unless:
 - (i) the product is supplied for the person on the prescription of a medical practitioner who holds an authority under Part 8, or under the *Drug Misuse and Trafficking Act 1985*, authorising the practitioner to treat the person with the product, and
 - (ii) in the case of a medicinal cannabis product—the product is supplied at the place identified in the prescription, and
- (b) a record is made in the records of the clinical trial of the number of the authority of any medical practitioner who prescribes the product for the treatment of a person in the clinical trial.

128J Misleading labelling of designated non-ARTG product

A dealer must not supply any substance in a container that has a label that states or implies that the substance is a designated non-ARTG product, or a designated non-ARTG product of a particular class, unless the substance is a designated non-ARTG product or a designated non-ARTG product of the particular class (as the case requires).

Maximum penalty: 10 penalty units.

128K Application of certain provisions to designated non-ARTG product

- (1) The following provisions apply, subject to the modifications set out in subclause (2), to a designated non-ARTG product as if it were a drug of addiction or as a drug of addiction (as the case requires):
 - (a) clauses 69, 71 and 72 apply to the packaging and labelling of a designated non-ARTG product,
 - (b) Division 2 of Part 4 applies to the storage of a designated non-ARTG product,
 - (c) clauses 80 and 82 apply to a prescription of a medical practitioner for a designated non-ARTG product for the treatment of a person,
 - (d) clauses 85–89 and 99 apply to the supply of a designated non-ARTG product,
 - (e) clauses 107 and 108 apply to the delivery of a designated non-ARTG product,
 - (f) clauses 110–113 and 115–119 apply to records of the supply of a designated non-ARTG product,
 - (g) clause 120 applies to the administration of a designated non-ARTG product,
 - (h) clause 124 applies to the loss or theft of a designated non-ARTG product,
 - (i) clauses 125–127 apply to the destruction of a designated non-ARTG product.
- (2) The provisions apply as if:
 - (a) a reference to a drug of addiction were a reference to a designated non-ARTG product, and
 - (b) the reference to “SCHEDULE EIGHT” in clause 108 (2) (c) (ii) were a reference to “PRODUCT CONTAINS SCHEDULE 8 SUBSTANCE OR MEDICINAL CANNABIS PRODUCT”, and
 - (c) a reference to an authorised practitioner were a reference to a medical practitioner who holds an authority under Part 8, or under the *Drug Misuse and Trafficking Act 1985*, authorising the practitioner to treat a person with a designated non-ARTG product.

128L Additional authorisations

- (1) A person for whom a designated non-ARTG product has been prescribed is authorised to possess the product for the sole purpose of self-administering the product in accordance with the prescription.
- (2) A person who has the care of, or is assisting in the care of, a person for whom a designated non-ARTG product has been prescribed is authorised to possess or supply the product for the sole purpose of administering, or assisting in the self-administration of, the product to the person in accordance with the prescription.
- (3) If the person responsible for the conduct of a clinical trial of a designated non-ARTG product is a medical practitioner or a person who holds a licence or authority under Part 8 authorising the use of the product in the trial, a person involved in the conduct of the trial is authorised to possess, supply, administer, or assist in self-administration of, the product for the sole purpose of the clinical trial.

Part 4B Etorphine

128M Obtaining etorphine

- (1) A person must not obtain etorphine unless the person is authorised to do so by a licence or authority under Part 8.
Maximum penalty: 20 penalty units.
- (2) A reference in this clause to a licence or authority under Part 8 includes a reference to a licence or authority issued before the commencement of this Part for the purposes of clause 105 as then in force.

128N Prescribing and supplying etorphine

- (1) A person must not prescribe or supply etorphine unless it is for the treatment of an animal.
Maximum penalty: 20 penalty units.
- (2) A veterinary practitioner must not prescribe or supply etorphine for the treatment of an animal unless the veterinary practitioner holds an authority under Part 8 authorising the practitioner to treat animals with the product.
Maximum penalty: 20 penalty units.
- (3) A reference in this clause to an authority under Part 8 includes a reference to an authority issued before the commencement of this Part.

128O Regulation applies as if etorphine were drug of addiction

This Regulation applies to etorphine as if it were a drug of addiction.

Part 4C Schedule 10 substances

128P Schedule 10 substances

- (1) A person must not manufacture, supply or use a Schedule 10 substance unless the person is authorised to do so by an authority under Part 8.
Maximum penalty: 20 penalty units or imprisonment for 6 months, or both.
- (2) In this clause:
 - (a) **Schedule 10 substance** means a substance specified in Schedule 10 of the current Poisons Standard, and
 - (b) for the purposes of determining whether a substance is so specified, the definitions, other interpretation provisions and Appendices of the current Poisons Standard apply.

[10] Clause 175A

Insert after clause 175:

175A Exemption from storage requirements for goods requiring refrigeration

- (1) The Secretary may grant an exemption (which may be conditional) from a requirement of this Regulation relating to the storage of goods on the grounds that compliance with the requirement is not reasonably practicable because the goods require refrigeration.
- (2) The exemption may be granted:
 - (a) to a person by written instrument on the application of the person, or

- (b) for a class of goods or class of persons, by order published in the Gazette.