



New South Wales

Poisons Amendment (Therapeutic Goods) Regulation 1996

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*.

Andrew Refshauge

Deputy Premier and Minister for Health

Explanatory note

The object of this Regulation is to amend the *Poisons Regulation 1994* as a consequence of the amendment of the *Poisons Act 1966* by the *Poisons Amendment (Therapeutic Goods) Act 1996*. The amendments provide for the following matters:

- (a) the regulation of various matters relating to therapeutic goods that are not dealt with by the *Therapeutic Goods Act 1989* of the Commonwealth (Schedule 1),
- (b) the revision of the penalties that may be imposed for contraventions of the Regulation (Schedule 2),
- (c) other matters of a minor, consequential or ancillary nature (such as the renaming of the Regulation as the *Poisons and Therapeutic Goods Regulation 1994*) arising out of the amendments to the *Poisons Act 1966*.

This Regulation is made under the *Poisons and Therapeutic Goods Act 1966*, including section 45C (the general regulation making power) and various other sections referred to in the Regulation.

Poisons Amendment (Therapeutic Goods) Regulation 1996

1 Name of Regulation

This Regulation is the *Poisons Amendment (Therapeutic Goods) Regulation 1996*.

2 Commencement

This Regulation commences on 1 September 1996.

3 Amendments: general

The *Poisons Regulation 1994* is amended as set out in Schedule 1.

4 Amendments: penalties

The *Poisons Regulation 1994* is further amended as set out in Schedule 2.

5 Explanatory note

The explanatory note does not form part of this Regulation.

Schedule 1 Amendments: general

(Clause 3)

[1] Clause 1

Omit the clause. Insert instead:

1 Name of Regulation

This Regulation is the *Poisons and Therapeutic Goods Regulation 1994*.

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

Omit clause 20 (4) (b). Insert instead:

(b) the supply by wholesale of any substance, or

[3] Clause 50 Supply in original containers: sec 10

Omit “pursuant to an authority under section 19 (1) (b) of the Act”. Insert instead “in accordance with section 10 (4) (c) of the Act”.

[4] Clause 55 Authority required to supply certain restricted substances

Omit clause 55 (3) (a). Insert instead:

(a) by wholesale, or

[5] Clause 62 Prescribed restricted substances: secs. 9, 10, 11, 16, 18, 18A

Insert after clause 62 (1):

(1A) The substances specified in Appendix D are also restricted substances for the purposes of sections 9, 10, 11 and 18 of the Act, as referred to in paragraph (a) of the matter specified at the end of sections 9 (1), 10 (3), 11(1) and 18 of the Act with respect to penalties.

[6] Clause 62 (2)

Omit “18A (2)” from clause 62 (2). Insert instead “1 8A (1)”.

[7] Clauses 63, 103, 114 123

Omit “appointed under the *Therapeutic Goods and Cosmetics Act 1872*” from clauses 63 (d), 103 (2) (b), 114 (1) (h) and 123 (2) (b) wherever occurring.

[8] Part 5, heading

Omit “WHOLESALE DEALING”.

Insert instead “SUPPLY BY WHOLESALE”.

[9] Clause 125

Omit the clause. Insert instead:

125 Authorised possession for supply by wholesale: sec 4

Each circumstance and activity referred to in Appendix E is prescribed for the purposes of paragraph (d) of the definition of *supply by wholesale* in section 4 (1) of the Act, but only:

- (a) in respect of the persons and substances referred to in that Appendix in relation to that circumstance or activity, and
- (b) where that Appendix indicates a maximum concentration or strength, in respect of substances in a concentration or strength not exceeding that maximum.

[10] Clause 126 Restrictions on supply by wholesale

Omit clause 126 (1).

[11] Clause 126 (2)

Omit “, in the course of wholesale dealing, supply”.
Insert instead “supply by wholesale”.

[12] Clause 127 Records of supply by wholesale

Omit “supplies any poison, restricted substance or drug of addiction in the ordinary course of wholesale dealing” from clause 127 (1).
Insert instead “supplies by wholesale any regulated goods”.

[13] Clause 128 Supply of clinical samples

Omit “, or wholesale dealing in,” from clause 128 (1) (a).
Insert instead “, or supply by wholesale of”.

[14] Clause 128 (1)

Omit “dealer” from clause 128 (1) (b).
Insert instead “supplier”.

[15] Clause 128A

Insert after clause 128:

128A Storage of therapeutic goods for human use

(1) A person who is engaged in the supply by wholesale of therapeutic goods for human use must ensure that the recommendations and requirements of the Wholesaling Code of Practice are complied with.

Maximum penalty: 20 penalty units.

(2) In this clause:

Wholesaling Code of Practice means the Code of Practice entitled *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use*, published by the Commonwealth Government, as in force from time to time.

[16] Clause 130 Supply of drug precursors

Insert “or 10” after “section9” in clause 130 (1) (a).

[17] Clause 130 (1) (b)

Omit the paragraph.

[18] Clause 130 (1) (c)

Omit “wholesale dealing”,. Insert instead “supply by wholesale”.

[19] Parts 6A, 6B

Insert after Part 6:

Part 6A Preparation, handling, supplying and labelling of therapeutic goods

Division 1 Preparation and handling of exposed substances

136A Application of Division

This Division applies to all therapeutic goods, and all substances used in the preparation of therapeutic goods, that are unpackaged or otherwise susceptible to contamination (in this Division referred to as *exposed substances*).

136B Preparation and handling generally

A medical practitioner, dentist, veterinary surgeon, pharmacist or practitioner of alternative medicine must ensure that:

- (a) all exposed substances that are prepared or handled on his or her business premises are free from any contamination and from anything that is likely to render them harmful or to have an adverse effect on their efficacy, and
- (b) all persons that he or she employs in the preparation or handling of exposed substances comply with the requirements of this Division.

Maximum penalty: 20 penalty units.

136C Personal cleanliness

A person who is involved in the preparation or handling of exposed substances:

- (a) must be clean and must wear clean clothing, and
- (b) must clean his or her hands (by means of soap or detergent and water or by some other suitable cleaning process) before starting work and before resuming work after using the toilet.

Maximum penalty: 10 penalty units.

136D Spitting and smoking etc

A person who is involved in the preparation or handling of exposed substances, or who is in a place that is used for preparing or handling exposed substances, must not:

- (a) urinate, defecate or spit, or
- (b) use, smoke or chew tobacco or any other similar substance, or
- (c) sit, walk, stand or lie on any surface used for the purpose of preparing or handling exposed substances.

Maximum penalty: 10 penalty units.

136E Contact with hands

A person who is involved in the preparation or handling of exposed substances:

- (a) must not have any unnecessary human contact with the substances, and
- (b) must not handle the substances with his or her fingers, but must use a suitable implement to do so, and
- (c) must not touch his or her mouth, eye, ear, nose or scalp while handling the substances, and
- (d) must not wipe his or her hands otherwise than with a clean towel, and

1996 No 423

Poisons Amendment (Therapeutic Goods) Regulation 1996

Schedule 1 Amendments: general

- (e) must not place, so that it can come into contact with the substances, any ticket, label or other article that is unclean or liable to contaminate the substances or that has been in contact with the person's mouth, and
- (f) must not place any implement used for preparing or handling the substances in his or her pockets.

Maximum penalty: 10 penalty units.

136F Contact with mouth

A person who is involved in the preparation or handling of exposed substances must not apply to his or her mouth any implement used for preparing or handling the substances.

Maximum penalty: 10 penalty units.

136G Bandages

A person who is wearing an unclean bandage or a medicated or absorbent bandage must not prepare or handle exposed substances, or use any appliance, article or fitting for preparing or handling exposed substances, unless the bandage is protected and covered with a waterproof covering.

Maximum penalty: 10 penalty units.

136H Persons suffering from infectious diseases

- (1) A person who is suffering from an infectious disease, or who has any exposed cut, sore, wound or skin eruption, must not prepare or handle exposed substances, or use any appliance, article or fitting for preparing or handling exposed substances.

Maximum penalty: 10 penalty units.

- (2) This clause does not apply to an activity carried out by a person if the Director-General has certified in writing that the person may carry out that activity and the person complies with any conditions contained in the certificate.

136I Appliances, articles, fittings and surfaces

- (1) A person who is involved in the preparation or handling of exposed substances must not use any appliance, article or fitting for preparing or handling the substances unless the appliance, article or fitting:
- (a) is designed and constructed so as to be easily cleaned, and
 - (b) is kept clean.

Maximum penalty: 10 penalty units.

- (2) A person who is involved in the preparation or handling of exposed substances must not cause or allow the substances to come into contact with any surface used for preparing or handling the substances unless the surface:
- (a) is designed and constructed so as to be easily cleaned, and
 - (b) is kept clean.

Maximum penalty: 10 penalty units.

Division 2 Supply of therapeutic goods

136J Premises to be free of vermin

A person must not use any premises for preparing, handling or supplying therapeutic goods unless the premises are clean and free from vermin.

Maximum penalty: 10 penalty units.

136K Animals not permitted on premises

- (1) A person who uses any premises for preparing, handling or supplying therapeutic goods must not cause or permit any animal or bird to be in those premises.
- Maximum penalty: 10 penalty units.
- (2) This clause does not apply to the premises of a veterinary surgeon.

Division 3 Labelling of unscheduled therapeutic substances

136L Labelling of unscheduled therapeutic substances

- (1) This clause applies to all therapeutic goods that are not therapeutic devices and are not included in a Schedule of the Poisons List (in this clause referred to as *unscheduled therapeutic substances*).
- (2) A medical practitioner, dentist, veterinary surgeon, pharmacist or practitioner of alternative medicine must ensure that any unscheduled therapeutic substances that are supplied from his or -her business premises for therapeutic use are labelled in accordance with the requirements of Appendix A.

Maximum penalty: 10 penalty units.

- (3) This clause does not apply to the supply of a substance by a person referred to in subclause (2). if
 - (a) the substance is supplied, unopened, in the container in which it was received by the person, and
 - (b) the container is labelled in accordance with the requirements of the Commonwealth therapeutic goods laws.

Part 6B Analysis and disposal of seized goods

Division 1 Analysis of seized goods

136M Samples for analysis

- (1) An inspector who seizes a portion or sample of regulated goods for analysis:
 - (a) must immediately notify the person from whom the portion or sample was taken of the inspector's intention to submit it for analysis, and
 - (b) must divide the portion or sample into 3 parts and properly fasten and seal each part or (if that is impracticable) properly fasten and seal the whole portion or sample.

- (2) If the portion or sample is divided into 3 parts, the inspector:
 - (a) must return one part to the person from whom it was taken, and
 - (b) must forward another part for analysis, and
 - (c) must retain the remaining part.
- (3) If the portion or sample is not divided into 3 parts, the inspector must forward the whole of it for analysis.
- (4) For the purposes of this clause, a portion or sample is properly fastened and sealed if:
 - (a) it is put into a container, and
 - (b) the container is marked with the name and address of the person from whom it was taken, and
 - (c) the container is fastened and sealed so as to prevent the container from being opened, or the name and address being removed, without the seal's being broken.

136N Payment for sample

Payment for a portion or sample of regulated goods that is seized for analysis is to be made by the State, at current market value:

- (a) to the person from whom those goods were taken, or
- (b) if the person is not the owner of those goods, to the owner.

Division 2 Disposal of seized goods

1360 Release of seized goods

- (1) Seized goods are to be released at the end of the period of 6 months after they were seized unless, before the end of that period, a Magistrate makes an order under this Division directing them to be forfeited to the State.

1996 No 423

Poisons Amendment (Therapeutic Goods) Regulation 1996

Schedule 1 Amendments: general

- (2) This clause does not prevent seized goods from being released before the expiration of that period.
- (3) Seized goods may be released:
 - (a) by or at the direction of the inspector who seized them or by or at the direction of the Director-General, and
 - (b) to the owner of the goods or the person in whose possession, care, custody or control they were at the time of the seizure.
- (4) This clause does not require the release of any goods that have been damaged or destroyed in the course of analysis.
- (5) A Magistrate may, in any particular case, extend the period referred to in subclause (1).

136P Order that seized goods be forfeited

- (1) A Magistrate may order that seized goods specified in the order be forfeited to the State on the expiration of any period so specified.
- (2) Such an order does not have effect in respect of any goods that have been released under this Division.
- (3) Before a Magistrate makes an order under this clause, the Magistrate may require such notice as he or she thinks fit to be given to such persons as he or she considers appropriate.

136Q Order that expenses be paid

- (1) A Magistrate may order that a person from whom goods have been seized under section 43 of the Act (being a person who has been convicted of an offence in connection with those goods) must pay to the Director-General such amount (not exceeding \$500) as the Magistrate considers appropriate to cover the reasonable costs of:
 - (a) seizing the goods, and
 - (b) dealing with them under this Division, and

- (c) conducting any analysis for which they have been submitted.
- (2) Before a Magistrate makes an order under this clause, the Magistrate may require such notice as he or she thinks fit to be given to such persons as he or she considers appropriate.
- (3) An order under this clause operates as an order under the *Local Courts (Civil Claims) Act 1970*, and is enforceable as such an order under the provisions of that Act.

136R Storage of and interference with seized goods

- (1) Subject to any direction of the Director-General, seized goods may be kept or stored:
 - (a) at the premises at which they were seized, or
 - (b) at such other place as the inspector who seized them considers appropriate.
- (2) A person must not remove, alter or interfere in any way with seized goods without the authority of an inspector or the Director-General.
Maximum penalty: 20 penalty units or imprisonment for 6 months, or both.

136S Forfeiture of goods with consent

If the owner of seized goods or the person in whose possession, care, custody or control they were at the time of their seizure consents in writing to their forfeiture, the goods are, by virtue of that consent, forfeited to the State.

136T Disposal of forfeited goods

Any goods forfeited under this Division may be disposed of in such manner as the Director-General may direct, either generally or in any particular case or class of cases.

[20] Clauses 138, 143, 147, 148

Omit "grant" "granted" and "granting" wherever occurring.
Insert instead "issue", "issued" and "issuing", respectively.

[21] Clause 138

Insert after clause 138 (1):

- (1A) In particular, the Director-General may refuse an application if of the opinion that the applicant is not a fit and proper person to hold the licence for which the application is made.

[22] Part 7, Division 1A

Insert after Division 1 of Part 7:

Division 1 A Licences to supply by wholesale poisons and restricted substances for use by humans

141A Applications for licences

- (1) Any person may apply to the Director-General for a licence to supply by wholesale any poisons or restricted substances.
- (2) The application:
 - (a) must be in the form approved by the Director-General, and
 - (b) must be accompanied by the relevant application fee, and
 - (a) must be lodged with the Director-General.
- (3) The relevant application fee is:
 - (a) \$40, in the case of an application by a public institution, or
 - (b) \$285, in any other case.
- (4) The Director-General may require an applicant to furnish such further information as is necessary to enable the Director-General to determine the application.

141B Consideration of applications

- (1) After considering an application under this Division, the Director-General may issue the licence for which the application is made or may refuse the application.
- (2) In particular, the Director-General may refuse an application if of the opinion that the applicant is not a fit and proper person to hold the licence for which the application is made.
- (3) A licence may not be issued unless the Director-General is satisfied that the premises to which the application relates are appropriate for the supply of the poisons or restricted substances concerned.
- (4) The application fee is to be refunded if the application is refused.

141C Licences

- (1) A licence is to be in a form for the time being approved by the Director-General.
- (2) A licence remains in force until suspended, cancelled or surrendered.
- (3) A licence is not transferable.

141D Conditions of licences

- (1) A licence is subject to such conditions as the Director-General may from time to time impose by order in writing served on the holder of the licence.
- (2) The Director-General may from time to time vary or revoke any condition of a licence by means of a further order in writing served on the holder of the licence.
- (3) A licence is ineffective unless its conditions are complied with.

141E Annual licence fees

The holder of a licence under this Division must, on or before 30 September in each year following that in which the licence was issued, pay to the Director-General an annual licence fee of:

- (a) \$40, if the holder is a public institution, or
- (b) \$285, in any other case.

[23] Clause 143

Insert after clause 143 (1):

- (1A) In particular, the Director-General may refuse an application if of the opinion that the applicant is not a fit and proper person to hold the licence for which the application is made.

[24] Clause 147 Authorities

Insert after clause 147 (2):

- (2A) In particular, the Director-General may refuse to issue an authority to a person if of the opinion that the person is not a fit and proper person to hold the authority.

[25] Part 7A

Insert after Part 7:

Part 7A Modification of applied provisions of Commonwealth therapeutic goods laws

150A Transitional modification of applied provisions of Commonwealth therapeutic goods laws: sec. 31 (3)

- (1) This clause applies to circumstances to which the *Therapeutic Goods Act 1989* of the Commonwealth applies by reason of section 31 of the *Poisons and Therapeutic Goods Act 1966*.

- (2) Sections 66 and 68 of the *Therapeutic Goods Act 1989* of the Commonwealth are modified in their application to circumstances to which this clause applies so that the references in those sections to the commencement of that Act are taken instead as references to the commencement of the *Poisons Amendment (Therapeutic Goods) Act 1996* (that is, 1 September 1996).

150B Modification of applied provisions of Commonwealth therapeutic goods laws with respect to advertising: sec. 31 (3)

- (1) This clause applies to circumstances to which the *Therapeutic Goods Act 1989* of the Commonwealth applies by reason of section 31 of the *Poisons and Therapeutic Goods Act 1966*
- (2) Part 2 of the *Therapeutic Goods Regulations* of the Commonwealth is modified in its application to circumstances to which this clause applies to the extent that the Director-General may, by order in writing, exempt any person or substance, or any class of persons or substances, from the requirements of that Part.
- (3) Such an exemption may be given unconditionally or subject to conditions.

[26] Clause 152 Appeals to the District Court

Omit clause 152 (1). Insert instead:

- (1) Any person who is aggrieved by a decision of the Director-General relating to:
- (a) the issue or renewal of, or the refusal to issue or renew, a licence or authority, or
- (b) the suspension, withdrawal or cancellation of a licence or authority,

may appeal to the District Court against the decision.

[27] Appendix A, heading

Omit “(Cll. 4, 27 and 72)”.
Insert instead “(Cll. 4, 27,72 and 136L)”.

[28] Appendix E, heading

Omit “WHOLESALE DEALING”.
Insert instead “SUPPLY BY WHOLESALE”.

[29] Dictionary

Insert in alphabetical order:

practitioner of alternative medicine means a herbalist, nutritionist, naturopath, practitioner of Chinese medicine or homoeopathic practitioner.

seized goods means regulated goods that have been seized under section 43 of the Act.

Schedule 2 Amendments: penalties

(Clause 4)

- [1] Clauses 4, 5, 6, 9, 10, 11, 12, 13, 14, 15, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 72, 73**

Insert at the end of each clause:

Maximum penalty: 10 penalty units.

- [2] Clause 7**

Insert at the end of the clause:

Maximum penalty: 2 penalty units.

- [3] Clauses 30, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 45, 46, 47, 50, 51, 53, 54, 55, 57, 58, 59, 60, 67, 68, 126, 128, 130, 131, 132, 134**

Insert at the end of each clause:

Maximum penalty: 15 penalty units.

- [4] Clauses 31, 32, 44, 52, 61, 64, 66, 69, 70, 74, 77A, 79, 80, 81, 82, 83, 84, 85, 87, 88, 89, 90, 91, 92, 93, 95, 96, 99, 100, 104, 105, 106, 107, 109, 110, 111, 113, 114, 115, 117, 118, 119, 120, 122, 124, 127, 153**

Insert at the end of each clause:

Maximum penalty: 20 penalty units.

- [5] Clauses 76, 78, 102, 123, 133, 135, 154, 155**

Insert at the end of each clause:

Maximum penalty: 20 penalty units or imprisonment for 6 months, or both.