

(Reprint No. 7)

South Australia

CONTROLLED SUBSTANCES (POISONS) REGULATIONS 1996

*These regulations are reprinted pursuant to the Subordinate Legislation Act 1978 and incorporate all amendments in force as at **6 December 2001**.*

REGULATIONS UNDER THE CONTROLLED SUBSTANCES ACT 1984

CONTROLLED SUBSTANCES (POISONS) REGULATIONS 1996

being

No. 4 of 1996: *Gaz.* 4 January 1996, p. 36¹

as varied by

No. 9 of 1997: *Gaz.* 30 January 1997, p. 728²

No. 94 of 1997: *Gaz.* 13 May 1997, p. 1895³

No. 229 of 1997: *Gaz.* 27 November 1997, p. 1454⁴

No. 243 of 1997: *Gaz.* 18 December 1997, p. 1707⁵

No. 83 of 1998: *Gaz.* 28 May 1998, p. 2349⁶

No. 205 of 1998: *Gaz.* 3 December 1998, p. 1747⁷

No. 83 of 1999: *Gaz.* 27 May 1999, p. 2858⁸

No. 91 of 2000: *Gaz.* 25 May 2000, p. 2774⁹

No. 126 of 2000: *Gaz.* 8 June 2000, p. 3101¹⁰

No. 161 of 2000: *Gaz.* 6 July 2000, p. 30¹¹

No. 198 of 2000: *Gaz.* 31 August 2000, p. 979¹²

No. 65 of 2001: *Gaz.* 31 May 2001, p. 1977¹³

No. 253 of 2001: *Gaz.* 6 December 2001, p. 5298¹⁴

¹ Came into operation 4 January 1996: reg. 2.

² Came into operation 30 January 1997: reg. 2.

³ Came into operation 1 July 1997: reg. 2.

⁴ Came into operation 27 March 1998: reg. 2.

⁵ Came into operation 19 December 1997: reg. 2.

⁶ Came into operation 1 July 1998: reg. 2.

⁷ Came into operation 3 December 1998: reg. 2.

⁸ Came into operation 1 July 1999: reg. 2.

⁹ Came into operation 1 July 2000: reg. 2.

¹⁰ Regulation 3 came into operation 1 July 2000: reg. 2(2); remainder of regulations came into operation 8 October 2000: reg. 2(1).

¹¹ Came into operation 6 July 2000: reg. 2.

¹² Came into operation 31 August 2000: reg. 2.

¹³ Came into operation 1 July 2001: reg. 2.

¹⁴ **Came into operation 6 December 2001: reg. 2.**

NOTE:

- Asterisks indicate repeal or deletion of text.
- Entries appearing in bold type indicate the amendments incorporated since the last reprint.
- For the legislative history of the regulations see Appendix.

SUMMARY OF PROVISIONS

**PART 1
PRELIMINARY**

1. Citation
2. Commencement
3. Revocation
4. Interpretation
5. Incorporation of the Uniform Poisons Standard
6. Declaration of poisons (s. 12(1))
7. Declaration of prescription drugs (s. 12(2))
- 7A. Declaration of drugs of dependence (s. 12(3))
8. Certain new substances to be taken to be schedule 4 poisons
9. Application of these regulations

**PART 2
LICENCES**

10. Licences
11. Restrictions on medicine sellers licences

**PART 3
APPLICATION OF GENERAL OFFENCES (PART 4) OF THE ACT**

12. Manufacture, production and packing (s. 13)
13. Sale by wholesale (s. 14)
14. Sale or supply to end user (s. 15)
15. Sale of certain poisons (s. 16)
16. Possession (s. 22)
17. Exemption from s. 22 may be granted to certain pest controllers
18. Packaging of poisons (s. 24)
19. Labelling of poisons (s. 24)
20. Storage of poisons (s. 25)
21. Transport of poisons (s. 26)
22. Prohibition on use of certain poisons for certain purposes (s. 27)
23. Restriction on advertising (s. 28)

**PART 4
PRESCRIPTIONS AND DISPENSING**

25. Prescription to be given in writing or by telephone or fax, etc.
26. Written prescriptions
27. Dispensing prescriptions for drugs

**PART 5
SPECIAL PROVISIONS RELATING TO CERTAIN S4 DRUGS**

28. Prescribed professions (s. 18(1)(b))
29. Additional requirements for S4 drugs listed in schedule K (s. 18(2))
30. Additional requirements for Nalbuphine
31. Exemptions from s. 18 of the Act

**PART 5A
SPECIAL PROVISIONS RELATING TO DRUGS OF DEPENDENCE**

- 31A. Interpretation
- 31B. Special restrictions on prescription or supply of drugs of dependence by medical practitioners, dentists and veterinary surgeons
- 31C. Additional requirements for prescribers of drugs of dependence
- 31D. Manufacturers of drugs of dependence to record stocks
- 31E. Supply of drugs of dependence in accordance with an order
- 31F. Persons receiving drugs of dependence on order to record details
- 31G. Supply or administration of drugs of dependence by medical practitioner, dentist or registered nurse
- 31H. Supply or administration of drugs of dependence by veterinary surgeon

Controlled Substances (Poisons) Regulations 1996

- 31I. Additional requirements for administration of drugs of dependence in health service
- 31J. Destruction of drugs of dependence
- 31K. Prescribed amounts (s. 32(3) and (5))
- 31L. Exemptions from s. 33 of the Act
- 31M. Non-compliance with Part 5A an offence

PART 6

SPECIAL PROVISIONS RELATING TO PRECURSOR CHEMICALS

- 32. Prohibition of manufacture, sale, possession, etc., of certain precursor chemicals
- 33. Strict regulation of storage and sale of certain precursor chemicals
- 34. Regulation of sale of other precursor chemicals

PART 7

OTHER OFFENCES

- 35. Restriction on giving samples of poisons
- 36. Offences relating to sale or supply of poisons
- 37. Offence to dispose of poison
- 38. Keeping of records, etc.
- 39. False information
- 40. Vicarious liability

PART 8

MISCELLANEOUS

- 40A. Personal identification code equivalent to signature
- 41. Analysis of substance (s. 53)
- 42. Research permit
- 43. Copies of codes, etc., to be kept available for public inspection
- 44. Transitional provision—licences

SCHEDULE A

*Modification of the Uniform Poisons Standard
(Regulation 5)*

SCHEDULE B

*Precursor chemicals declared as Poisons (Possession and Sale Prohibited)
(Regulations 6 and 32)*

SCHEDULE C

*Precursor Chemicals declared as Poisons (Sale Regulated)
(Regulations 6, 33 and 34)*

SCHEDULE D

*Fees
(Regulations 10 and 41)*

SCHEDULE E

*Schedule 2 Poisons Authorised to be Sold by Holder of a Medicine Sellers Licence
(Regulation 11(2))*

SCHEDULE F

*Prescribed Poisons for the Purposes of s. 22 of the Act
(Regulation 16)*

SCHEDULE G

Schedule 3 Poisons to which Regulation 14(2) applies

SCHEDULE H

*Poisons that must be Packed in Child-resistant Containers
(Regulation 18)*

SCHEDULE I

*S4 Drugs that may be Administered by Prescribed Professionals
(Regulation 28)*

Controlled Substances (Poisons) Regulations 1996

SCHEDULE J

*S4 drugs that may be Supplied or Prescribed by a Surgical Podiatrist
(Regulation 28)*

SCHEDULE K

*Restrictions on Prescribing Certain S4 Drugs
(Regulation 29)*

SCHEDULE KA

Prescribed Amounts for the Purposes of Section 32(3) of the Act

SCHEDULE KB

Prescribed Amounts for the Purposes of Section 32(5) of the Act

SCHEDULE L

Controlled Substances Act 1984

END USER STATEMENT

(Regulations 33 and 34)

SCHEDULE M

*Certificate of Analysis
(Regulation 41)*

APPENDIX

LEGISLATIVE HISTORY

**PART 1
PRELIMINARY**

Citation

1. These regulations may be cited as the *Controlled Substances (Poisons) Regulations 1996*.

Commencement

2. These regulations will come into operation on 4 January 1996.

Revocation

3. (1) The *Controlled Substances (Poisons) Regulations 1991* (see *Gazette* 24 January 1991 p. 238), as varied, are revoked.

(2) The *Controlled Substances (Possession of Poisons) Regulations 1988* (see *Gazette* 19 May 1988 p. 1265), as varied, are revoked.

(3) The *Controlled Substances (Declared Prescription Drugs) Regulations 1992* (see *Gazette* 14 May 1992 p. 1400) are revoked.

(4) The *Drugs of Dependence (General) Regulations 1985* (see *Gazette* 9 May 1985 p. 1498), as varied, are revoked.

(5) The *Controlled Substances (Declared Drugs of Dependence) Regulations 1993* (see *Gazette* 13 May 1993 p. 1639), as varied, are revoked.

Interpretation

4. (1) In these regulations, unless the contrary intention appears—

"**the Act**" means the *Controlled Substances Act 1984*;

"**address**" means the street address of the relevant premises;

"**CEO**" means the Chief Executive of the Department;

"**chiroprapist**" means a person registered as a chiroprapist under the *Chiroprapists Act 1950*;

"**dental therapist**" has the same meaning as in section 85 of the *Dentists Act 1984*;

"**to dispense**" means to supply a drug in accordance with a prescription for that drug;

"**drug**" means a poison designed for human or animal therapeutic use;

"**health service**" means a health service provided for the public or any section of the public for the purpose of curing, alleviating, diagnosing or preventing the spread of any mental or physical illness, disease, injury, abnormality or disability, and includes a hospital and a nursing home;

"**National Drugs and Poisons Schedule Committee**" means the National Drugs and Poisons Schedule Committee established by the *Therapeutic Goods Act 1989* of the Commonwealth;

"**optometrist**" means a person registered as an optometrist under the *Optometrists Act 1920*;

"**poison**" means a substance declared by these regulations to be a poison;

"**prescriber**" means a person who lawfully gives a prescription for a drug;

Controlled Substances (Poisons) Regulations 1996

"**record**" means—

- (a) a documentary record; or
- (b) a record made by an electronic, electromagnetic, photographic or optical process; or
- (c) any other kind of record,

and "**to record**" has a corresponding meaning;

"**S4 drug**" means a schedule 4 poison;

"**schedule F poison**" means a poison that is listed in schedule F of these regulations;

"**surgical podiatrist**" means a person registered as a chiropodist under the *Chiropodists Act 1950* who—

- (a) is a member of the Australian College of Surgical Podiatrists Inc.; or
- (b) has successfully completed the course of instruction required to qualify for membership of the Australian College of Surgical Podiatrists Inc.;

"**Uniform Poisons Standard**" mean the *Standard for the Uniform Scheduling of Drugs and Poisons* published by the National Drugs and Poisons Schedule Committee.

(2) In these regulations—

- (a) a reference to "**schedule 1**", "**schedule 2**", "**schedule 3**", "**schedule 4**", "**schedule 5**", "**schedule 6**", "**schedule 7**", or "**schedule 8**" is a reference to the corresponding schedule in the *Uniform Poisons Standard* (as incorporated into these regulations); and
- (b) a reference to a "**schedule 1 poison**" is a reference to a poison listed in schedule 1, a reference to a "**schedule 2 poison**" is a reference to a poison listed in schedule 2, and so on.

Incorporation of the Uniform Poisons Standard

5. The *Uniform Poisons Standard*, as modified by schedule A of these regulations, is incorporated into these regulations.

Declaration of poisons (s. 12(1))

6. (1) Pursuant to section 12(1) of the Act, the following substances (whether in a pure form, or contained in a preparation or admixture) are declared to be poisons:

primary substances:

- (a) the substances listed in schedules 1 to 8 of the *Uniform Poisons Standard*, as modified by schedule A of these regulations; and
- (b) the substances listed in appendix C of the *Uniform Poisons Standard*; and
- (c) the substances listed in schedules B and C of these regulations; and

related substances:

- (d) the following substances, but subject to any express exclusion contained in the Standard:
- (i) the artificial form of a primary substance;
 - (ii) where a primary substance is a plant (other than a plant included in schedule 8)—that plant, or any part of that plant, when packed or prepared for therapeutic use;
 - (iii) every salt, active principle or derivative (including an ester or ether) of a primary substance and every salt of such an active principle or derivative;
 - (iv) every alkaloid of a primary substance and every salt of such an alkaloid;
 - (v) except in the case of levomethorphan or levorphanol, every stereoisomer of a primary substance and every salt of such a stereoisomer.

(2) A related substance will be taken to be included in the schedule, or schedules, of the *Uniform Poisons Standard* in which the primary substance to which it is related is included.

(3) A reference in these regulations to a particular primary poison will be taken to include a reference to its related substances.

Declaration of prescription drugs (s. 12(2))

7. Pursuant to section 12(2) of the Act, the poisons listed in schedule 4 and schedule 8 are declared to be prescription drugs.

Declaration of drugs of dependence (s. 12(3))

7A. Pursuant to section 12(3) of the Act, the poisons listed in schedule 8 (including all their related substances referred to in regulation 6) are declared to be drugs of dependence, (whether in a pure form, or contained in a preparation or admixture).

Certain new substances to be taken to be schedule 4 poisons

8. On a substance designed for human or animal therapeutic use being approved by—

- (a) the Therapeutic Goods Administration of the Commonwealth for inclusion in the *Australian Register of Therapeutic Goods*; or
- (b) the National Registration Authority of the Commonwealth for inclusion in the *Australian Register of Agricultural and Veterinary Chemical Products*,

the substance will be taken to be a schedule 4 poison until—

- (c) it is listed in some other schedule to the *Uniform Poisons Standard*; or
- (d) it is exempted from listing in the *Uniform Poisons Standard*.

Application of these regulations

9. These regulations do not apply in relation to—

- (a) a poison when contained in a product that is listed in appendix A of the *Uniform Poisons Standard*; or

Controlled Substances (Poisons) Regulations 1996

- (b) a poison listed in appendix G of the *Uniform Poisons Standard* when contained in a preparation in a concentration not exceeding the concentration specified in appendix G for that poison; or
- (c) a poison that is listed in any of the schedules 1 to 6 (but is not listed in schedule 7 or 8) of the *Uniform Poisons Standard* when contained in a preparation in a concentration not exceeding 10 milligrams per litre or 10 milligrams per kilogram.

**PART 2
LICENCES**

Licences

10. (1) Licences under the Act will be of the following classes:

- (a) manufacturers licence (s. 13; s. 32; ss. 13 and 32);
- (b) wholesale dealers licence (s. 14; s. 32; ss. 14 and 32);
- (c) retail sellers licence (s. 15);
- (d) medicine sellers licence (s. 15);
- (e) licence to supply and administer an S4 drug (s. 18);
- (f) licence to possess schedule F poisons (s. 22);
- (g) licence to possess drugs of dependence or equipment (s. 31);
- (h) licence to sell (other than by wholesale dealing), supply, administer or possess drugs of dependence (s. 32).

(2) An application for a licence must be made to the Minister on a form approved by the Minister, completed and signed by the applicant in accordance with the instructions contained in the form, and must be accompanied by the appropriate fee set out in schedule D of these regulations.

(3) Where a licence is to be granted or renewed for a term of less than 12 months, the fee payable is a proportion of the appropriate fee, being the proportion that the number of whole months in the term of the licence bears to 12 months.

(4) Licences expire as follows:

- (a) manufacturers licence or wholesale dealers licence—on 28 February next following the date on which the licence was granted or last renewed;
- (b) retail sellers licence or medicine sellers licence—on 30 November next following the date on which the licence was granted or last renewed;
- (c) licence to supply or administer an S4 drug or licence to possess schedule F poisons—on 31 May next following the date on which the licence was granted or last renewed;
- (d) licence to possess drugs of dependence or equipment (s. 31)—31 May next following the date on which the licence was granted or last renewed;
- (e) licence to sell (other than by wholesale dealing), supply, administer or possess drugs of dependence (s. 32)—31 May next following the date on which the licence was granted or last renewed.

Note: Section 55 of the Act provides that the Minister may grant a licence subject to such conditions as the Minister thinks fit and specifies in the licence and may at any time, by notice in writing given personally or by post to the holder, vary or revoke a condition, or attach a further condition, to the licence.

Controlled Substances (Poisons) Regulations 1996

Restrictions on medicine sellers licences

11. (1) A person is not eligible to be granted a medicine sellers licence unless he or she is carrying on the business of selling goods by retail in premises that are open for business for not less than 38 hours per week and—

- (a) the premises are at least 25 kilometres (by the shortest practical route) from the nearest pharmacy that is open for not less than 3 hours per day (excluding Saturdays, Sundays and public holidays); or
- (b) he or she satisfies the Minister that the local community is in particular need of a licensed medicine seller.

(2) A medicine sellers licence will be subject to a condition that the holder of the licence must not sell a schedule 2 poison other than one that is listed in schedule E of these regulations.

PART 3
APPLICATION OF GENERAL OFFENCES (PART 4) OF THE ACT

Manufacture, production and packing (s. 13)

12. (1) Section 13 of the Act applies to all poisons listed in schedules 1 to 7.

(2) *Exemption*—A person who holds a licence under the *Therapeutic Goods Act 1989* of the Commonwealth to manufacture goods that are poisons listed in schedules 1 to 7 is exempt from the requirement to hold a licence under section 13 of the Act in respect of the manufacture of those goods.

(3) *Exemption*—A person who packs for retail sale a liquid hydrocarbon listed in schedule 5 is exempt from the requirement to hold a licence under section 13 of the Act to the extent that he or she packs the substance at the place at which the sale takes place.

Sale by wholesale (s. 14)

13. Section 14 of the Act applies to all poisons listed in schedules 1 to 7.

Sale or supply to end user (s. 15)

14. (1) Section 15 of the Act applies to all poisons listed in schedules 1 to 3 and schedule 7.

(2) A person who sells by retail or supplies to a person a schedule 3 poison—

(a) must personally (that is to say, not through an assistant) give oral directions, supplemented wherever practicable with written directions, for the safe and proper use of the poison to the person purchasing or being supplied with the poison; and

(b) in respect of a schedule 3 poison that is listed in schedule G of these regulations, must (unless he or she is a medical practitioner, dentist or veterinary surgeon)—

(i) record—

(A) the name and address of the person for whom the poison is purchased or supplied; and

(B) the date of sale or supply; and

(C) the directions given for the safe and proper use of the poison; and

(D) the trade name or the approved name of the poison sold or supplied, or, if it does not have either a trade or approved name, its ingredients and the form, strength and quantity sold or supplied; and

(E) a unique identifier enabling those records to be linked with the poison sold or supplied; and

(ii) lodge with the Department within 15 days of the end of each month a copy of the records kept under this subregulation in respect of the poisons sold or supplied during that month.

Maximum penalty: \$3 000.

(3) Despite subregulation (2)(a), an interpreter may be used to assist in the giving of oral directions to a person who is not sufficiently familiar with the English language.

Controlled Substances (Poisons) Regulations 1996

Sale of certain poisons (s. 16)

15. (1) Section 16 of the Act applies to all poisons listed in schedule 7.

(2) For the purposes of section 16(4)(c) of the Act, the additional matters that a person who sells a schedule 7 poison must record are as follows:

- (a) the date of purchase; and
- (b) the address and usual occupation of the purchaser; and
- (c) the trade name or the approved name of the poison purchased; and
- (d) the form and strength of the poison purchased; and
- (e) the quantity of the poison purchased.

Possession (s. 22)

16. (1) Section 22 of the Act applies to all schedule F poisons.

(2) *Exemption*—A person is exempt from section 22 of the Act in respect of possession of—

- (a) strychnine, if—
 - (i) the person is the owner or occupier, or an agent or employee of an owner or occupier, of land situated outside Metropolitan Adelaide and outside any township; and
 - (ii) the strychnine is a constituent of baits designed for destroying mice; and
 - (iii) the quantity of baits in the person's possession does not exceed 5 kilograms; and
 - (iv) the amount of strychnine present in any quantity of the baits does not exceed 0.5 per cent; or
- (b) chloropicrin, if—
 - (i) in the case of pure chloropicrin, the quantity in the person's possession does not exceed 7 litres;
 - (ii) in the case of chloropicrin in a compound preparation, the concentration of chloropicrin does not exceed 5 per cent; or
- (c) sodium fluoroacetate if—
 - (ai) the sodium fluoroacetate is a constituent of baits designed for destroying dingoes or foxes; and
 - (i) the concentration of sodium fluoroacetate in each bait does not exceed 0.03 per cent; and
 - (ii) the total amount of sodium fluoroacetate present in the particular quantity of baits does not exceed 10 grams; and

- (iii) the person—
 - (A) has the written approval of the Animal and Plant Control Commission ("the APCC") to acquire and possess those baits; and
 - (B) acquires the baits from a supplier approved by the APCC; and
 - (C) complies with any conditions imposed by the APCC on granting the approval to acquire and possess baits.

(2a) A person lawfully in possession of baits containing strychnine under subregulation (2)(a) must not use those baits except for the purpose of destroying mice in or around storage areas on land situated outside Metropolitan Adelaide and outside any township.

Maximum penalty: \$3 000.

(3) The APCC may, on granting an approval under subregulation (2)(c)(iii), impose such conditions as it thinks fit.

(4) A person who does not comply with a condition imposed under subregulation (3) is guilty of an offence.

Maximum penalty: \$3 000.

(5) The APCC may, for such reasons as it thinks fit, vary or revoke an approval given under this regulation.

(6) In this regulation—

"**Metropolitan Adelaide**" means Metropolitan Adelaide within the meaning of the *Development Act 1993*.

Exemption from s. 22 may be granted to certain pest controllers

17. (1) The Minister may exempt a person who is licensed under the *Controlled Substances (Pesticide) Regulations 1988* from the requirement to hold a licence under section 22 of the Act in respect of the use of a pesticide that is a schedule F poison.

(2) The Minister may, by notice in writing to an exempted person, vary or revoke the exemption.

Packaging of poisons (s. 24)

18. (1) For the purposes of section 24(b) of the Act, the requirements as to packaging with which the seller or supplier of a poison must comply are—

- (a) the requirements set out in the *Uniform Poisons Standards* (as incorporated into these regulations); and
- (b) the additional requirements set out in subregulation (3) in the case of a poison referred to in that subregulation.

(2) The Minister may grant an exemption from subregulation (1) to a seller or supplier in respect of a particular product if the Minister is satisfied that the product is otherwise adequately packaged.

Controlled Substances (Poisons) Regulations 1996

- (3) Subject to subregulation (4)—
- (a) a poison listed in clause 1 of schedule H of these regulations that is in the form of a tablet, capsule, lozenge, pastille, suppository or similar discrete solid dosage unit must be enclosed in a child-resistant package or container approved by the Minister; and
 - (b) a poison in liquid form listed in clause 2 of schedule H of these regulations must be packed in a child-resistant package or container approved by the Minister.
- (4) Subregulation (3) does not apply to a poison that is listed in schedule H of these regulations if the poison—
- (a) is packed as an individually wrapped powder; or
 - (b) is packed in a package or container containing not less than 500 solid dosage units; or
 - (c) is sold to a person who is likely to suffer undue hardship through difficulty in opening a package or container that complies with subregulation (3)(a); or
 - (d) is sold to a health service for administration to an inpatient of the health service.

Labelling of poisons (s. 24)

19. (1) For the purposes of section 24(c) of the Act, the requirements as to labelling with which the seller or supplier of a poison must comply are as follows:

- (a) in the case of the supply in the course of professional practice or the sale by retail (other than pursuant to dispensing a prescription) of a poison designed for human or animal therapeutic use (not being a schedule 3 poison that is listed in schedule G of these regulations), the package or container in which the poison is supplied or sold must have affixed to it—
 - (i) the manufacturer's label, if that label conforms with the requirements of the *Uniform Poisons Standard* (as incorporated into these regulations); or
 - (ii) a label that conforms with subregulation (2);
- (b) in the case of the supply or sale by retail of a schedule 3 poison that is listed in schedule G of these regulations, the package or container in which the poison is supplied or sold must have affixed to it a label that conforms with subregulation (2);
- (c) in the case of the sale of a poison designed for human or animal therapeutic use pursuant to dispensing a prescription for the poison, the package or container in which the poison is sold must have affixed to it a label that conforms with subregulation (2);
- (d) in any other case, the package or container in which the poison is sold (whether by wholesale or retail) must have affixed to it a label that conforms with the requirements of the *Uniform Poisons Standard* (as incorporated into these regulations).

(2) For the purposes of paragraphs (a)(ii), (b) and (c) of subregulation (1), the label must have the following information clearly printed on it:

- (a) the name (or business name), business address and telephone number of the person by whom the poison is sold or supplied; and

- (b) —
- (i) the name of the person for whose use the poison is sold or supplied; or
 - (ii) where the poison is intended for an animal—the species of animal for which it is intended and the name of the owner of the animal and the name (if any) of the animal; and
- (c) the trade name or the approved name of the poison or, if it does not have either a trade or approved name, its ingredients; and
- (d) if the poison is part of a preparation or admixture—the strength or proportion of poison contained in the preparation or admixture; and
- (e) directions for the safe and proper use of the poison, including (where relevant) the route of administration; and
- (f) the date on which the poison is sold or supplied; and
- (g) in the case of a poison sold pursuant to dispensing a prescription for the poison—a unique identifier that enables the poison to be linked with the prescription; and
- (h) in the case of a schedule 3 poison that is listed in schedule G of these regulations—a unique identifier enabling that poison to be linked with the records required to be kept under regulation 14(2)(b); and
- (i) in the case of a preparation for internal use by humans (other than infants)—
- (i) that contains a poison listed in appendix K of the Uniform Poisons Standard—one of the following statements:
 - "This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol."; or
 - "This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery."; or
 - (ii) that contains levocabastine—the following statement:
 - "Do not use if pregnant."; or
 - (iii) that contains misoprostol—the following statement:
 - "CAUTION—Misoprostol should not be used by pregnant women."

(3) The Minister may grant an exemption from this regulation, or any provision of this regulation, to a seller or supplier in respect of a particular product if the Minister is satisfied that the product is otherwise adequately labelled.

Storage of poisons (s. 25)

20. For the purposes of section 25 of the Act, a person must not store—

- (a) any poison in a container that—
 - (i) is normally used for containing food or beverages; or

Controlled Substances (Poisons) Regulations 1996

- (ii) is similar to a container that is normally used for containing food or beverages; or
- (b) a schedule 3, 4 or 7 poison in retail premises unless it is stored in a part of the premises to which the public is not permitted access; or
- (c) a schedule 2, 5 or 6 poison (other than a schedule 6 poison that is a hair colouring preparation) in retail premises unless—
 - (i) it is stored in a part of the premises to which the public is not permitted access; or
 - (ii) if it is stored in a part of the premises to which the public is permitted access, it—
 - (A) is stored not less than 1.2 metres above floor level; or
 - (B) is enclosed in a child-resistant package or container approved by the Minister; or
 - (C) is enclosed in a blister pack; or
 - (D) is stored in a container that has a capacity of not less than five litres; or
 - (E) is stored in a container that has a gross weight of not less than five kilograms; or
- (d) a drug of dependence except in accordance with the requirements of the **Code of Practice for the Storage and Transport of Drugs of Dependence**, developed by the Department, dated 31 July 2000 and published in the *Gazette* on 24 August 2000.

Transport of poisons (s. 26)

21. For the purposes of section 26 of the Act, a person must not—

- (a) consign a poison for transport unless it is packed in such a way as to avoid leakage arising from the ordinary risks of handling and transport; or
- (b) transport a poison in a vehicle in which any food, or component of food, for human or animal consumption is being transported unless the poison is carried in a part of the vehicle effectively separated from that part of the vehicle containing the food; or
- (c) consign for transport, or transport, a drug of dependence except in accordance with the requirements of the **Code of Practice for the Storage and Transport of Drugs of Dependence**, developed by the Department, dated 31 July 2000 and published in the *Gazette* on 24 August 2000.

Prohibition on use of certain poisons for certain purposes (s. 27)

22. (1) For the purposes of section 27 of the Act, a person must not—

- (a) sell, supply, purchase or use a schedule 7 poison for a domestic, or domestic gardening, purpose; or

- (b) prescribe, sell, supply, purchase or use a poison that is listed in appendix C of the *Uniform Poisons Standard* for the purpose or purposes indicated in relation to that poison in appendix C; or
- (c) in the case of a poison produced for the treatment of animals—
 - (i) prescribe, sell, supply or purchase such a poison if he or she knows, or if there are reasonable grounds for suspecting, that the poison is intended for human use; or
 - (ii) administer to any person (including himself or herself) such a poison; or
- (d) use chloramphenicol for the treatment of stock bred, raised or used for the purpose of providing a product for human consumption.

(2) In this regulation—

"**stock**" means any animal or bird and any bee of the genus *Apis* or *Megachile*.

Restriction on advertising (s. 28)

23. (1) Section 28 of the Act applies to all poisons listed in schedules 3, 4 and 8, except where the advertisement of such a poison appears in a journal that is circulated predominantly among medical professionals.

(2) In this regulation—

"**journal**" means a newsletter, magazine or other periodical, whether published for sale or for distribution without charge;

"**medical professionals**" includes medical practitioners, dentists, veterinary surgeons, nurses, pharmacists, chiropractors, optometrists, dental therapists, medical administrators, physiotherapists registered under the *Physiotherapists Act 1945*, scientists working in medical laboratories and those who hold a wholesale dealers licence.

Controlled Substances (Poisons) Regulations 1996

**PART 4
PRESCRIPTIONS AND DISPENSING**

* * * * *

Prescription to be given in writing or by telephone or fax, etc.

25. (1) Subject to subregulation (2), a prescriber must give a prescription for a drug in writing, and must give it to the person for whom the drug is to be supplied, or to a person acting on behalf of that person.

Maximum penalty: \$5 000.

(2) A prescriber may, if of the opinion that good reason exists for doing so, give a prescription for a drug to a pharmacist by telephone, facsimile transmission or some other form of electronic transmission.

(3) If a prescription is given by telephone or by some form of electronic transmission (other than facsimile), the prescriber—

- (a) must give the pharmacist the following information:
 - (i) his or her name and full address; and
 - (ii) the full name and address of the person to whom the drug is to be supplied; and
 - (iii) the name, dose form and (if relevant) the route of administration of the drug to be dispensed; and
 - (iv) where applicable—the strength of the drug to be dispensed; and
 - (v) the dose of the drug to be administered to the person for whom the drug is prescribed or to the animal in relation to which the drug is prescribed; and
 - (vi) the total amount of the drug to be dispensed; and
 - (vii) the frequency at which the drug is to be administered; and
- (b) must, immediately after giving the prescription by that method, complete a written prescription that—
 - (i) clearly states that it is given in confirmation of the prescription given by telephone or by electronic transmission (as the case may be) on the particular date on which it was so given; and
 - (ii) otherwise complies with these regulations; and
- (c) must—
 - (i) where the prescription is for a drug of dependence, forward the written prescription to the pharmacist within 24 hours of giving the prescription by telephone or by electronic transmission; or
 - (ii) in any other case, forward the written prescription to the pharmacist as soon as practicable after giving the prescription by that method.

Maximum penalty: \$3 000.

- (4) If a prescription is given to a pharmacist by facsimile transmission, the prescriber must—
- (a) where the prescription is for a drug of dependence, forward the original prescription to the pharmacist within 24 hours of giving the prescription by facsimile transmission; or
 - (b) in any other case, forward the original prescription to the pharmacist as soon as practicable after giving the prescription by that method.

Maximum penalty: \$3 000.

Written prescriptions

26. (1) A prescriber who writes a prescription for the supply of a drug must—

- (a) write it legibly in ink or cause it to be printed; and
- (b) date the prescription with the date on which the prescription is written and personally sign the prescription; and
- (c) include on the prescription—
 - (i) his or her professional name, address and telephone number; and
 - (ii) —
 - (A) the full name and address of the person for whom the prescription is intended; or
 - (B) where the prescription is intended for an animal—the species of animal for which it is intended, the name and address of the owner of the animal and the name (if any) of the animal; and
 - (iii) where the prescriber is a dentist—the words "For dental treatment only"; and
 - (iv) where the prescriber is a veterinary surgeon—the words "For animal treatment only"; and
 - (v) where the prescriber is a surgical podiatrist—the words "For podiatric treatment only"; and
- (d) specify—
 - (i) the name, dose form and (if relevant) the route of administration of the drug being prescribed; and
 - (ii) where applicable—the strength of the drug; and
 - (iii) the dose of the drug to be administered to the person for whom, or the animal for which, it is prescribed; and
 - (iv) the frequency at which the drug is to be administered; and
 - (v) the total amount of the drug to be supplied each time the prescription is dispensed; and
 - (vi) the total number of times the drug may be dispensed; and

Controlled Substances (Poisons) Regulations 1996

- (e) if the prescription is for a drug of dependence for human use, comply with the following additional requirements:
- (i) include on the prescription—
 - (A) the date of birth of the person for whom the prescription is intended; and
 - (B) where the prescriber is acting under a section 33 authority—the authority number; and
 - (ii) express the total amount of the drug to be specified under subregulation (d)(v) in both words and numerals; and
 - (iii) keep a record of the details required to be included and specified under this regulation.

(2) If the prescriber is prescribing an above average strength or potentially dangerous dose of the drug, he or she must—

- (a) underline the statement of the dose of the drug in the prescription; and
- (b) sign his or her initials alongside the underlined portion of the prescription referred to in paragraph (a).

(3) A person who contravenes or fails to comply with this regulation is guilty of an offence.

Maximum penalty: \$3 000.

Dispensing prescriptions for drugs

27. (1) A pharmacist or medical practitioner who dispenses a prescription for a drug—

- (a) must write in ink on the face or back of the prescription—
 - (i) his or her name, business name and business address; and
 - (ii) the date on which the drug is dispensed; and
 - (iii) the unique identifier applicable to the drug; and
- (b) must, on the day on which the drug is dispensed, record—
 - (i) the unique identifier applicable to the drug dispensed on the prescription; and
 - (ii) his or her name as the dispenser; and
 - (iii) the date; and
 - (iv) the trade name or the approved name of the drug, or, if it does not have either a trade or approved name, its ingredients; and
 - (v) —
 - (A) the full name and address of the person for whose use the drug is dispensed; or

- (B) where the drug is intended for an animal—the species of animal for which it is intended, the name and address of the owner of the animal and the name (if any) of the animal; and
- (vi) the form, strength and quantity of the dispensed drug; and
- (vii) the directions given for the safe and proper use of the dispensed drug; and
- (viii) the name, address and business telephone number of the person who prescribed the drug; and
- (ix) the number of times the prescription may be dispensed and (where the prescription so specifies) the intervals at which the drug may be dispensed; and
- (c) if the prescription is for a schedule 4 poison and does not specify the number of times the drug is to be dispensed, must—
 - (i) dispense it once only pursuant to that prescription; and
 - (ii) write "CANCELLED" on the prescription; and
 - (iii) unless it is for any reason forwarded to the Department or the Minister, retain the original or duplicate prescription (as the case may be) for at least one year and have it readily available for inspection during that period; and
- (d) if the prescription specifies the number of times and the intervals at which the drug may be dispensed—must not dispense the drug more times than the number specified or at intervals less than those specified; and
- (da) if the prescription specifies the number of times but not the intervals at which the drug may be dispensed—must not dispense the drug more frequently than he or she considers appropriate; and
- (e) in the case of a prescription for a drug of dependence, must, each time the drug is dispensed, except where the drug is fully dispensed, forward a copy of the prescription to the CEO no later than the 7th day of the month following the month in which the drug was so dispensed or such later date as the CEO may, on application by the pharmacist or medical practitioner, authorise; and
- (f) where a prescription is fully dispensed, must—
 - (i) on the day on which the prescription is fully dispensed, write "CANCELLED" on the prescription; and
 - (ii) —
- (A) in the case of a prescription for a drug of dependence, forward it to the CEO no later than the 7th day of the month following the month in which the drug was so dispensed or such later date as the CEO may, on application by the pharmacist or medical practitioner, authorise;
- (B) in any other case, retain the original or duplicate prescription (as the case may be), for at least two years and have it readily available for inspection during that period.

Maximum penalty: \$5 000.

Controlled Substances (Poisons) Regulations 1996

(1a) A pharmacist in charge of a pharmacy at which no drugs of dependence are dispensed for a period of 30 consecutive days must, no later than the 7th day of the month following the month during which the 30th day of that period falls, notify the CEO of that fact in writing.

Maximum penalty: \$5 000.

(2) If a prescription has been issued in duplicate and the original is retained by the pharmacist or medical practitioner, it is sufficient compliance with this regulation if the required information is marked on the duplicate prescription.

(3) Despite subregulation (1)(d), if a pharmacist or medical practitioner is satisfied that a person—

- (a) has lost a previously dispensed supply of a drug; or
- (b) will, through absence from the State or otherwise, find it unduly difficult to have future supplies of a drug dispensed as needed,

he or she may (but is not obliged to) dispense a prescription for the person at an interval earlier than that specified on the prescription.

(4) If, pursuant to subregulation (3), a pharmacist or medical practitioner dispenses a drug of dependence at an earlier interval than that specified on the prescription, the pharmacist or practitioner must notify the prescriber of that fact in writing.

(5) A pharmacist or medical practitioner must not dispense a prescription for a drug—

- (a) if the prescription—
 - (i) is presented—
 - (A) in the case of a drug of dependence—more than 6 months after the date on which it was written; or
 - (B) in any other case—more than 12 months after the date on which it was written; or
 - (ii) has been cancelled; or
 - (iii) is partly or wholly illegible; or
 - (iv) does not comply with the Act or regulations; or
- (b) if there are reasonable grounds for suspecting that the prescription has been altered, forged or obtained by false pretences; or
- (c) unless—
 - (i) in the case of a prescription that is to be dispensed for the first or only time—an original prescription is presented; or

- (ii) in the case of a prescription that is to be dispensed for the second or subsequent time—
 - (A) the original prescription and a written record (whether made on the prescription or on a separately attached repeat authorisation) of the number of times the drug has been dispensed are presented; or
 - (B) a duplicate or copy of the prescription and a written record (made both on the duplicate or copy (as the case may be) and on a separately attached repeat authorisation) of the number of times the drug has been dispensed are presented.

Maximum penalty: \$5 000.

- (6) A pharmacist or medical practitioner must not, in respect of a drug of dependence—
 - (a) dispense more than 2 days' supply of the drug unless at least one of the following applies:
 - (i) the person for whose use the drug is prescribed is known to the pharmacist or practitioner; or
 - (ii) the pharmacist or practitioner recognises the signature on the prescription as that of the prescriber who purportedly gave the prescription; or
 - (iii) the pharmacist or practitioner has verified with the prescriber who purportedly gave the prescription that the prescription was in fact given by that prescriber; or
 - (b) hand over the dispensed drug until—
 - (i) the person for whose use the drug is dispensed has signed and dated the prescription and, unless the person is known to the pharmacist or practitioner, has produced satisfactory evidence of his or her identity; or
 - (ii) an agent acting on behalf of the person for whose use the drug is intended has signed and dated the prescription and, unless the agent is known to the pharmacist or medical practitioner, has produced satisfactory evidence of his or her identity.

Maximum penalty: \$5 000.

- (7) In this regulation—

"fully dispensed", in relation to a prescription, means dispensed for the only or, in the case of a prescription that authorises the drug to be dispensed more than once, for the last time.

Controlled Substances (Poisons) Regulations 1996

**PART 5
SPECIAL PROVISIONS RELATING TO CERTAIN S4 DRUGS**

Prescribed professions (s. 18(1)(b))

28. (1) Subject to the limitations set out in this regulation, the following professions are prescribed professions for the purposes of section 18(1)(b) of the Act:

Chiropody;
Dental therapy;
Optometry.

(2) Subject to subregulation (3), a chiropodist or dental therapist may only administer an S4 drug listed in clause 1 of Schedule I of these regulations.

(3) A chiropodist who is a surgical podiatrist may, for the purpose of podiatric treatment, prescribe, supply or administer an S4 drug that is listed in schedule J of these regulations in a form and quantity that complies with that schedule.

(4) An optometrist may only administer an S4 drug listed in clause 2 of schedule I of these regulations.

Additional requirements for S4 drugs listed in schedule K (s. 18(2))

29. (1) For the purposes of section 18(2) of the Act—

- (a) the S4 drugs listed in schedule K of these regulations are prescribed prescription drugs; and
- (b) the qualifications and authorisations referred to in subregulations (2), (3) and (4) are prescribed qualifications.

(2) A person must not prescribe for human use an S4 drug that is listed in clause 1 of schedule K of these regulations unless he or she is a medical practitioner who—

- (a) is a specialist in endocrinology; or
- (b) is a specialist in obstetrics and gynaecology; or
- (c) provides services to a fertility unit, an endocrinology unit or obstetrics and gynaecology unit of a teaching hospital in South Australia.

(3) A person must not prescribe for human internal use an S4 drug that is listed in clause 2 of schedule K of these regulations unless he or she is a medical practitioner who—

- (a) is a specialist in dermatology; or
- (b) is a specialist in another field and is authorised to prescribe such drugs by the Minister.

(4) A person must not prescribe for human use an S4 drug that is listed in clause 3 of schedule K of these regulations unless he or she is a medical practitioner who is authorised by the Minister to prescribe that drug for a specified patient.

(5) Where a medical practitioner prescribes an S4 drug that is listed in clause 2 or 3 of schedule K of these regulations, he or she must—

- (a) inform the patient of the name of the drug and that the drug may cause birth defects; and

- (b) provide the patient with written information about the drug and its potential side effects; and
- (c) inform the patient of the dangers should the patient unlawfully supply the drug to another person; and
- (d) where the patient is a female of child-bearing age—
 - (i) ensure that the possibility of pregnancy has been excluded prior to commencement of treatment; and
 - (ii) inform her that she must not become pregnant during treatment or within the prescribed period after completion of treatment; and
- (e) obtain written consent for the treatment from the patient.

Maximum penalty: \$5 000.

(6) A person who sells or supplies for human internal use an S4 drug that is listed in clause 2 or 3 of schedule K of these regulations must include (in prominent print) on the label to be affixed to the package or container in which the drug is sold or supplied the following statement:

"WARNING—Causes birth defects. Do not use if pregnant. Do not become pregnant during use or within [*insert prescribed period*] of stopping treatment."

Maximum penalty: \$5 000.

(7) In this regulation—

"**prescribed period**" means—

- (a) in the case of treatment with etretinate or acitretin—24 months;
- (b) in the case of treatment with isotretinoin, thalidomide or tretinoin—one month.

Additional requirements for Nalbuphine

30. (1) In relation to the S4 drug Nalbuphine—

- (a) a medical practitioner must not—
 - (i) prescribe Nalbuphine for use by a person for a period of more than two consecutive months without reporting details of the person's case and treatment to the Minister; or
 - (ii) prescribe a further dose of the drug for that person without an authority to do so from the Minister;
- (b) when a pharmacist cancels a prescription for Nalbuphine after dispensing the prescription for the drug for the last time, he or she must forward the cancelled prescription to the Department at the end of the month in which the drug was dispensed;
- (c) a medical practitioner, veterinary surgeon or pharmacist who sells or supplies Nalbuphine must record—
 - (i) the amount of Nalbuphine obtained by him or her and the name and address of the person from whom the drug was obtained; and

Controlled Substances (Poisons) Regulations 1996

- (ii) the quantity of any of the drug sold or supplied by him or her and the quantity remaining in his or her possession; and
- (iii) in the case of sale by a pharmacist, the name of the prescriber and the identification number of the prescription.

Maximum penalty: \$5 000.

(2) The holder of a wholesale dealers licence who sells Nalbuphine must record—

- (a) the quantities of Nalbuphine obtained by him or her; and
- (b) the quantities of Nalbuphine sold by him or her; and
- (c) the order numbers of the orders for any Nalbuphine.

Maximum penalty: \$3 000.

Exemptions from s. 18 of the Act

31. (1) Section 18 of the Act does not apply to the supply of an S4 drug by a council or a health service to a person where the drug is provided pursuant to a community immunisation program run by the council or health service.

(2) Section 18 of the Act does not apply to a pharmacist in relation to the supply of an S4 drug (without dispensing a prescription) provided that—

- (a) the drug is supplied to a council or a health service for use in a community immunisation program and the pharmacist has received a written order for the drug from the council or health service; or
- (b) the drug is for use by a person who holds a licence to supply or administer an S4 drug and the pharmacist has received a written order for the drug from the licensee; or
- (c) the drug is supplied for the mass treatment of certain animals to the owner of the animals and—
 - (i) the pharmacist has received a written order for the drug from a veterinary surgeon; or
 - (ii) —
 - (A) the drug is an antibiotic; and
 - (B) the pharmacist has received a written order for the drug from an inspector appointed under the *Stock Act 1990*; and
 - (C) the written order is on a form approved by the Chief Inspector of Stock under that Act and has been countersigned by the Chief Inspector; or
- (d) the drug is supplied to a member of a profession authorised by the Act or these regulations to supply or administer S4 drugs and the pharmacist has received a written order for the drug from that person; or

- (e) the drug is authorised or required by the law of any place to be carried on board a ship and the pharmacist has received a written order for the drug from the master or medical officer of the ship; or
- (f) the drug is not one that is listed in schedule K of these regulations and the pharmacist—
 - (i) is satisfied that—
 - (A) the person for whom it is to be supplied is being medically treated with the drug; and
 - (B) the continued supply of that drug is essential to the health of that person; and
 - (C) there is good reason for the person's inability to produce a prescription for the drug; and
 - (ii) supplies—
 - (A) in the case of a drug that is a cream, ointment or liquid or one that is packaged in such a manner as to promote the safe and proper use of the drug—the smallest standard package or container made by the manufacturer; or
 - (B) in any other case—no more than three days' dosage of the drug; and
 - (iii) on the day on which the drug is supplied, records—
 - (A) his or her name as the supplier of the drug; and
 - (B) the date; and
 - (C) the trade name or the approved name of the drug, or, if it does not have either a trade or approved name, its ingredients; and
 - (D) the name and address of the person for whom the drug is supplied; and
 - (E) the form, strength and quantity of the drug; and
 - (F) the directions given for the safe and proper use of the drug, including (where appropriate) the route of administration of the drug.

(3) In this regulation—

"**council**" means a council constituted under the *Local Government Act 1934*.

Controlled Substances (Poisons) Regulations 1996

**PART 5A
SPECIAL PROVISIONS RELATING TO DRUGS OF DEPENDENCE**

Interpretation

31A. (1) In this Part, unless the contrary intention appears—

"**health service pharmacy**" means a pharmacy that is part of a health service;

"**order**" means an order other than a prescription, and "**to order**" has a corresponding meaning;

"**supplier**" means a pharmacist or a licensed manufacturer, licensed wholesale dealer or other person licensed under the Act to supply drugs of dependence;

"**ward of a health service**" means a ward, clinic, unit, operating theatre or any other section of a health service in which persons receive medical or dental treatment.

(2) For the purposes of this Part—

(a) a reference to the administration of a drug is, where the drug is administered continuously over an extended period (eg. by means of an intravenous drip or pump) a reference to the commencement of administration by that means;

(b) the medical practitioner or dentist **principally responsible** for the treatment of a person is the practitioner or dentist having, for the time being, the greatest input in the determination of the course of treatment of the person.

Special restrictions on prescription or supply of drugs of dependence by medical practitioners, dentists and veterinary surgeons

31B. (1) A medical practitioner or dentist must not, except in a verifiable emergency—

(a) prescribe or supply a drug of dependence for use by a person without having first examined the person; or

(b) prescribe or supply a drug of dependence for use by himself or herself; or

(c) prescribe or supply a drug of dependence for use by his or her spouse, parent, grandparent, child, grandchild, brother or sister unless authorised to do so by the Minister.

(2) A veterinary surgeon must not, except in a verifiable emergency, prescribe or supply a drug of dependence for an animal without having first examined the animal.

(3) In this regulation—

"**spouse**" includes putative spouse (whether or not a declaration of the relationship has been made under the *Family Relationships Act 1975*).

Additional requirements for prescribers of drugs of dependence

31C. (1) A prescriber must not prescribe or supply for use by a person who the prescriber knows or has reasonable cause to believe is dependent on drugs (or prohibited substances), a schedule 2, 3 or 4 poison that contains a poison listed in schedule 8, for the purposes of maintaining or treating the person's dependence unless the prescriber prescribes or supplies the drug in accordance with an authority granted by the Minister.

Note: Section 55 of the Act provides that the Minister may grant an authority subject to such conditions as the Minister thinks fit and specifies in the authority and may at any time, by notice in writing given personally or by post to the holder, vary or revoke a condition, or attach a further condition, to the authority.

Manufacturers of drugs of dependence to record stocks

31D. A person who manufactures a drug of dependence must, immediately after the drug is manufactured, record the following details:

- (a) the date of manufacture; and
- (b) the trade name or the approved name of the drug or, if it does not have either a trade or approved name, its ingredients; and
- (c) the amount and, where applicable, the strength of the drug manufactured; and
- (d) the total amount of the drug now on the premises on which the drug was manufactured.

Supply of drugs of dependence in accordance with an order

31E. (1) A supplier who supplies a drug of dependence in accordance with an order—

- (a) must, immediately after the drug is supplied, record the following details and sign the record:
 - (i) the full name and address of the person who ordered the drug; and
 - (ii) the order number, if any; and
 - (iii) the date of supply; and
 - (iv) the trade name or approved name of the drug or, if it does not have either a trade or approved name, its ingredients; and
 - (v) the amount and, where applicable, the strength of the drug supplied; and
 - (vi) the total amount of the drug (if any) now remaining in the possession of the supplier; and
- (b) must—
 - (i) in the case of an order in writing—
 - (A) as soon as practicable after supplying the drug, cancel the order by writing "CANCELLED" on it; and
 - (B) unless exempted under subregulation (2), forward the cancelled order to the CEO no later than the 7th day of the month following the month in which the drug was supplied or such later date as the CEO may, on application by the supplier, authorise;
 - (ii) in any other case, unless exempted under subregulation (2), forward, no later than the 7th day of the month following the month in which the drug was supplied or such later date as the CEO may, on application by the supplier, authorise, a written notice giving details of the supply of the drug pursuant to the order.

Controlled Substances (Poisons) Regulations 1996

(2) The requirement to forward an order or notice to the CEO under subregulation (1)(b) does not apply to—

- (a) licensed manufacturers or licensed wholesale dealers; or
- (b) pharmacies (including health service pharmacies) in respect of the supply of drugs of dependence to a health service.

(3) A supplier must not supply a drug of dependence in accordance with an order—

- (a) unless the supplier has reasonable cause to believe that the person who ordered the drug is lawfully authorised to do so; and
- (b) unless the person receiving the drug—
 - (i) provides the supplier with a signed and dated receipt for the drug; and
 - (ii) is known to the supplier or produces satisfactory evidence of his or her identity.

(4) A supplier must not supply a drug of dependence where the drug is authorised or required by the law of any place to be carried on board a ship unless the supplier has received a written order for the drug from the master or medical officer of the ship.

Persons receiving drugs of dependence on order to record details

31F. A person who receives from a supplier on order a drug of dependence must, immediately after taking delivery of the drug—

- (a) provide the supplier with a signed and dated receipt for the drug; and
- (b) record the following details and sign the record:
 - (i) the name of the person taking delivery of the drug; and
 - (ii) the trade or approved name or, if it does not have either a trade or approved name, its ingredients; and
 - (iii) the amount and, where applicable, the strength of the drug; and
 - (iv) the date; and
 - (v) the name and business address of the supplier of the drug; and
 - (vi) the total amount of the drug now in stock on the premises at which the drug is received.

Supply or administration of drugs of dependence by medical practitioner, dentist or registered nurse

31G. (1) A medical practitioner, dentist or registered nurse who supplies (other than by dispensing a prescription) for use by a person or administers a drug of dependence to a person must, immediately after the drug is so supplied or administered, record the following details and sign the record:

- (a) his or her name; and

- (b) the full name and address (or, in the case of a patient in a ward of a health service, the location of the ward) of the person to whom the drug is supplied or administered; and
- (c) in the case of the supply of the drug to a person acting on behalf of the person for whose use the drug is intended, the full name and address of the person for whose use the drug is intended; and
- (d) the trade name or approved name of the drug or, if it does not have either a trade or approved name, its ingredients; and
- (e) the amount and, where applicable, the strength of the drug supplied or administered; and
- (f) the date; and
- (g) the time at which the drug was supplied or administered; and
- (h) the amount of the drug (if any) now in stock on the premises at which the drug is administered or otherwise in the possession of the practitioner, dentist or nurse.

(2) Where an error is discovered in such a record, it must be corrected in the following way by a person authorised under subregulation (1) to make the record:

- (a) it must not be deleted, whited out with correction fluid or erased; and
- (b) it must be ruled out or otherwise marked so as to still be clearly legible after it has been so ruled out or marked; and
- (c) a footnote or margin note reference must be made alongside the error; and
- (d) the footnote or margin note must—
 - (i) be made on the same page as the page on which the error occurs; and
 - (ii) contain the correct information and the date of the correction; and
 - (iii) be endorsed with the name and signature of the person making the correction.

Supply or administration of drugs of dependence by veterinary surgeon

31H. A veterinary surgeon who supplies (other than by dispensing a prescription) a drug of dependence for an animal or administers such a drug to an animal must, on the day on which the drug is so supplied or administered, record the following details and sign the record:

- (a) his or her name; and
- (b) the species of animal for which the drug is supplied or administered, the name and address of the owner of the animal and the name (if any) of the animal; and
- (c) the trade name or approved name of the drug or, if it does not have either a trade or approved name, its ingredients; and
- (d) the amount and, where applicable, the strength of the drug administered or supplied; and
- (e) the date; and
- (f) the time at which the drug was supplied or administered; and

Controlled Substances (Poisons) Regulations 1996

- (g) the amount of the drug (if any) now remaining in stock on the premises at which the drug is supplied, administered or otherwise in the possession of the veterinary surgeon.

Additional requirements for administration of drugs of dependence in health service

31L. (1) The administration of a drug of dependence to a person in a health service must be carried out in accordance with the following additional provisions:

- (a) the medical practitioner or dentist principally responsible for the treatment of the person while in the health service must ensure that the prescribed instructions in respect of the drug are included in the person's medication record and that he or she endorses the relevant entries with his or her name and signature;
- (b) the drug must be administered to the person in accordance with all instructions in the person's medication record;
- (c) the drug must not be administered to the person—
 - (i) unless the administration is witnessed by a nurse, or, where a nurse is not reasonably available, by some other responsible person; or
 - (ii) for a period exceeding 30 consecutive days without renewal of the instructions by the medical practitioner or dentist (as the case may be) principally responsible for the treatment of the person;
- (d) the practitioner, dentist or registered nurse who administers the drug must, immediately after doing so, ensure that the name and signature of the person who witnessed the administration of the drug is recorded;
- (e) if a medical practitioner or dentist gives prescribed instructions by telephone as to the administration of a drug of dependence to a person in a health service—
 - (i) the practitioner or dentist must give the instructions to a registered nurse and one other responsible person employed by the health service; and
 - (ii) the registered nurse must, immediately after receiving the instructions by that method, ensure that the following information is recorded in the person's medication record and sign the record:
 - (A) his or her full name; and
 - (B) the prescribed instructions in respect of the drug; and
 - (C) the words "by telephone"; and
 - (D) the date upon which the telephone instructions were given; and
 - (E) the name of the medical practitioner or dentist who gave the telephone instructions; and
 - (F) the name and signature of the other person to whom the instructions were given in accordance with subparagraph (i); and

- (iii) the practitioner or dentist must, within 48 hours of giving the instructions by that method, endorse the relevant entries in the medication record with his or her signature and the date.

(2) The registered nurse in charge of a ward of a health service during a particular shift must ensure that the following additional record-keeping requirements are met in respect of drugs of dependence in the ward:

- (a) all relevant records required to be kept under these regulations in respect of those drugs must be kept in the ward; and
- (b) all drugs of dependence must be counted at the end of the shift and—
 - (i) if the balance in respect of a particular drug is found to be correct, the word "correct", the time and date and the nurse's name and signature must be recorded alongside the entry for the drug;
 - (ii) if the balance in respect of a particular drug is found to be incorrect—
 - (A) the word "incorrect", a brief explanation of the discrepancy, if known, the time and date and the nurse's name and signature must be recorded alongside the entry for the drug; and
 - (B) the Director of Nursing or manager of the health service, and the health service pharmacist, if any, must be notified, as soon as practicable, that an incorrect amount of drugs is stored in the ward; and
- (c) the drugs count and records made under paragraph (b)—
 - (i) must be witnessed by the registered nurse in charge of the ward during the next shift and endorsed with his or her name and signature; or
 - (ii) must, if the next shift does not commence immediately after the previous shift—
 - (A) be witnessed by a nurse working on the same shift as the registered nurse who made the entry and be endorsed with the name and signature of the witnessing nurse; and
 - (B) be checked by the registered nurse in charge of the ward during the next shift at the commencement of that shift and be endorsed with his or her name and signature.

(3) The manager of a health service must take all reasonable steps to ensure that—

- (a) all drugs of dependence delivered to the health service or a ward of the health service are received by a medical practitioner, dentist or registered nurse employed by the health service or, if such a practitioner, dentist or nurse is not reasonably available, by some other responsible person; and
- (b) an accurate and up-to-date balance of stocks of all drugs of dependence in each ward of the health service is maintained at all times; and
- (c) the requirements of this regulation are complied with.

Controlled Substances (Poisons) Regulations 1996

(4) In this regulation—

"**health service pharmacist**" means the pharmacist in charge of a health service pharmacy;

"**prescribed instructions**", in respect of a drug, means the form and strength of the drug and the route, frequency and duration of administration of the drug.

Destruction of drugs of dependence

31J. (1) Subject to this regulation or any order of a court, a person must not destroy a drug of dependence unless—

- (a) the destruction is witnessed by another person, being an authorised officer, police officer, medical practitioner, dentist, veterinary surgeon, pharmacist or nurse; and
- (b) the person destroying the drug ensures that the following information is recorded in respect of the drug immediately after its destruction:
 - (i) the full names and the signatures of the person and the witness to the destruction; and
 - (ii) the trade name or approved name of the drug or, if it did not have either a trade or approved name, its ingredients; and
 - (iii) the amount and, where applicable, the strength of the drug; and
 - (iv) the date and time of the destruction; and
 - (v) the amount of the drug (if any) now remaining in stock on the premises at which the destroyed drug was stored.

(2) This regulation does not apply to the destruction of a drug of dependence by—

- (a) a person for whose use the drug was lawfully prescribed or supplied; or
- (b) a member of the police force or an authorised officer.

Prescribed amounts (s. 32(3) and (5))

31K. (1) For the purposes of section 32(3) of the Act, the prescribed amount of a drug of dependence is the amount listed in the second column of Schedule KA opposite the entry listing the drug of dependence.

(2) For the purposes of section 32(5) of the Act, the prescribed amount of a drug of dependence (not being cannabis or cannabis resin) is the amount listed in the second column of Schedule KB opposite the entry listing the drug of dependence.

Exemptions from s. 33 of the Act

31L. (1) Section 33 of the Act does not apply to the prescription or supply by a medical practitioner of a drug of dependence for use by—

- (a) a person of or over 70 years of age, provided that the drug to be prescribed or supplied is not dextromoramide, hydromorphone or pethidine; or

- (b) a person whose life expectancy is reasonably believed, by the medical practitioner principally responsible for treatment of the person, to be less than 12 months, provided that—
- (i) the drug to be prescribed or supplied is not dextromoramide, hydromorphone or pethidine; and
 - (ii) the medical practitioner has informed the Minister of the person's name and address, date of birth and the nature of the condition for which the drug is prescribed or supplied; and
 - (iii) each prescription (if any) is endorsed either "Notified Palliative Care Patient" or "NPCP"; or
- (c) a person receiving treatment in a hospital in respect of whom a section 33 authority exists, provided that—
- (i) the practitioner notifies the authorised prescriber that the practitioner has prescribed or supplied the drug or is intending to prescribe or supply the drug in respect of the person; and
 - (ii) the drug is only administered to the person while in hospital; and
 - (iii) if the drug is solely for the treatment of drug dependence, the dose administered does not exceed the dose authorised; or
- (d) any other person in respect of whom a section 33 authority exists, provided that the medical practitioner prescribing or supplying the drug—
- (i) is a medical practitioner (including a locum for the time being substituting for such a practitioner) in the same practice as the authorised prescriber; and
 - (ii) does so with the approval of the authorised prescriber; or
- (e) a person who is receiving treatment in a public hospital in respect of whom a section 33 authority does not exist, provided that the duration of the treatment of the person with the drug while the person is in hospital does not exceed 14 days.

(3) In this regulation—

"authorised prescriber" means the holder of a section 33 authority;

"section 33 authority" means an authority granted by the Minister to a medical practitioner under section 33 of the Act to prescribe or supply a drug of dependence.

Non-compliance with Part 5A an offence

31M. A person who contravenes or fails to comply with a regulation under this Part, for breach of which no penalty is specified, is guilty of an offence and liable to a penalty not exceeding \$5 000.

Controlled Substances (Poisons) Regulations 1996

**PART 6
SPECIAL PROVISIONS RELATING TO PRECURSOR CHEMICALS**

Prohibition of manufacture, sale, possession, etc., of certain precursor chemicals

32. A person must not, unless he or she holds a permit from the Minister to do so, manufacture, sell, supply or be in possession of a poison listed in schedule B of these regulations.

Maximum penalty: \$5 000.

Strict regulation of storage and sale of certain precursor chemicals

33. (1) This regulation applies to the following poisons:

Acetic anhydride
Bromobenzene
Cathine (nor-pseudoephedrine)
Ephedrine
Ethyl phenylacetate
Hydriodic acid
Hypophosphorous acid
Isosafrole
Methyl phenylacetate
N-methylephedrine
N-methylpseudoephedrine
Phenyl-2-propanone
Phenylacetamide
Phenylacetic acid
Phenylacetonitrile
Phenylacetyl chloride
Phenylpropanolamine
Phosphorus, red
Piperonal
Pseudoephedrine
Safrole.

(2) A person must not sell a poison to which this regulation applies to another person unless—

- (a) the purchaser holds an account with the seller; and
- (b) the sale is transacted as a sale on account pursuant to a duly completed order form supplied by the purchaser; and
- (c) the order form is accompanied by a duly completed end user statement in the form set out in schedule L of these regulations; and
- (d) the seller is satisfied, on the production of a driver's licence, passport or other sufficient evidence, as to the identity of the person collecting the poison and that the person is the purchaser or is acting on behalf of the purchaser; and
- (e) the seller duly completes the seller's section of the end user statement.

Maximum penalty: \$5 000.

- (3) A seller of poisons to which this regulation applies—
- (a) must, in relation to each sale of such a poison, keep a record of—
 - (i) the name and address of the purchaser; and
 - (ii) the name of the poison and the quantity sold; and
 - (iii) the date of the sale; and
 - (b) must retain an end user statement for at least five years after the date of the sale to which it relates; and
 - (c) must make the record referred to in paragraph (a) and the end user statements available for inspection at any time by an authorised officer under the Act; and
 - (d) must, if at any time he or she forms a suspicion that an order or enquiry for the purchase of such a poison may be connected to an unlawful use of the poison, inform the Commissioner of Police of the suspicion.

Maximum penalty: \$3 000.

- (4) A seller of poisons to which this regulation applies—
- (a) must keep those poisons in storage that is secure from access by any person other than a person who is authorised in writing by the seller to have such access; and
 - (b) must retain such a written authorisation while it is current and for at least five years after it ceases to have effect and make it available for inspection at any time by an authorised officer under the Act; and
 - (c) must cause the stock of those poisons to be checked, after each sale, by some person other than the person who directly handled the sale.

Maximum penalty: \$3 000.

(5) This regulation does not apply in relation to the sale of a poison to which this regulation applies if the sale—

- (a) is of a poison contained in a preparation designed, packaged and labelled for human or animal therapeutic use; and
- (b) is made to, or by, a medical practitioner, dentist, veterinary surgeon, nurse, optometrist or pharmacist acting in the ordinary course of his or her profession.

Regulation of sale of other precursor chemicals

34. (1) This regulation applies to the following poisons:

N-acetylanthranilic acid
Anthranilic acid
Benzaldehyde
Benzyl chloride
Boron tribromide
Ethylamine
N-ethylephedrine

Controlled Substances (Poisons) Regulations 1996

N-ethylpseudoephedrine
Formamide
Methylamine
Nitroethane
3-Phenyl-1-propene
Piperidine
Propionic anhydride
Pyridine.

(2) A person must not sell a poison to which this regulation applies to another person unless—

- (a) the purchaser provides the seller with a duly completed end user statement in the form set out in schedule L of these regulations; and
- (b) the seller is satisfied, on the production of a driver's licence, passport or other sufficient evidence, as to the identity of the purchaser; and
- (c) the seller duly completes the seller's section of the end user statement.

Maximum penalty: \$3 000.

(3) A seller of poisons to which this regulation applies must, if at any time he or she forms a suspicion that an order or enquiry for the purchase of such a poison may be connected to an unlawful use of the poison, inform the Commissioner of Police of the suspicion.

Maximum penalty: \$3 000.

(4) This regulation does not apply in relation to the sale of a poison to which this regulation applies if the sale—

- (a) is of a poison contained in a preparation designed, packaged and labelled for human or animal therapeutic use; and
- (b) is made to, or by, a medical practitioner, dentist, veterinary surgeon, nurse, optometrist or pharmacist acting in the ordinary course of his or her profession.

**PART 7
OTHER OFFENCES**

Restriction on giving samples of poisons

35. (1) Subject to this regulation, a person must not promote a poison for human, or animal, therapeutic use by supplying samples of the poison.

Maximum penalty: \$5 000.

(2) The holder of a manufacturers licence or wholesale dealers licence may give a sample of a poison for human, or animal, therapeutic use to a medical practitioner, dentist, veterinary surgeon, podiatrist, optometrist, dental therapist or pharmacist.

(3) A medical practitioner, dentist, veterinary surgeon, podiatrist, optometrist or dental therapist acting in the ordinary course of his or her profession may give to a person a sample of a poison for human, or animal, therapeutic use.

(4) A pharmacist acting in the ordinary course of his or her profession may give to a person a sample of a poison (other than an S4 drug) for human, or animal, therapeutic use.

(5) On each occasion that the holder of a manufacturers licence or wholesale dealers licence gives a sample of a poison, he or she must record—

- (a) the date on which the sample of poison was supplied; and
- (b) the name and address of the person supplied; and
- (c) the trade name or the approved name of the poison supplied, or if it has neither a trade nor an approved name, its ingredients; and
- (d) the quantity of the poison supplied.

Maximum penalty: \$3 000.

(6) Nothing in this regulation empowers any person to give a sample of a schedule 8 poison.

Offences relating to sale or supply of poisons

36. (1) A person must not sell or supply a poison in any residential premises, or from door to door, or in a public place.

(2) A person must not sell or supply a poison in a container that—

- (a) is normally used for containing food or beverages; or
- (b) is similar to a container that is normally used for containing food or beverages.

(3) A person must not sell camphor or naphthalene in block, ball, disc or pellet form for domestic use unless the blocks, balls, discs or pellets are enclosed in a device that restricts removal or ingestion of its contents.

(4) A person must not sell any liquid preparation or admixture containing paraquat unless it is coloured blue or green and contains a stenching agent in sufficient quantity to produce an offensive odour.

Controlled Substances (Poisons) Regulations 1996

(5) A person who contravenes or fails to comply with this regulation is guilty of an offence.

Maximum penalty: \$5 000.

(6) In this regulation—

"**public place**" includes—

- (a) a place to which free access is permitted to the public, with the express or tacit consent of the owner or occupier of that place; and
- (b) a place to which the public are admitted on payment of money, the test of admittance being the payment of money only; and
- (c) a road, street, footway, court, alley or thoroughfare that the public are allowed to use, notwithstanding that the road, street, footway, court, alley or thoroughfare is on private property.

Offence to dispose of poison

37. A person must not dispose of or use, or cause to be disposed of or used, a poison in any place or manner that constitutes, or is likely to constitute, a risk to public health or safety.

Maximum penalty: \$5 000.

Keeping of records, etc.

38. (1) Subject to these regulations, a person who is required by these regulations to keep certain records must—

- (a) in respect of any entry in the records, retain the records at the registered address of the business in this State for a period of two years from the day on which the entry was made; and
- (b) have the records readily available for inspection at all reasonable times; and
- (c) during that period, take all reasonable steps to ensure that the records are protected against deterioration, loss, theft and unauthorised access, modification or use.

Maximum penalty: \$3 000.

(2) Where the information contained in the records is available only after the record is subjected to an electronic or other process, it is sufficient for the purposes of subregulation (1)(b) for the person to produce for inspection a reproduction or computerised record of any entry in the records.

(3) Where details are to be recorded under these regulations in respect of drugs of dependence, they must, unless otherwise specified, be recorded in a drugs of dependence register in a form approved by the Minister.

(4) A receipt required to be provided to a person under these regulations must be kept by that person in the manner set out in this regulation as if it were a record.

False information

39. A person who, in providing any information required under these regulations, furnishes any information that is false or misleading in a material particular is guilty of an offence.

Maximum penalty: \$5 000.

Vicarious liability

40. For the purposes of these regulations, an act or omission of an employee or agent will be taken to be the act or omission of the employer or principal unless it is proved that the act or omission did not occur in the course of the employment or agency.

Controlled Substances (Poisons) Regulations 1996

**PART 8
MISCELLANEOUS**

Personal identification code equivalent to signature

40A. (1) Where a provision of these regulations requires a person to sign a record or receipt that is in electronic form, evidence on the record or receipt that the person has entered his or her personal identification code will be taken to be sufficient compliance by that person with the requirement.

(2) In this regulation—

"**personal identification code**" means a code that—

- (a) is allotted to a person by his or her employer for use by that person in connection with official duties; and
- (b) is known only by that person and such other persons as may be authorised by the employer for management purposes.

Analysis of substance (s. 53)

41. (1) A person who initiates an analysis pursuant to section 53(2) of the Act, must do so by notice in writing that—

- (a) is signed by him or her; and
- (b) is addressed to a person appointed as an analyst under the Act; and
- (c) describes the substance to be analysed; and
- (d) is accompanied by the appropriate fee set out in schedule D of these regulations.

(2) A Certificate of Analysis must be given in the form set out in schedule M of these regulations.

Research permit

42. An application for a research permit under section 56 of the Act must be made in writing to the Minister and be signed by the applicant.

Copies of codes, etc., to be kept available for public inspection

43. For the purposes of section 63(5a) of the Act, the office of the Department at 11-13 Hindmarsh Square, Adelaide is the place at which copies of codes, standards, etc., must be kept and made available for inspection by members of the public.

Transitional provision—licences

44. A hospital or nursing home is exempted until 1 June 1996 from the requirement to hold a licence under section 18 of the Act in respect of supplying or administering an S4 drug to a patient in the hospital or nursing home.

SCHEDULE A
Modification of the Uniform Poisons Standard
(Regulation 5)

The *Uniform Poisons Standard* is to be read as if—

1. Part 3 were struck out.
2. Part 4 were varied—
 - (a) by the entry in schedule 2 relating to ATROPA BELLADONNA being struck out;
 - (b) by the entry in schedule 2 relating to ATROPINE being struck out and the following entry being substituted:

ATROPINE (excluding atropine methonitrate):

 - (a) in preparations containing 0.25 per cent or less of atropine; or
 - (b) in tablets, each containing 0.6 mg of atropine sulfate, in a pack that contains 20 tablets and is labelled for treatment of organophosphorus poisoning.;
 - (c) by the following entry being inserted alphabetically in schedule 2:

BELLADONNA in preparations containing 0.25 per cent or less of the alkaloids of belladonna.;
 - (d) by the entries in schedule 2 relating to DATURA STRAMONIUM and DATURA TATULA being struck out and the following entry being substituted:

DATURA spp. in preparations containing 0.25 per cent or less of the alkaloids of datura.;
 - (e) by the entries in schedule 2 relating to DUBOISIA LEICHARDTII and DUBOISIA MYOPOROIDES being struck out and the following entries being substituted:

DUBOISIA LEICHARDTII in preparations containing 0.25 per cent or less of the alkaloids of duboisia.

DUBOISIA MYOPOROIDES in preparations containing 0.25 per cent or less of the alkaloids of duboisia.;
 - (f) by the entry in schedule 2 relating to HYOSCINE being struck out and the following entry being substituted:

HYOSCINE (excluding hyoscine butylbromide):

 - (a) in preparations containing 0.25 per cent or less of hyoscine; or
 - (b) in transdermal applicators containing 2 mg or less of hyoscine.;
 - (g) by the entries in schedule 2 relating to HYOSCYAMINE and HYOSCYAMUS NIGER being struck out and the following entries being substituted:

HYOSCYAMINE in preparations containing 0.25 per cent or less of hyoscyamine.

HYOSCYAMUS in preparations containing 0.25 per cent or less of the alkaloids of hyoscyamus.;
 - (h) by inserting the following item alphabetically in schedule 2:

STRAMONIUM in preparations containing 0.25 per cent or less of the alkaloids of stramonium, **except** in preparations for smoking or burning.;
 - (i) by the entry in schedule 4 relating to ATROPA BELLADONNA being struck out;
 - (j) by inserting the following entry alphabetically in schedule 4:

BELLADONNA **except** when included in Schedule 2.;
 - (k) by the entries in schedule 4 relating to DATURA STRAMONIUM and DATURA TATULA being struck out;

Controlled Substances (Poisons) Regulations 1996

- (l) by the entry in schedule 4 relating to DUBOISIA LEICHARDTII being struck out and the following entry being substituted:

DUBOISIA LEICHARDTII **except** when included in Schedule 2.;

- (m) by the entry in schedule 4 relating to HYOSYCAMUS NIGER being struck out and the following entry being substituted:

HYOSCYAMUS **except** when included in Schedule 2.;

- (n) by inserting the following entry alphabetically in schedule 4:

STRAMONIUM **except**:

- (a) when included in Schedule 2; or
- (b) in preparations for smoking or burning.;

- (o) by the following entries in schedule 8 being struck out:

ACETYLMORPHINES
CONCENTRATE OF POPPY STRAW
4-CYANO-1-METHYL-4-PHENYLPYPERIDINE
1-METHYL-4-PHENYLPYPERIDINE-4-CARBOXYLIC ACID
4-PHENYLPYPERIDINE-4-CARBOXYLIC ACID ETHYL ESTER;

- (p) by the following entry being inserted alphabetically in schedule 8:

MORAMIDE;

- (q) by schedule 9 being struck out.

3. Part 5 were varied by the following Appendices being struck out:

B, D, and J.

SCHEDULE B

Precursor chemicals declared as Poisons (Possession and Sale Prohibited)
(Regulations 6 and 32)

Ephedrone
2-Chloro-1-phenylpropane
2-Nitro-1-phenyl-1-propene
2-Amino-1-chloro-1-phenylpropane
2-Bromo-1-phenylpropane
2-Iodo-1-phenylpropane
2-(N-methylamino)-1-chloro-1-phenylpropane
3,4-Methylenedioxyphenylpropan-2-one.

Controlled Substances (Poisons) Regulations 1996

SCHEDULE C

Precursor Chemicals declared as Poisons (Sale Regulated)
(Regulations 6, 33 and 34)

N-acetylanthranilic acid
Anthranilic acid
Benzaldehyde
Benzyl chloride
Boron tribromide
Bromobenzene
Ethyl phenylacetate
Ethylamine
N-ethylephedrine
N-ethylpseudoephedrine
Formamide
Hydriodic acid
Hypophosphorous acid
Isosafrole
Methylamine
Methyl phenylacetate
N-methylpseudoephedrine
Nitroethane
Phenyl-2-propanone
Phenylacetamide
Phenylacetic acid
Phenylacetonitrile
Phenylacetyl chloride
3-Phenyl-1-propene
Phosphorus, red
Piperidine
Piperonal
Propionic anhydride
Pyridine.

SCHEDULE D

Fees

(Regulations 10 and 41)

1. Annual fee for manufacturers licence—

(a) for a manufacturer who manufactures only schedule 1 poisons	0
(b) for a manufacturer who manufactures schedule 2 poisons	\$172
(c) for a manufacturer who manufactures schedule 3 poisons	\$172
(d) for a manufacturer who manufactures schedule 4 poisons	\$172
(e) for a manufacturer who manufactures schedule 5 poisons	\$115
(f) for a manufacturer who manufactures schedule 6 poisons	\$172
(g) for a manufacturer who manufactures schedule 7 poisons	\$172
(h) for a manufacturer who manufactures drugs of dependence	\$228

NB The maximum cumulative annual fee is

- for a manufacturer of poisons other than drugs of dependence—\$575
- for a manufacturer of drugs of dependence—\$700

2. Annual fee for wholesale dealers licence—

(a) for a wholesaler who sells only schedule 1 poisons	0
(b) for a wholesaler who sells schedule 2 poisons	\$56.50
(c) for a wholesaler who sells schedule 3 poisons	\$56.50
(d) for a wholesaler who sells schedule 4 poisons	\$115
(e) for a wholesaler who sells schedule 5 poisons	\$56.50
(f) for a wholesaler who sells schedule 6 poisons	\$56.50
(g) for a wholesaler who sells schedule 7 poisons	\$115
(h) for a wholesaler who sells drugs of dependence	\$228

NB The maximum cumulative annual fee is

- for a wholesaler who sells poisons other than drugs of dependence—\$287
- for a wholesaler who sells drugs of dependence—\$430

3. Annual fee for retail sellers licence \$115

4. Annual fee for medicine sellers licence \$28

5. Annual fee for a licence to supply or administer—

(a) an S4 drug (other than a drug of dependence)	\$56.50
(b) a drug of dependence	\$56.50

NB The maximum cumulative annual fee for a licence to supply or administer S4 drugs and drugs of dependence is \$77.50

6. Annual fee for licence to possess schedule F poisons \$85.50

7. Annual fee for licence to possess drugs of dependence or equipment (s. 31) \$56.50

Controlled Substances (Poisons) Regulations 1996

- 8. Annual fee for licence to sell (other than by wholesale dealing) or possess drugs of dependence (s. 32) \$56.50
- 9. Application fee for analysis of substance \$172

SCHEDULE E

*Schedule 2 Poisons Authorised to be Sold by Holder of a Medicine Sellers Licence
(Regulation 11(2))*

The following poisons are authorised to be sold by the holder of a medicine sellers licence:

Aciclovir	Gelsemium	Paracetamol (excluding packs of more than 50 dosage units)
Antazoline	Glutaraldehyde	Penciclovir
Aspirin (excluding packs of more than 50 dosage units)	Guaiphenesin	Phenazone
Atropine	Hexachlorophane	Pheniramine
Belladonna	Homatropine	Phenol
Benzamine	Hydroquinone	Phenylenediamines and alkylated phenylenediamines
Benzocaine	8-Hydroxyquinoline	Phenylephrine
Benzoyl peroxide	Hyoscyne	Pholcodine
Benzydamine	Hyoscyamine	Piroxicam
Bifonazole	Hyoscyamus	Prilocaine
Bromhexine	Ibuprofen	Promethazine
Brompheniramine	Indomethacin	Propranolol
Butylaminobenzoate	Iodine	Pseudoephedrine (excluding packs of more than 30 dosage units)
Carbenoxolone	Ipratropium	Pyrantel
Carbetapentane	Iron compounds	Salicylamide
Cetirizine	Ketoconazole	Silver salts
Chloroform	Ketoprofen	Sodium cromoglycate
Chlorpheniramine	Levocabastine	Staphisagria
Clotrimazole	Lignocaine	Stramonium
Codeine	Lindane	Terbinafine
Creosote	Lobeline	Tetrahydrozoline
Dexchlorpheniramine	Lobelia	Thenylamine
Dextromethorphan	Lodoxamide	Trimeprazine
Diclofenac	Loperamide	Tripolidine
Dicyclomine (excluding preparations for infants)	Loratadine	Tymazoline
Dihydrocodeine	Mebendazole	Xylometazoline.
Dimenhydrinate	Mefenamic acid	
Diphemanil methylsulphate	Mercuric oxide	
Diphenhydramine	Mercury organic compounds	
Diphenylpyraline	Methoxamine	
Doxylamine	Miconazole	
Econazole	Naphazoline	
Ether	Naproxen	
Ethylmorphine	Niclosamide	
Fexofenadine	Nystatin	
Fluorides	Oxethazaine	
	Oxymetazoline	
	Papaverine	

Controlled Substances (Poisons) Regulations 1996

SCHEDULE F

*Prescribed Poisons for the Purposes of s. 22 of the Act
(Regulation 16)*

Section 22 of the Act applies to the following poisons:

Acrolein
Arsenic when included in schedule 7
Chloropicrin
Cyanides when included in schedule 7
DDT
Fluoroacetamide
Fluoroacetic acid
Hydrocyanic acid when included in schedule 7
Methyl bromide
Mirex
Sodium fluoroacetate
Strychnine when included in schedule 7
Thallium.

SCHEDULE G

Schedule 3 Poisons to which Regulation 14(2) applies

Adrenaline (in metered aerosols)
Dihydrocodeine (in cough preparations)
Doxylamine (in preparations also containing codeine)
Promethazine (in preparations also containing codeine).

Controlled Substances (Poisons) Regulations 1996

SCHEDULE H

*Poisons that must be Packed in Child-resistant Containers
(Regulation 18)*

1. Poisons in the form of tablets, capsules, etc.—

ANTI-HISTAMINES—

Antazoline	Dexbrompheniramine	Methdilazine
Astemizole	Dexchlorpheniramine	Phenindamine
Azatadine	Dimenhydrinate	Pheniramine
Bamipine	Dimethindene	Phenyltoloxamine
Brompheniramine	Dimethothiazine	Promethazine
Bromodiphenhydramine	Diphenhydramine	Prothipendyl
Buclizine	Diphenidol	Pyrathiazine
Carbinoxamine	Diphenylpyraline	Pyroxamine
Cetoxime	Doxylamine	Pyrobutamine
Chlorocyclizine	Embramine	Rotoxamine
Chloropyrilene	Halopyramine	Terfenadine
Chlorpheniramine	Histapyrodine	Thenalidine
Chlorphenoxamine	Homochlorcyclizine	Thenylidamine
Cinnarizine	Hydroxyzine	Thiazinamium
Clemastine	Isothipendyl	Thonzylamine
Clemizole	Loratadine	Tolpropamine
Cycliramine	Mebhydroin	Trimeprazine
Cyclizine	Meclozine	Trimethobenzamid
Cyproheptadine	Mepyramine	Tripeleennamine
Deprorine	Methaphenilene	Triprolidine

TRICYCLIC ANTIDEPRESSANTS—

Amitriptyline	Imipramine	Monometacrine
Amoxapine	Intripyline	Nortriptyline
Butriptyline	Iprindole	Noxiptyline
Cidoxepin	Ketipramine	Octriptyline
Clomipramine	Lofepamine	Opipramol
Desipramine	Loxapine	Pirandamine
Dibenzepin	Maprotiline	Prazepine
Dothiepin	Melitracen	Protriptyline
Doxepin	Mezepine	Tandamine
Fantridone	Mianserin	Trimipramine

MONOAMINE OXIDASE INHIBITORS—

Iproniazid	Phenelzine
Isocarboxazid	Tranlycypromine

ANTIARRHYTHMICS—

Amiodarone	Mexiletine	Quinidine
Bretylum	Procainamide	Verapamil
Flecainide		

ANTICONVULSANTS—

Carbamazepine
Phenytoin

OTHER—

Aspirin	Glutethimide	Lithium carbonate
Chloroquine	Iron compounds (in substances	Orphenadrine
Digitalis glycosides	containing more than the equivalent of	Paracetamol
Diphenoxylate hydrochloride with	5mg of elemental iron in each solid	Quinine
atropine sulphate	dosage form)	Salicylamide
Fluoride salts in packs containing the		
equivalent of more than 100		
milligrams of elemental fluorine		

2. Poisons in liquid form—

Digitalis glycosides

Iron compounds (in preparations containing the equivalent of more than 250 mg of elemental iron in the total content of the container)

Paracetamol (in preparations where paracetamol is the only therapeutically active substance *except* in paediatric drops in packs containing not more than 2 gm of paracetamol).

Controlled Substances (Poisons) Regulations 1996

SCHEDULE I

*S4 Drugs that may be Administered by Prescribed Professionals
(Regulation 28)*

1. The following S4 drugs may be administered by chiroprodists or dental therapists:

Amethocaine
Amylocaine
Benzocaine
Bupivacaine
Butacaine
Butylaminobenzoate
Cinchocaine
Diperodon
Etidocaine
Lignocaine
Mepivacaine
Oxybuprocaine
Prilocaine
Procaine
Proxymetacaine.

2. The following S4 drugs may be administered (as eye drops only) by optometrists:

Cyclopentolate
Oxybuprocaine
Phenylephrine
Physostigmine
Pilocarpine
Proxymetacaine
Tropicamide.

SCHEDULE J

*S4 drugs that may be Supplied or Prescribed by a Surgical Podiatrist
(Regulation 28)*

1. The following S4 drugs may be supplied or prescribed by a surgical podiatrist:

(a) as an oral preparation only—

Amoxicillin
Amoxicillin and clavulanic acid
Cephalexin
Ciprofloxacin (when microbiological tests
indicate it is the only effective drug)
Codeine phosphate 30mg (in combination
with paracetamol 500mg only)
Diazepam
Diclofenac
Doxycycline
Erythromycin
Flucloxacillin
Loratidine
Phenoxymethyl penicillin
Promethazine
Roxithromycin
Sulindac
Temazepam;

(b) as an oral preparation or as a suppository—

Metronidazole
Naproxen;

(c) as a cream—

Hydrocortisone cream 0.5 - 1%;

(d) as an ointment—

Mupirocin.

2. The maximum quantity of an S4 drug listed in clause 1 that may be provided by a surgical podiatrist to any person, whether by direct supply or prescription or both, in the course of treating that person for a particular condition, is that usually required for 10 days' treatment of the condition with that drug.

Controlled Substances (Poisons) Regulations 1996

SCHEDULE K

*Restrictions on Prescribing Certain S4 Drugs
(Regulation 29)*

1. S4 drugs to be prescribed for human use only by registered endocrinologists, obstetricians and gynaecologists—

Clomiphene
Cyclofenil
Follitropin alpha (recombinant human follicle stimulating hormone)
Follitropin beta (recombinant human follicle stimulating hormone)
Luteinising hormone
Urofollitrophin (follicle stimulating hormone).

2. S4 drugs to be prescribed only by registered dermatologists or other authorised specialist medical practitioners—

Acitretin
Etretinate
Isotretinoin
Tretinoin.

3. S4 drugs to be prescribed only by medical practitioners authorised to prescribe the drug for a specified patient—

Thalidomide.

SCHEDULE KA
Prescribed Amounts for the Purposes of Section 32(3) of the Act

Class of Drug of Dependence	Prescribed amount (grams)
ACETYLDIHYDROCODEINE	2.0
ACETYLMETHADOL	2.0
ALFENTANIL	2.0
ALPHACETYLMETHADOL	10.0
ALPHAPRODINE	25.0
AMPHETAMINE	2.0
AMYLOBARBITONE	50.0
ANILERIDINE	25.0
BENZYL MORPHINE	5.0
BEZITRAMIDE	5.0
BUPRENORPHINE	0.04
BUTOBARBITONE	50.0
BUTORPHANOL	2.0
CARFENTANYL	0.005
COCAINE	2.0
CODEINE	10.0
CODEINE-N-OXIDE	10.0
CYCLOBARBITONE	50.0
DEXAMPHETAMINE	2.0
DEXTROMORAMIDE	5.0
DEXTROPROPOXYPHENE	0.5
DIFENOXIN	2.0
DIHYDROCODEINE	10.00
DIHYDROMORPHINE	10.0
DIPHENOXYLATE	2.0
DIPIANONE	10.0
DRONABINOL	0.15
DROTEBANOL	2.0
ETHYLAMPHETAMINE	2.0
ETHYLMORPHINE	2.0
FENTANYL	0.005
FLUNITRAZEPAM	0.03
HYDROCODONE	2.0
HYDROMORPHINOL	2.0
HYDROMORPHONE	2.0

Controlled Substances (Poisons) Regulations 1996

LEVAMPHETAMINE	2.0
LEVOMETHAMPHETAMINE	2.0
LEVOMORAMIDE	5.0
LEVORPHANOL	1.0
METHADONE	2.0
METHYLAMPHETAMINE	2.0
METHYLDIHYDROMORPHINE	2.0
METHYLPHENIDATE	2.0
MORAMIDE	5.0
MORPHINE	2.0
MORPHINE METHOBROMIDE	2.0
MORPHINE-N-OXIDE	2.0
NABILONE	2.0
NORCODEINE	2.0
NORMETHADONE	2.0
OPIUM	20.0
OXYCODONE	5.0
OXYMORPHONE	2.0
PENTAZOCINE	20.0
PENTOBARBITONE	50.0
PETHIDINE	10.0
PHENDIMETRAZINE	0.35
PHENMETRAZINE	5.0
PHENOPERIDINE	1.0
PHOLCODINE	5.0
PIRITRAMIDE	1.0
PROPIRAM	2.0
QUINALBARBITONE	50.0
RACEMORAMIDE	5.0
REMIFENTANIL	0.005
SECBUTOBARBITONE	50.0
SUFENTANIL	1.0
THEBACON	2.0
THEBAINE	2.0
TILIDINE	2.0

SCHEDULE KB
Prescribed Amounts for the Purposes of Section 32(5) of the Act

Class of Drug of Dependence	Prescribed amount (kilograms)
COCAINE	0.4
DEXTROMORAMIDE	0.75
HYDROMORPHONE	0.3
METHADONE	0.3
MORPHINE	0.3
OPIUM	4.0
OXYCODONE	0.75
PETHIDINE	1.5

Controlled Substances (Poisons) Regulations 1996

SCHEDULE L
Controlled Substances Act 1984
END USER STATEMENT
(Regulations 33 and 34)

CLIENT NOTE

The chemical product for which this statement is required may be used in the manufacture of illicit drugs. This statement, with section A filled in, must be provided to the seller. Cash sale transactions will not be accepted for certain chemicals.

A. (this section to be completed by purchaser)

PRODUCT/CHEMICAL

Product Name:

Supplier Catalogue No:

Quantity:

Pack Size:

INTENDED USE (tick appropriate box)

Analytical

Manufacturing

Resale

Research and Development

Other (please specify)

PURCHASER

Business/Company/Institution Name:

Address:

Licence Type and No (if relevant):

Account No (if relevant):

Name of person authorising purchase:

SIGNED Date:.....
(person authorising purchase)

B. (this section to be completed by seller)

COLLECTION AGENT

Name:

Date of Birth:

Home Address:

Vehicle Reg. No. (vehicle used in collection):

Status (tick appropriate box):

Purchaser

Employee of purchaser

Contractor

Employee of contractor

VERIFICATION

I sighted the following proof of identity produced by the above COLLECTION AGENT (tick appropriate box):

Current Driver's Licence No:

Current Passport No: issued at:

Other ID (please specify):

Name of person handling sale:

SIGNED
(person handling sale)

Date:

Controlled Substances (Poisons) Regulations 1996

SCHEDULE M
Certificate of Analysis
(Regulation 41)

Pursuant to section 53 of the *Controlled Substances Act 1984*,

I
(Print name in full)

an Analyst appointed under the *Controlled Substances Act 1984*, certify that

.....
.....
.....
.....
.....
.....

(insert results of analysis)

Signature of Analyst

Date

APPENDIX

LEGISLATIVE HISTORY

Transitional Provisions

(Transitional provision from Regulation No. 198 of 2000, reg. 20)

20. Despite regulation 10 of the principal regulations as amended by these regulations, a licence in force under the revoked *Drugs of Dependence (General) Regulations 1985* immediately before the commencement of these regulations will expire at midnight on 30 September 2000.

Legislative History

(entries in bold type indicate amendments incorporated since the last reprint)

Regulation 3(4) and (5):	inserted by 198, 2000, reg. 3
Regulation 4(1):	definitions of "address" and "CEO" inserted by 198, 2000, reg. 4(a) definition of "drug" inserted by 198, 2000, reg. 4(b) definition of "health service" varied by 198, 2000, reg. 4(c) definition of "National Drugs and Poisons Schedule Committee" inserted by 126, 2000, reg. 3(a) definition of "prescriber" substituted by 198, 2000, reg. 4(d) definition of "Uniform Poisons Standard" substituted by 126, 2000, reg. 3(b)
Regulation 7A:	inserted by 198, 2000, reg. 5
Regulation 10(1):	varied by 198, 2000, reg. 6(a)-(c)
Regulation 10(2):	varied by 9, 1997, reg. 3; 161, 2000, reg. 3(a)
Regulation 10(4):	varied by 198, 2000, reg. 6(d)
Regulation 11(1):	varied by 161, 2000, reg. 4
Regulation 14(1):	varied by 198, 2000, Sched.
Regulation 14(2):	varied by 161, 2000, reg. 5
Regulation 16(2):	varied by 229, 1997, reg. 3(a)-(d)
Regulation 16(2a):	inserted by 229, 1997, reg. 3(e); varied by 198, 2000, Sched.
Regulation 16(4):	varied by 198, 2000, Sched.
Regulation 16(6):	definition of "bait" revoked by 229, 1997, reg. 3(f) definition of "Metropolitan Adelaide" inserted by 229, 1997, reg. 3(f)
Regulation 17(1):	varied by 161, 2000, reg. 6(a)
Regulation 17(2):	varied by 161, 2000, reg. 6(b)
Regulation 18(2):	substituted by 161, 2000, reg. 7(a)
Regulation 18(3):	varied by 161, 2000, reg. 7(b), (c)
Regulation 19(2):	varied by 9, 1997, reg. 4
Regulation 19(3):	substituted by 161, 2000, reg. 8
Regulation 20:	varied by 161, 2000, reg. 9; 198, 2000, reg. 7
Regulation 21:	varied by 198, 2000, reg. 8
Regulation 24:	revoked by 198, 2000, reg. 9
Regulation 25(1):	varied by 198, 2000, Sched.
Regulation 25(3):	varied by 198, 2000, reg. 10(a), (b), Sched.
Regulation 25(4):	substituted by 198, 2000, reg. 10(c)
Regulation 26(1):	varied by 198, 2000, reg. 11(a)-(d)
Regulation 26(3):	varied by 198, 2000, Sched.
Regulation 27(1):	varied by 161, 2000, reg. 10; 198, 2000, reg. 12(a)-(c), Sched.
Regulation 27(1a):	inserted by 198, 2000, reg. 12(d)
Regulation 27(4):	substituted by 198, 2000, reg. 12(e)
Regulation 27(5) - (7):	inserted by 198, 2000, reg. 12(e)
Part 5 heading:	varied by 198, 2000, reg. 13
Regulation 28(2):	substituted by 9, 1997, reg. 5(a)
Regulation 28(4):	substituted by 9, 1997, reg. 5(b)
Regulation 29(2):	varied by 205, 1998, reg. 3
Regulation 29(3):	varied by 9, 1997, reg. 6(a); 161, 2000, reg. 11(a)
Regulation 29(4):	varied by 161, 2000, reg. 11(b)

Controlled Substances (Poisons) Regulations 1996

Regulation 29(5):	varied by 9, 1997, reg. 6(b); 198, 2000, Sched.
Regulation 29(6):	substituted by 9, 1997, reg. 6(c); varied by 198, 2000, Sched.
Regulation 29(7):	inserted by 9, 1997, reg. 6(c)
Regulation 30(1):	varied by 161, 2000, reg. 12; 198, 2000, Sched.
Regulation 30(2):	varied by 198, 2000, Sched.
Regulation 31(2):	varied by 198, 2000, reg. 14
	Part 5A comprising regs. 31A - 31M and heading inserted by 198, 2000, reg. 15
Regulation 32:	varied by 161, 2000, reg. 13; 198, 2000, Sched.
Regulation 33(1):	varied by 9, 1997, reg. 7
Regulation 33(2) - (4):	varied by 198, 2000, Sched.
Regulation 34(2) and (3):	varied by 198, 2000, Sched.
Regulation 35(1) and (5):	varied by 198, 2000, Sched.
Regulation 36(5):	varied by 9, 1997, reg. 8; 198, 2000, Sched.
Regulation 37:	varied by 198, 2000, Sched.
Regulation 38(1):	varied by 198, 2000, reg. 16(a), (b), Sched.
Regulation 38(3) and (4):	inserted by 198, 2000, reg. 16(c)
Regulation 39:	varied by 198, 2000, Sched.
Regulation 40A:	inserted by 198, 2000, reg. 17
Regulation 42:	varied by 161, 2000, reg. 14
Regulation 43:	varied by 161, 2000, reg. 15
Schedule A	
Clause 2:	varied by 243, 1997, reg. 3; substituted by 253, 2001, reg. 3
Schedule B heading:	varied by 9, 1997, reg. 9
Schedule C heading:	varied by 9, 1997, reg. 10
Schedule C:	varied by 9, 1997, reg. 11
Schedule D:	substituted by 94, 1997, reg. 3; 83, 1998, reg. 3; 83, 1999, reg. 3; 91, 2000, reg. 3; varied by 198, 2000, reg. 18; substituted by 65, 2001, reg. 3
Schedule E:	varied by 126, 2000, reg. 4
Schedule I	
Clause 2:	substituted by 9, 1997, reg. 12
Schedule K	
Clause 1:	varied by 229, 1997, reg. 4; 205, 1998, reg. 4
Clause 2:	varied by 9, 1997, reg. 13
Schedules KA and KB:	inserted by 198, 2000, reg. 19
Schedule L heading:	varied by 9, 1997, reg. 14