

Western Australia

Poisons Act 1964

Poisons Regulations 1965

Poisons Regulations 1965

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Western Australia

Poisons Act 1964

Poisons Regulations 1965

Part 1 — Preliminary

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

1. Citation

These regulations may be cited as the *Poisons Regulations 1965* ¹.

[Regulation 1 amended in Gazette 12 Oct 1984 p. 3267.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

2. Interpretation

- (1) In these regulations unless the context requires otherwise —

animal includes bees, birds, cetaceans, crustaceans, fish, molluscs and reptiles;

approved electronic prescribing system means a system of electronic prescribing approved by the CEO under regulation 32B;

approved needle and syringe programme means a needle and syringe programme that has been approved by the CEO;

certificated commercial vessel means a fishing vessel, passenger vessel or trading ship as defined in the *Western Australian Marine Act 1982* section 3(1);

child means a person under the age of 12 years;

coordinator, in relation to an approved needle and syringe programme, means the person nominated in an application referred to in regulation 12A to be the coordinator of that programme;

dermatologist means a medical practitioner who has qualifications recognised by the Medical Board as appropriate to a specialist in dermatology;

direction means regular and frequent supervision but does not necessarily imply continuous personal supervision;

director of nursing means a registered nurse appointed —

- (a) to be in charge of a hospital; or
- (b) to a remote area nursing post;

dispense, in relation to a medicine or a poison —

- (a) means supply the medicine or poison on and in accordance with a prescription duly given by a medical practitioner, a nurse practitioner, a dentist or a veterinary surgeon; and
- (b) in relation to a drug of addiction, has a meaning affected by regulation 42A;

distributor means a person who imports, sells or otherwise supplies a poison;

dosage unit means an individual dose of a poison and includes a tablet, capsule, cachet, single dose powder, or a single dose sachet of powders or granules;

experienced person means a person who for at least 5 years has been employed in the manufacture, handling or selling of poisons;

external in relation to the use of a poison, means application in the ears, eyes or nose, or to a body surface other than in the mouth, rectum, vagina, urethra or other body orifice;

gynaecologist means a medical practitioner who has qualifications recognised by the Medical Board as appropriate to a specialist in gynaecology;

immediate container includes any form of container in which a poison is directly packed, but does not include any such container intended for consumption or any immediate wrapper;

immediate wrapper means metal foil, plastic foil, waxed paper, or any other such material not intended for consumption, when used as the first wrapper for a dosage unit or dressing;

manufacture includes the processes of packing and repacking, refining manipulating and mixing any poison;

manufacturer means a person who manufactures, produces, or packs a poison;

Medical Board means the Medical Board established under section 4 of the *Medical Act 1894*;

obstetrician means a medical practitioner who has qualifications recognised by the Medical Board as appropriate to a specialist in obstetrics;

permit means a permit granted pursuant to the Act;

personal supervision means close and continuous control requiring the actual presence of the person exercising the supervision;

physician means a medical practitioner who has qualifications recognised by the Medical Board as appropriate to a specialist in general medicine;

poisons cupboard means a substantially made cupboard provided with an effective locking device and, except in the case of a cupboard used for the storage of a drug of addiction, having the word "Poison" conspicuously painted on the outside of the cupboard;

prescribe, in relation to a drug of addiction, has a meaning affected by regulation 42A;

psychiatrist means a medical practitioner whose name is contained in a register under section 89(1) of the *Mental Health Act 1962* ²;

public hospital means a public hospital as defined in section 2(1) of the *Hospitals and Health Services Act 1927*;

qualified person means —

- (a) a medical practitioner, pharmaceutical chemist, dentist, veterinary surgeon;
- (b) a person who is the holder of a degree approved by the CEO conferred by a University of the British Commonwealth;
- (c) a person who is eligible to be —
 - (i) a Fellow or Associate of the Royal Australian Chemical Institute; or
 - (ii) a Fellow, Associate or Licentiate of the Royal Institute of Chemistry;

or

- (d) any other person approved of by the CEO;

quarter means any one of the 3 monthly periods of any year ending on 31 March, 30 June, 30 September or 31 December;

racing yacht means a yacht participating in a race departing from this State;

registered nurse means a nurse whose name is entered in division 1 of the register referred to in section 33 of the *Nurses Act 1992*;

remote area nursing post means a remote area site designated as a remote area nursing post by the CEO under regulation 11;

sale includes exposing or offering for sale or having in possession for sale, whether by wholesale or retail, and also delivery with or without consideration, in any shop or store or premises appurtenant thereto by the keeper thereof or by his servant or agent; and the verb **to sell** has a corresponding meaning;

Schedule has the meaning given in the Act;

supply includes **distribute** and **sell** but the administration to a patient of any substance specified in any of the Schedules to the Act by a medical practitioner, nurse practitioner or dentist, or by a registered nurse when acting under the direction of a medical

practitioner, or the administration of any substance specified in any of the Schedules to the Act to an animal under the direct personal supervision or under the direction of a veterinary surgeon, shall not be deemed to be supplying within the meaning of these regulations;

SUSDP has the meaning given in clause 1(1) of Appendix A to the Act;

the Act means the *Poisons Act 1964*.

- (2) A prescription is issued electronically if it is issued under regulation 37(1A) or 51(1A).

[Regulation 2 amended in Gazette 23 Sep 1983 p. 3803; 29 Jun 1984 p. 1784; 28 Feb 1986 p. 618; 5 Dec 1986 p. 4467; 27 May 1988 p. 1769; 25 Aug 1989 p. 2842 (as amended in Gazette 6 Oct 1989 p. 3738); 8 Jun 1990 p. 2626; 23 Nov 1990 p. 5791; 12 Apr 1991 p. 1608; 7 Aug 1992 p. 3868; 25 Jun 1993 p. 3078-9; 26 May 1994 p. 2197; 24 Jun 1994 p. 2865; 2 Sep 1994 p. 4533; 23 Dec 1994 p. 7076; 28 Apr 1995 p. 1466 and 1466-7; 5 Sep 1995 p. 4162; 19 Sep 1995 p. 4383; 17 Jan 1996 p. 267; 19 Mar 1996 p. 1216-17; 11 Apr 1997 p. 1829; 27 Nov 1998 p. 6343; 12 Aug 2003 p. 3658; 15 Nov 2005 p. 5603; 15 Dec 2006 p. 5630; 7 Nov 2008 p. 4805; 12 Jun 2009 p. 2109; amended by No. 9 of 2003 s. 41.]

2AA. Prescribed office (section 64B)

For the purposes of section 64B of the Act, the office of the Pharmaceutical Services, Environmental Health Branch of the department, located at Grace Vaughan House, 227 Stubbs Terrace, Shenton Park, is prescribed as the office of the department at which a copy of every standard referred to in the Act is to be kept and made available to the public for inspection.

[Regulation 2AA inserted in Gazette 19 Mar 1996 p. 1217.]

r. 2A

2A. Exemptions

Excluding substances included in Schedule 8 and Schedule 9 and specified drugs, the provisions of the Act do not apply to —

- (a) poisons listed in Column 1 of Appendix G to the SUSDP in a product at a concentration the same or less than that specified in Column 2;
- (b) poisons in a product listed in Appendix A to the SUSDP;
- (c) paints, except when prepared for medicinal or cosmetic purposes, which contain substances included in Schedule 5; and
- (d) paints, except when prepared for medicinal or cosmetic purposes, which contain poisons listed in the First, Second or Third Schedule of Appendix I to the SUSDP, if —
 - (i) the proportion of the poison is less than the proportion specified in those schedules; or
 - (ii) the proportion of the poison is within the limits specified in those schedules and the container is labelled in accordance with the provisions of Part 2 of the SUSDP.

*[Regulation 2A inserted in Gazette 12 Nov 1993 p. 6146-7;
amended in Gazette 19 Sep 1995 p. 4383; 19 Mar 1996 p. 1217;
14 Sep 2001 p. 5073.]*

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

Part 2 — Licences and permits

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

Division 1 — General

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

3. Wholesaler's licences and permits

- (1) A wholesaler's licence authorises the licensee to procure, manufacture and supply by wholesale dealing specified poisons at or from specified premises.
- (2) A wholesaler's licence is to be in the form of Form 1 in Appendix A.
- (3) A wholesaler's licence is subject to the condition that any manufacture of a poison under the licence be carried out by —
 - (a) a specified qualified person or a qualified person authorised under subregulation (4); or
 - (b) an experienced person acting under the personal supervision of a person referred to in paragraph (a).
- (4) A wholesaler's licence is subject to the condition that any supply of a poison under the licence be carried out by —
 - (a) a specified qualified person or a qualified person authorised under subregulation (4); or
 - (b) a specified experienced person or an experienced person authorised under subregulation (4).
- (5) If a person specified in a wholesaler's licence for the purposes of subregulation (3)(a) or (4) —
 - (a) ceases to work for the licensee; or
 - (b) in the case of a qualified person specified for the purposes of subregulation (3), is unable to exercise the necessary supervision,

the CEO may in writing authorise another qualified or experienced person (as the case requires) to act in the specified person's stead.

- (6) In this regulation —

specified means specified in a wholesaler's licence.

*[Regulation 3 inserted in Gazette 14 Sep 2001 ³ p. 5073-4;
amended in Gazette 15 Dec 2006 p. 5630.]*

[4. Deleted in Gazette 14 Sep 2001 p. 5073.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

5. Pharmaceutical chemist's licence to sell poisons

A pharmaceutical chemist shall not sell or supply any poison except at or from a pharmacy registered under the *Pharmacy Act 1964*, and described in the licence issued under these regulations as provided in Form 3 in Appendix A.

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

[6. Deleted in Gazette 19 Mar 1996 p. 1217.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

7. Retailer's licence to sell poisons specified in Schedule 2 to the Act

This licence shall authorise the licensee to procure, and to sell by retail, poisons included in Schedule 2 at the premises described in the licence, and shall be in the Form 5 in Appendix A.

*[Regulation 7 amended in Gazette 23 May 1986 p. 1716;
19 Mar 1996 p. 1217.]*

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

8. Retailer's licence to sell poisons included in Schedule 7 to the Act

This licence shall authorise the licensee to procure, and to sell by retail, poisons included in Schedule 7 to the Act at the premises described in the licence, and shall be in the Form 6 in Appendix A.

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

8A. Poisons permit (distribution of samples)

- (1) This permit shall, subject to the succeeding provisions of this regulation, authorise the holder to procure from any manufacturer or wholesale supplier specified therein and to supply to certain persons, samples of poisons included in Schedule 2, 3 or 4 and the permit shall be in the Form 6B in Appendix A.
- (1a) A permit under this regulation may not be issued in respect of a drug declared to be a *specified drug* for the purposes of the Act.
- (2) A permit under this regulation may be granted only to a person who is —
 - (a) a representative of a person —
 - (i) licensed to manufacture poisons or to supply poisons by wholesale dealing; or
 - (ii) licensed under the provisions of the laws of any other State or Territory of the Commonwealth to manufacture poisons or to supply poisons by wholesale dealing;
 - (b) not less than 21 years of age; and
 - (c) of good character,and the holder of a permit shall, for the purposes of these regulations, be known as a detailer.
- (3) A permit under this regulation shall contain the name and address of the detailer and the name of each manufacturer or wholesale supplier whom he represents.

- (4) Where a detailer ceases to represent a manufacturer or wholesale supplier named in his permit —
- (a) the permit shall thereupon cease to authorise the detailer to procure samples from that manufacturer or wholesale supplier or to supply to any person samples procured at any time from that manufacturer or wholesale supplier;
 - (b) the detailer shall return to the manufacturer or wholesale supplier any samples that were procured from the manufacturer or wholesale supplier and that are still in the possession or control of the detailer; and
 - (c) within 7 days of ceasing to represent the manufacturer or wholesale supplier, the detailer shall advise the CEO in writing of the fact and deliver up therewith his permit to the CEO and the CEO shall delete from the permit the name of the manufacturer or wholesale supplier or shall cancel the permit, as the case requires.
- (5) A detailer shall not supply a sample to any person who is not —
- (a) a medical practitioner;
 - (b) a veterinary surgeon;
 - (c) a dentist; or
 - (d) a pharmacist.
- (6) A detailer shall not procure, carry or supply a sample —
- (a) in the case of an oral contraceptive, for more than 2 months use; or
 - (b) in any other case, for more than 7 days use,
- where the use is in accordance with directions with the sample for maximum dosage, unless the person wishing to be supplied with a larger sample has first made a written request to the manufacturer or wholesale supplier represented by the detailer for the supply of the sample.
- (7) Subregulation (6) does not apply to a sample of a proprietary preparation where —

- (a) the sample is the smallest size manufactured for sale;
and
- (b) the CEO, on the recommendation of the Poisons Advisory Committee, has declared such a sample to be a sample to which subregulation (6) does not apply, notwithstanding that the sample may be used —
 - (i) in the case of an oral contraceptive, for more than 2 months; or
 - (ii) in any other case, for more than 7 days,

where the use is in accordance with directions with the sample for maximum dosage.

- (8) A detailer shall not carry more than —
 - (a) 25 samples of any single proprietary preparation; or
 - (b) samples of more than 5 different proprietary preparations,in a vehicle at any one time.
- (9) Where the proper storage of a poison requires that poison be stored under special conditions or at specific temperatures, a detailer shall not store or transport that poison except in a manner which maintains those conditions or temperatures.
- (10) Subject to subregulation (11), a detailer shall not cause or permit samples in his possession or control to be stored other than —
 - (a) on the premises of the manufacturer or wholesale supplier whom he represents; or
 - (b) at his address as specified in his permit.
- (11) A detailer may keep samples in a vehicle while he is actually using that vehicle in the course of his business, but at no other time.
- (12) Where pursuant to this regulation samples are stored at an address specified in a detailer's permit which is not a wholesale supplier's premises, the detailer shall cause those samples to be

stored in a locked cupboard or locked refrigerator and a detailer shall not cause or permit —

- (a) more than 100 samples of any single proprietary preparation; or
- (b) samples of more than 5 different proprietary preparations,

to be kept at that address at any one time.

(13) A detailer shall not supply a sample unless —

- (a) he has received a signed request from a person to whom he is authorised in accordance with subregulation (5) to supply the sample; and
- (b) immediately upon supplying the sample, he signs and dates the request form to certify that the sample has been delivered.

(14) A detailer shall keep a record of every sample received or supplied by him and shall preserve all records so kept together with consignment notes, invoices, advice notes and request forms relating thereto, for not less than 2 years.

(15) Upon receiving a written request from the CEO a detailer shall submit all records of samples received and delivered and shall make an account of those samples to the CEO or a person authorised in accordance with section 54 of the Act.

(16) For the purposes of this regulation —

proprietary preparation means one or more forms of a poison intended for therapeutic use boxed or wrapped in a single sample package;

sample means a sample package containing a poison intended for therapeutic use included in Schedule 2, 3 or 4.

[Regulation 8A inserted in Gazette 22 Sep 1969 p. 2874-6; amended in Gazette 29 Jun 1984 p. 1784; 12 Apr 1991 p. 1608; 16 Apr 1992 p. 1634; 7 Aug 1992 p. 3865; 25 Jun 1993 p. 3079 and 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1218; 15 Dec 2006 p. 5630.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

9. Poisons permit (industrial)

This permit shall authorise the holder to purchase from a manufacturer or wholesale supplier such poisons as are specified in the permit, which shall be in the Form 7 in Appendix A.

[Regulation 9 amended in Gazette 19 Mar 1996 p. 1218.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

10. Poisons permit (educational, advisory or research)

This permit shall authorise the holder to purchase from a manufacturer or wholesale supplier such poisons as are specified in the permit, which shall be in the Form 8 in Appendix A.

[Regulation 10 amended in Gazette 19 Mar 1996 p. 1218.]

10AA. Poisons permit (Health services)

- (1) This permit shall authorise the holder to purchase from a manufacturer or wholesale supplier such poisons as are specified in the permit, which shall be in the Form 8AA in Appendix A.
- (2) The permit may not be granted to —
 - (a) a department or instrumentality of the State or of the Commonwealth; or
 - (b) a public hospital.

[Regulation 10AA inserted in Gazette 4 Apr 2006 p. 1406.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

10A. Poisons permit (departmental and hospital)

- (1) This permit shall authorise the holder to purchase from a manufacturer or wholesale supplier such poisons as are

specified in the permit which shall be in the Form 13 in Appendix A and shall not, except in the case of a permit held by a public hospital, authorise the sale of any poison obtained by the permit holder under the authority of the permit.

- (2) This permit may be granted only to —
- (a) a department or instrumentality of the State or of the Commonwealth; and
 - (b) a public hospital.

[Regulation 10A inserted in Gazette 14 Jun 1967 p. 1582; amended in Gazette 19 Mar 1996 p. 1219; 12 Aug 2003 p. 3658.]

10B. Licence to cultivate prohibited plants

A licence under section 41A of the Act shall be in the form of Form 13A in Appendix A.

[Regulation 10B inserted in Gazette 23 Aug 1996 p. 4089.]

[Heading deleted in Gazette 27 May 1988 p. 1789.]

11. CEO may designate remote area nursing posts

- (1) The CEO may, in writing, designate a remote area site to be a remote area nursing post for the purposes of these regulations.
- (2) The CEO may amend or withdraw a designation under subregulation (1), in writing, at any time.

[Regulation 11 inserted in Gazette 24 Jun 1994 p. 2865; amended in Gazette 15 Dec 2006 p. 5630 and 5631.]

11A. CEO may designate areas for the purposes of section 23 of the Act

- (1) The CEO may, in writing, designate an area for the purposes of section 23(2)(e) of the Act.

- (2) The CEO may amend or withdraw a designation under subregulation (1), in writing, at any time, subject to subregulation (4).
- (3) The CEO may not designate an area under subsection (1) until after receiving —
 - (a) written advice with respect to the proposal to designate the area from the officer of the department who is principally responsible for providing advice on matters related to nursing; and
 - (b) clinical protocols for the proposed area approved in writing by —
 - (i) the officer referred to in paragraph (a);
 - (ii) the person holding or acting in the office of Executive Director, Personal Health Services in the department; and
 - (iii) the person holding or acting in the office known as Executive Director, Population Health, or if there is no such office at the relevant time, the office of Executive Director, Public Health and Scientific Support Services in the department.
- (4) The CEO may not amend or withdraw a designation under this section until after receiving written advice with respect to the proposed action from the officer of the department who is principally responsible for providing advice on matters related to nursing.

[Regulation 11A inserted by Act No. 9 of 2003 s. 42; amended in Gazette 15 Dec 2006 p. 5630 and 5631.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

12. Application for licence or permit (sections 24 and 25)

- (1) A person who wishes to apply for a licence under section 24 of the Act or a permit under section 25 of the Act shall lodge with

the CEO an application in such form as may be approved by the CEO from time to time for that purpose.

- (2) An applicant under this regulation must indicate in the application whether the application is for a period of one year or for 3 years.
- (3) The appropriate fees for licences or permits, and renewals of licences or permits, are those set out in Appendix G.
- (4) Where the applicant for a licence or permit applies on behalf of a corporate body or firm the application shall contain the name of a natural person who, in respect of the premises named in the application, shall be responsible for carrying out the provisions of the Act and these regulations.
- (5) The CEO may only grant an application and issue a licence or permit, or renew a licence or permit, if the application under this regulation is accompanied by the appropriate fee set out in Appendix G.

*[Regulation 12 inserted in Gazette 19 Mar 1996 p. 1219;
amended in Gazette 15 Dec 2006 p. 5630.]*

Division 2 — Needle and syringe programme

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

12A. Approval of needle and syringe programme

- (1) A person may apply to the CEO for the approval of a needle and syringe programme.
- (2) An application referred to in subregulation (1) shall —
 - (a) be in the form of Form 14 in Appendix A; and
 - (b) nominate a person to be the coordinator of the programme.
- (3) The CEO may by notice in writing require an applicant to provide further information with respect to the application.

- (4) An approval of a needle and syringe programme shall —
- (a) be given by instrument in writing signed by the CEO;
 - (b) clearly identify the programme that is being approved by reference to the activity or activities, and the persons or class of persons engaging in the activity or activities, that constitute the programme; and
 - (c) specify the period during which the programme is approved.
- (5) The CEO is not to approve a needle and syringe programme unless the CEO is satisfied that the coordinator of the programme —
- (a) has attained the age of 18 years;
 - (b) is a person of good character and repute and is a fit and proper person to coordinate the needle and syringe programme; and
 - (c) understands his or her duties as the coordinator of the programme.

[Regulation 12A inserted in Gazette 26 May 1994 p. 2197-8; amended in Gazette 15 Dec 2006 p. 5630.]

12B. Copy of approval to be provided

Where the CEO approves a needle and syringe programme, the CEO is to provide a copy of the instrument of approval to the coordinator of the programme.

[Regulation 12B inserted in Gazette 26 May 1994 p. 2198; amended in Gazette 15 Dec 2006 p. 5630.]

12C. Duties of coordinator

The coordinator of an approved needle and syringe programme shall —

- (a) maintain a register of all persons who participate in the conduct of the programme;

- (b) ensure that persons who participate in the conduct of the programme understand the requirements of these regulations and are appropriately instructed and trained;
- (c) submit to the CEO before 30 June in each year an annual report on the needle and syringe programme; and
- (d) report to the CEO any irregularities that occur in the conduct of the programme.

*[Regulation 12C inserted in Gazette 26 May 1994 p. 2198;
amended in Gazette 15 Dec 2006 p. 5630.]*

12D. Requirements relating to programme

- (1) Where the CEO approves a needle and syringe programme, the CEO may specify in the approval a requirement that the programme only be conducted —
 - (a) at a specified place or specified places; or
 - (b) between specified times.
- (2) A person shall not conduct, or participate in the conduct of, an approved needle and syringe programme except at a place or between times specified in the approval.

*[Regulation 12D inserted in Gazette 26 May 1994 p. 2199;
amended in Gazette 15 Dec 2006 p. 5630.]*

12E. Direction to person

- (1) Where the CEO is of the opinion that a person is not a suitable person to participate in the conduct of an approved needle and syringe programme, the CEO may, by notice in writing served on that person, direct the person not to participate in the programme.
- (2) A person shall not contravene a direction under subregulation (1).

*[Regulation 12E inserted in Gazette 26 May 1994 p. 2199;
amended in Gazette 15 Dec 2006 p. 5630.]*

12F. Requirements relating to used hypodermic needles and syringes

- (1) A person shall not, in the course of the conduct of an approved needle and syringe programme, accept any used hypodermic syringe or used hypodermic needle unless the syringe or needle has been exhausted.
- (2) For the purposes of subregulation (1), a hypodermic syringe or a hypodermic needle shall be taken to have been exhausted if it contains no more than the residue of any drug.
- (3) A person who, in the course of the conduct of an approved needle and syringe programme, receives any used hypodermic needle or used hypodermic syringe shall immediately place the needle and syringe in a receptacle of a type approved by the CEO and the Commissioner of Police.

*[Regulation 12F inserted in Gazette 26 May 1994 p. 2199;
amended in Gazette 15 Dec 2006 p. 5630.]*

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

[13, 14. Deleted in Gazette 19 Mar 1996 p. 1219.]

Division 3 — Restrictions and obligations

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

15. Restriction to issue of licence or permit

A licence or permit shall not be issued to any person under the age of 21 years, unless he is a qualified person approved by the CEO.

[Regulation 15 amended in Gazette 29 Jun 1984 p. 1784; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 15 Dec 2006 p. 5630.]

16. Sale of poison only by licensee

A sale of any poison shall not be made by any person other than the licensee or a person, not less than 15 years of age, acting on his behalf.

[Regulation 16 amended in Gazette 21 Nov 1986 p. 4270; 24 Jun 1994 p. 2865.]

17. Licence or permit not transferable

A licence or permit is not transferable from one person to another.

Provided that —

- (a) a licence or permit held in the name of a person on behalf of a firm or corporate body may, on endorsement by the CEO, be transferred into the name of another person on behalf of the firm or corporate body;
- (b) the holder of a licence or permit who ceases to carry on or conduct the business or practice to which the licence or permit relates shall within 14 days surrender such licence or permit to the CEO.

[Regulation 17 amended in Gazette 29 Jun 1984 p. 1784; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 15 Dec 2006 p. 5630.]

18. Licensee to display licence

The holder of a licence shall keep such licence displayed in a conspicuous place within the premises specified in the licence.

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

Part 3 — Containers and labels

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

Division 1 — Containers

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

19. Adoption of SUSDP for containers and labels

- (1) Except as provided by these regulations a person shall not store, supply or transport a poison unless the immediate container in which the poison is stored, supplied or transported complies with Part 2 of the SUSDP.
- (2) Except as provided by these regulations a person shall not store, supply or transport a poison unless the container referred to in subregulation (1) bears or has securely affixed to it a label which complies with Part 2 of the SUSDP.
- (2a) For the purposes of this regulation, the interpretation provisions of Part 1 of the SUSDP shall be used to interpret Part 2 of the SUSDP as adopted by this regulation.

*[Regulation 19 inserted in Gazette 23 Nov 1990 p. 5791;
amended in Gazette 24 Jun 1994 p. 2865; 19 Mar 1996
p. 1219.]*

19AA. Certain containers prohibited

- (1) An immediate container on which the name of any poison is embossed or otherwise permanently marked shall not be used except to contain that poison.
- (2) A paper or plastic bag or envelope, or a cardboard box shall not be used as a container for a Schedule 2, 3, 4, 8 or 9 poison whether dispensed or not, unless the poison is also presented to the purchaser in foil or in individually sealed, measured amounts, commonly described as strip packaging, or unless the container is approved by the CEO.

- (3) A paper bag shall not be used as the sole container of any poison unless it has been approved by the CEO.

[Regulation 19AA inserted in Gazette 23 Nov 1990 p. 5791; amended in Gazette 26 May 1994 p. 2201; 19 Mar 1996 p. 1219-20; 15 Dec 2006 p. 5630.]

19A. Food etc. containers to be distinguishable from poison containers

A person shall not sell any food, drink, or condiment, or any drug or medicine for internal use, in a container —

- (a) of a description which is not readily distinguishable by sight and touch from a container in which a poison intended for external use may be sold; or
- (b) of a like description to that prescribed for a container in which a poison intended for external use may be sold.

[Regulation 19A inserted in Gazette 26 May 1971 p. 1773; amended in Gazette 19 Mar 1996 p. 1220.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

[20. Deleted in Gazette 23 Nov 1990 p. 5792.]

Division 2 — Labels

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

21. Labels on medicines or preparations

- (1) Notwithstanding regulation 19, a medicine or preparation containing any poison dispensed or supplied in the course of the professional practice of —
- (a) a pharmaceutical chemist, medical practitioner, nurse practitioner, registered nurse at a remote area nursing post, or dentist, for human internal use shall comply with that regulation if it is labelled in the English language with —
 - (i) the words “Keep out of reach of children”;

- (ii) the name and strength or amount of each poison in the preparation, or the trade name and strength of the preparation (unless the trade name also uniquely identifies the strength, in which case only the trade name need be given);
 - (iii) the name of the patient;
 - (iv) a date of dispensing or supply, and a number identifying the prescription or supply which corresponds to —
 - (I) the entry in the Prescription Book referred to in regulation 36(3)(c), in the case of a pharmaceutical chemist; or
 - (II) the patient's records, in the case of a medical practitioner, nurse practitioner, registered nurse at a remote area nursing post, or dentist;
 - (v) the name and address of the pharmacy, or medical or dental surgery, or area designated under section 23(2)(e) of the Act, or remote area nursing post, from which it is supplied;
 - (vi) the instructions given on the prescription, if dispensed by a pharmaceutical chemist, or directions for use, if supplied by a medical practitioner, nurse practitioner, registered nurse at a remote area nursing post, pharmaceutical chemist or dentist; and
 - (vii) the total quantity contained;
- (b) a pharmaceutical chemist, medical practitioner, nurse practitioner, registered nurse at a remote area nursing post or dentist, for human external use shall comply with that regulation if it is labelled in accordance with paragraph (a), together with the words "Not to be taken";

- (c) a pharmaceutical chemist or veterinary surgeon, for use on any animal shall comply with that regulation if it is labelled in the English language with —
 - (i) the words “Keep out of reach of children”;
 - (ii) the name and strength or amount of each poison in the preparation, or the trade name and strength of the preparation (unless the trade name also uniquely identifies the strength, in which case only the trade name need be given);
 - (iii) the owner’s surname and the species of animal;
 - (iv) instructions for the use of that medicine or preparation;
 - (v) a date of dispensing, and a number identifying the prescription or supply which corresponds to —
 - (I) the entry in the Prescription Book referred to in regulation 36(3)(c), in the case of a pharmaceutical chemist; or
 - (II) the patient’s records, in the case of a veterinary surgeon;
 - (vi) the name and address of the pharmacy, or veterinary practice, from which it is supplied;
 - (vii) the words “For veterinary use only” or “For animal treatment only”, together with the words “For external use only” if the medicine or preparation is not prepared for internal use; and
 - (viii) the total quantity contained.
- (2) Subregulations (1)(a) and (b) do not apply to a medicine or preparation (containing a poison) labelled in accordance with regulation 19, if it is supplied by a medical practitioner for the purposes of therapeutic treatment of a patient over a period of not more than 3 days.

*[Regulation 21 inserted in Gazette 7 Aug 1992 p. 3865-6;
amended in Gazette 24 Jun 1994 p. 2865-6; 19 Mar 1996
p. 1220; amended by Act No. 9 of 2003 s. 43.]*

21A. Appendix K container must have appropriate label

- (1) A person, whether a pharmaceutical chemist or otherwise, shall not sell, supply, distribute or dispense a poison for internal human use set out in Appendix K of the SUSDP unless the container immediately containing the poison bears, or has securely affixed to it a label bearing either of the following statements —

“This medicine may cause drowsiness. If affected do not drive a motor vehicle or operate machinery. Avoid alcohol.”; or

“This medicine may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.”.

- (2) Subregulation (1) shall not apply to —
- (a) a person licensed pursuant to section 24(1)(a) of the Act; and
 - (b) the supply by a medical practitioner of any poison or substance containing a poison for the purposes of therapeutic treatment to a patient while that patient is hospitalised.
- (3) A statement set out in subregulation (1) shall be in letters not less than 1.5 mm in height and in a colour which provides a distinct contrast to the background colour of the container or label on which the statement appears.
- (4) In this regulation —
- height** means the height of capital letters or lower case letters having an ascender or a descender.

*[Regulation 21A inserted in Gazette 11 Jul 1986 p. 2339;
amended in Gazette 19 Mar 1988 p. 838; 24 Jun 1994 p. 2866;
19 Mar 1996 p. 1220.]*

[22-24. Deleted in Gazette 23 Nov 1990 p. 5792.]

24A. Carcinogenicity and teratogenicity warnings to be approved

A person shall not include on a label a statement relating to carcinogenicity or teratogenicity in relation to any poison unless the statement in relation to the poison has been approved by the CEO.

*[Regulation 24A inserted in Gazette 17 Aug 1990 p. 4081;
amended in Gazette 26 May 1994 p. 2201; 19 Mar 1996 p. 1220;
15 Dec 2006 p. 5630.]*

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

Division 3 — General

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

25. CEO may approve container or label

The CEO may approve, in writing, a container or label which does not comply with these regulations if, having regard to the nature of the poison and the purpose for which it is to be used, it is unlikely that the interests of safety will be adversely affected by the use of such container or label.

*[Regulation 25 amended in Gazette 29 Jun 1984 p. 1784;
25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 15 Dec 2006
p. 5630 and 5631.]*

26. CEO may suspend use of container or label

The CEO may, in the interest of safety, suspend or prohibit the use of any form of container or label for the packing or labelling of any poison.

*[Regulation 26 amended in Gazette 29 Jun 1984 p. 1784;
25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 15 Dec 2006
p. 5630 and 5631.]*

[27. Deleted in Gazette 23 Nov 1990 p. 5792.]

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[27AA, 27A. Deleted in Gazette 24 Jun 1994 p. 2866.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

[28. Deleted in Gazette 23 Nov 1990 p. 5792.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

[29, 29A, 29B. Deleted in Gazette 28 May 1993 p. 2595.]

Part 4 — Storage, disposal and loss or theft of poisons

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

30. Storage of substances other than those specified in regulation 56

Any person having a poison, other than those specified in regulation 56, in or on any premises for the purpose of sale or use in his profession, business, trade or industry shall keep that poison in such a manner as to preclude contamination of any food, drink or condiment by the poison; and to preclude access to the poison by children.

[Regulation 30 amended in Gazette 1 Aug 1986 p. 2739; 28 May 1993 p. 2595; 19 Mar 1996 p. 1220.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

31. Disposal of poisons

A person shall not dispose of any poison in any place or manner likely to constitute a risk to the public.

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

32. Notification of loss or theft of poison

Every person who loses any poison or from whom any poison is stolen shall immediately notify a police officer of such loss or theft.

[Regulation 32 amended in Gazette 19 Mar 1996 p. 1220.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

Part 4A — Electronic prescribing systems

[Heading inserted in Gazette 7 Nov 2008 p. 4806.]

32A. Terms used in this Part

- (1) In this Part and Appendix K —

access code, of an individual, means a password or other means by which the individual gains access to a system of electronic prescribing;

inappropriate use, in relation to a system of electronic prescribing, includes using the system in a way that is not in accordance with the procedures that control access to and use of the system;

system identifier, of an individual, means the code by which the identity of the individual is recorded by a system of electronic prescribing.

- (2) For the purposes of this Part, an entry is made in a system of electronic prescribing if —

- (a) a prescription is issued, amended or cancelled via the system; or
- (b) a poison is dispensed in accordance with a prescription issued via the system; or
- (c) information is otherwise entered into or retrieved from the system in relation to —
 - (i) issuing, amending or cancelling a prescription via the system; or
 - (ii) dispensing a poison in accordance with a prescription issued via the system.

[Regulation 32A inserted in Gazette 7 Nov 2008 p. 4806.]

32B. Approval of electronic prescribing systems

- (1) The CEO may approve a system of electronic prescribing if satisfied that the system —

- (a) is sufficiently secure; and
 - (b) is designed so that, to the extent practicable —
 - (i) for any particular poison — only persons authorised to prescribe that poison can use the system to prescribe the poison; and
 - (ii) for any particular poison — only a pharmaceutical chemist authorised to dispense the poison, or an assistant under the direct personal supervision of the pharmaceutical chemist, can use the system to dispense the poison; and
 - (iii) a poison dispensed in accordance with a prescription issued via the system is dispensed for the person for whom it was prescribed; and
 - (iv) a poison dispensed to a person in accordance with a prescription issued via the system is the poison prescribed for the person;and
 - (c) complies substantially with the criteria in Appendix K; and
 - (d) complies with any other criteria the CEO thinks relevant.
- (2) A reference in subregulation (1)(b) to a person authorised to prescribe or dispense a particular poison is a reference to a person authorised to do so under the Act.
- (3) Before being satisfied that a system of electronic prescribing is sufficiently secure, the CEO must be satisfied that, to the extent practicable —
- (a) personal information relating to prescribers, patients of prescribers and pharmaceutical chemists is protected; and
 - (b) access to and use of the system is controlled by appropriate procedures; and

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- (c) only persons permitted to have access to the system according to those procedures can have access to the system; and
- (d) every occurrence of —
 - (i) a prescription being issued or amended via the system; and
 - (ii) a poison being dispensed in accordance with a prescription issued via the system,is recorded by the system in a way that cannot be amended or erased.
- (4) Subregulation (3) does not limit the matters that the CEO may take into account for the purposes of subregulation (1)(a).
- (5) The CEO may approve a component of a system of electronic prescribing if satisfied as to the matters in subregulation (1) in relation to the component, to the extent relevant to the component.

[Regulation 32B inserted in Gazette 7 Nov 2008 p. 4806-7.]

32C. System administrators

A system of electronic prescribing is not approved while there is no individual who is designated as the administrator of the system by the CEO.

[Regulation 32C inserted in Gazette 7 Nov 2008 p. 4808.]

32D. Offence provisions

- (1) A person must not access an approved electronic prescribing system unless the person —
 - (a) is permitted to have access to the system according to the procedures that control access to the system; and
 - (b) gained access according to those procedures.

Penalty: a fine of \$5 000.

- (2) A person who has an access code for an approved electronic prescribing system must not —

- (a) reveal the person's access code to another person; or
- (b) otherwise allow another person to have access to the system unless to do so is in accordance with the procedures that control access to the system.

Penalty: a fine of \$5 000.

- (3) A person must not make inappropriate use of an approved electronic prescribing system.

Penalty: a fine of \$5 000.

- (4) An administrator of an approved electronic prescribing system must, to the extent practicable, ensure that —

- (a) a person who is permitted to have access to the system in accordance with the procedures that control access to the system is not given more than one access code; and
- (b) each person who is responsible to the administrator for the operation and control of the system does not make inappropriate use of the system.

Penalty: a fine of \$5 000.

*[Regulation 32D inserted in Gazette 7 Nov 2008 p. 4808;
amended in Gazette 28 Jul 2009 p. 2979.]*

32E. Miscellaneous rules

- (1) In any proceedings under this Act or the *Misuse of Drugs Act 1981*, if it is proved that the system identifier of a person has been recorded in the system in respect of an entry, then, in the absence of evidence to the contrary, that person is to be taken to have made the entry.
- (2) Despite anything else in this Part, the administrator must, as soon as is practicable, comply with a written request by a person authorised under section 52A of the Act to make records of the system available to the person.

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*[Regulation 32E inserted in Gazette 7 Nov 2008 p. 4808-9;
amended in Gazette 28 Jul 2009 p. 2979.]*

Part 5 — Sale, supply and use of poisons

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

Division 1 — Restrictions

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

33. Poison not to be sold to persons under 16 years

A person who sells or supplies any poison to any person who is apparently under 16 years of age commits an offence against these regulations, but this regulation does not apply to sales of pharmaceutical preparations or medicines by persons licensed to sell poisons by retail.

33A. Restrictions applying to veterinary preparations

A person shall not —

- (a) administer to himself or another person; or
- (b) sell or supply for human use,

a medicine or other product which contains a poison and which was prepared for use in animals.

[Regulation 33A inserted in Gazette 11 Nov 1988 p. 4444.]

33B. Adoption of SUSDP for certain paints

- (1) If a paint contains a substance listed in the First, Second or Third Schedule to Appendix I of SUSDP, a person shall not manufacture, sell or use that paint except in accordance with that Appendix.
- (2) For the purposes of this regulation the interpretation provisions of Part 1 of the SUSDP shall be used to interpret Appendix I of the SUSDP.

[Regulation 33B inserted in Gazette 12 Apr 1991 p. 1608; amended in Gazette 24 Jun 1994 p. 2866-7; 16 Sep 1994 p. 4748; 19 Sep 1995 p. 4383; 14 Sep 2001 p. 5074.]

[Heading deleted in Gazette 23 May 1986 p. 1716.]

[34. Deleted in Gazette 23 May 1986 p. 1716.]

[Heading deleted in Gazette 23 May 1986 p. 1716.]

[34A-34C. Deleted in Gazette 23 May 1986 p. 1716.]

[34D. Deleted in Gazette 19 Mar 1996 p. 1220.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

35. Restrictions on retail sale of substances included in Schedule 2

A substance included in Schedule 2 shall not be stored for retail sale in any area or in any manner that allows physical access to that substance by any person other than —

- (a) the owner of the business carried on; or
- (b) a person employed,

on the premises where it is stored.

[Regulation 35 inserted in Gazette 8 Feb 1985 p. 521; amended in Gazette 19 Mar 1996 p. 1220.]

[Heading deleted in Gazette 8 Feb 1985 p. 521.]

35A. Restrictions on retail sale of substances included in Schedule 3

- (1) The retail sale of a substance included in Schedule 3 shall only be by way of direct, personal sale by a pharmaceutical chemist or graduate trainee in pharmacy under the personal supervision of a pharmaceutical chemist.
- (1a) Before a substance included in Schedule 3 is delivered as part of a retail sale, the pharmaceutical chemist or graduate trainee shall take all reasonable steps to ensure that there is a therapeutic need for the substance.

- (1b) A pharmaceutical chemist shall not store in any part of the retail area of premises any of the substances referred to in Appendix J.
- (1c) A substance referred to in Appendix J shall only be sold or supplied by direct, personal sale by a pharmaceutical chemist or by a graduate trainee in pharmacy under the personal supervision of a pharmaceutical chemist and, in the case of pseudoephedrine, before it is delivered to the purchaser, the purchaser shall give photographic evidence of his or her identity to the pharmaceutical chemist or graduate trainee, unless the purchaser's identity is known to the pharmaceutical chemist or graduate trainee.
- (2) Before a substance referred to in Appendix J is delivered to a purchaser as part of a retail sale, the pharmaceutical chemist or graduate trainee making the sale shall —
 - (a) record in the prescription book referred to in regulation 36(3)(c) the following details —
 - (i) the date of sale;
 - (ii) the name and address of the purchaser;
 - (iii) if the person for whom the substance is intended is not the purchaser, the name and address of that other person;
 - (iv) the name and quantity of the substance supplied;and
 - (b) allocate to each sale a unique identification number or alpha-numerical code, and record that number or code in the register; and
 - (c) label the product containing the substance with —
 - (i) the name and address of the pharmacy; and
 - (ii) the number or code allocated under paragraph (b).
- (3) The prescription book referred to in this regulation shall be available for inspection upon request by an authorised officer.

- (4) The seller shall retain the records required to be made under this regulation for a period of at least 2 years.

[Regulation 35A inserted in Gazette 28 Nov 1968 p. 3458; amended in Gazette 20 Sep 1985 p. 3743; 29 Aug 1990 p. 3028; 30 Nov 1990 p. 5908; 13 Dec 1991 p. 6190; 19 Mar 1996 p. 1221; 24 Jul 2007 p. 3664-5.]

[35AA. Deleted in Gazette 11 Apr 1997 p. 1829.]

35B. Storage of substances included in Schedule 3

A substance included in Schedule 3 shall not be stored in a pharmacy in any area or in any manner that allows physical access to that substance by any person other than a person who is a member of the staff of the pharmacy.

[Regulation 35B inserted in Gazette 29 Aug 1980 p. 3028; amended in Gazette 19 Mar 1996 p. 1221.]

35C. Advertising of substances included in Schedule 3

- (1) Subject to subregulations (2) and (3), a substance included in Schedule 3 shall not be advertised except in a bona fide professional or trade journal or other publication intended for circulation only within the medical, veterinary, dental or pharmaceutical professions or the wholesale and manufacturing drug trade.
- (2) A substance both included in Schedule 3 and listed in Appendix H of SUSDP may be advertised by its brand name or its approved name.
- (3) A substance included in Schedule 3 may be advertised if the substance is in a pregnancy testing kit.
- (4) In this regulation —
approved name, in relation to a poison, means the name for the poison that is listed in the Australian Register of Therapeutic Goods, other than a brand name of the poison;

Australian Register of Therapeutic Goods means the register of that name maintained under section 17 of the *Therapeutic Goods Act 1989* of the Commonwealth;

brand name, in relation to a poison, means a name given to the poison by a manufacturer of it and listed in the Australian Register of Therapeutic Goods, other than its approved name.

[Regulation 35C inserted in Gazette 23 Sep 1983 p. 3803; amended in Gazette 2 Oct 1987 p. 3776; 19 Mar 1996 p. 1221; 27 Nov 1998 p. 6343-4.]

35D. Advertising of substances included in Schedule 4

A substance included in Schedule 4 shall not be advertised except in a publication that is normally sold or intended for sale or circulation only among —

- (a) persons of the kind referred to in section 23(2) of the Act; or
- (b) persons who are holders of licences granted under section 24(1)(a), (b) or (c) of the Act.

[Regulation 35D inserted in Gazette 19 Feb 1999 p. 555.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

Division 2 — Schedule 4 poisons

[Heading inserted in Gazette 12 Aug 2003 p. 3664; amended in Gazette 4 Jan 2005 p. 3.]

36. Supply of poisons included in Schedule 4

- (1) Subject to the Act and these regulations, a person shall not sell or supply a poison included in Schedule 4 to any person unless —
 - (a) he or she —
 - (i) is satisfied that the person to whom the poison is sold or supplied is authorised under regulation 40(1) to procure the poison; and

- (ii) receives from that person a written order in accordance with regulation 40(1a) or makes a record under regulation 41B;
 - (b) the person to whom the poison is sold or supplied is the person (or an agent of the person) in respect of whom a prescription for the poison was issued by a medical practitioner, nurse practitioner, dentist or veterinary surgeon prescribing the poison according to the requirements of these regulations;
 - (c) satisfied that the person to whom the poison is sold or supplied is under medical treatment with the poison and requires emergency treatment with the poison and does not sell or supply to that person more than —
 - (i) 3 days medication of the poison; or
 - (ii) where the poison is supplied in prepacked individual packs, one individual standard pack;or
 - (d) he or she is a registered nurse working at a remote area nursing post and he or she supplies a poison, not being a psychoactive poison —
 - (i) in accordance with regulation 36(1)(c)(i);
 - (ii) for the treatment of an acute medical condition in compliance with the written standing orders of a medical practitioner which have been approved in writing by the CEO; or
 - (iii) for the treatment of an acute medical condition in compliance with oral instructions of a medical practitioner for that particular patient.
- (1a) A person who has received a written order under subregulation (1)(a)(ii) shall keep that order for at least 2 years from the time he or she received it and produce it at any time during the 2 years from the time he or she received it when required to do so by the Executive Director.

- (2) A medical practitioner, nurse practitioner, pharmaceutical chemist, or veterinary surgeon or an assistant under the direct personal supervision of a medical practitioner, nurse practitioner, pharmaceutical chemist, or veterinary surgeon shall be the only person who shall dispense a poison included in Schedule 4.
- (3) The following conditions shall be observed by persons dispensing such prescriptions —
 - (a) the prescription shall not be dispensed more than the maximum number of times indicated by it, and on each occasion upon which it is dispensed the dispenser shall —
 - (i) in the case of a prescription that is not issued electronically — stamp or mark the prescription to show clearly the date upon which it is dispensed and the name and address of the pharmacy at which it is dispensed; and
 - (ii) in the case of a prescription that is issued electronically — indicate the date upon which it is dispensed and the name and address of the pharmacy at which it is dispensed using the means provided by the approved electronic prescribing system;
 - (b) the person who dispenses a prescription which does not clearly indicate the maximum number of times it is to be dispensed, or which has reached the last occasion upon which it may be dispensed according to the maximum indicated by it, shall —
 - (i) in the case of a prescription that is not issued electronically — write in ink, stamp or mark in legible letters across the prescription the word “cancelled”; and
 - (ii) in the case of a prescription that is issued electronically — cancel the prescription using

the means provided by the approved electronic prescribing system;

(c) (i) for the purposes of this paragraph —

- (I) handwritten records in a bound book with sequentially numbered pages;
- (II) computer records on disk or tape that can be displayed and from which printed copies of the records can be produced on demand;
- (III) microfilm, microfiche, or any other photographic systems in logical sequence and retrievable form;
- (IV) client record cards, which include the details set out in a prescription; or
- (V) alternative recording methods which have been specifically and individually approved in writing by the CEO for the purposes of this paragraph,

are deemed to be the Prescription Book;

(ii) before the poison is handed to the purchaser the following details from the prescription shall be entered into the Prescription Book —

the name and quantity of the poison, the direction for use (if applicable), the date of issue of the prescription, the name and address of the patient, the name and address, or the name and identifying initials, of the prescriber, the date of dispensing the prescription, and the entry shall be given an identifying letter or number or combination of letter and number;

(iii) in the event of the dispensing of a repeated prescription an annotation of this fact showing

- the date of the repeat on the original entry in the Prescription Book shall be sufficient compliance with this regulation;
- (iv) the label on the bottle or package containing the poison shall be marked with the identifying letter or number of the prescription as appearing in the Prescription Book; and
 - (v) the Prescription Book shall be kept at the place at which the poison included in Schedule 4 was dispensed for at least 2 years and shall be produced on demand to any person authorised in that behalf under the Act or these regulations;
- (d) a prescription shall not be dispensed if it is —
- (i) cancelled; or
 - (ii) more than 12 months old;
- (e) a prescription which is illegible or defaced, or appears to have been altered or which appears to be for the purpose of enabling some unauthorised person to obtain a poison included in Schedule 4, or which does not appear to be genuine, shall not be dispensed;
- (f) a pharmaceutical chemist given a prescription referred to in paragraph (e) shall forthwith inform the CEO of the relevant circumstances and the reasons for his refusal to dispense the prescription, and, in the case of a prescription that was not issued electronically, retain it.
- (4) The following conditions shall be observed by persons supplying poisons included in Schedule 4 under subregulation (1)(d) —
- (a) the supply shall be recorded in the client record cards of the remote area nursing post and the record cards kept for a minimum of 2 years following the last entry in those records; and

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- (b) the poisons shall be labelled in accordance with regulation 21(1)(a) or 21(1)(b).

[Regulation 36 amended in Gazette 19 Feb 1971 p. 518-19; 29 Aug 1980 p. 3028; 29 Jun 1984 p. 1784; 5 Jul 1985 p. 2392; 7 Aug 1987 p. 3038; 18 Sep 1987 p. 3596; 2 Jun 1989 p. 1603; 3 Jun 1990 p. 2626; 16 Apr 1992 p. 1634; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 24 Jun 1994 p. 2867; 19 Mar 1996 p. 1221-2; 15 Dec 2006 p. 5630; 7 Nov 2008 p. 4809-10; amendeded by Act No. 9 of 2003 s. 44.]

36AA. Provision of “approved starter packs” by registered nurses

- (1) In this regulation —

approved health service means a health service (as defined in section 3(1) of the *Health Services (Conciliation and Review) Act 1995*, other than a health service provided by way of medical or epidemiological research) that —

- (a) operates outside the metropolitan region (as defined in section 6 of the *Metropolitan Region Town Planning Scheme Act 1959*); and
- (b) has been approved by the CEO for the purposes of this regulation;

approved name has the same meaning as in regulation 35C;

approved starter pack means a starter pack approved by the CEO for the purposes of this regulation;

brand name has the same meaning as in regulation 35C;

starter pack means a quantity of a poison included in Schedule 4, prepared by a pharmaceutical chemist and consisting of —

- (a) if the poison is supplied in prepacked individual packs, one individual standard pack;
- (b) if the poison is a liquid, the smallest pack of the poison available from the manufacturer; or

- (c) otherwise, not more than 3 days medication of the poison;

starter pack instruction means an instruction of the kind described in subregulation (2).

- (2) A registered nurse at an approved health service may give an approved starter pack to a patient, other than an in-patient, at the health service if orally instructed to do so by a medical practitioner, who need not be present at the health service.
- (3) Before giving an approved starter pack to a patient a registered nurse must —
 - (a) ensure that the approved starter pack is labelled in accordance with subregulation (8); and
 - (b) record the details of the provision of the approved starter pack in accordance with subregulation (10).
- (4) A medical practitioner must not give a starter pack instruction unless satisfied that —
 - (a) the patient has an acute medical condition;
 - (b) there is no other medical practitioner at the health service who could reasonably attend to the patient in person; and
 - (c) the distance from the health service to the nearest pharmacy registered under the *Pharmacy Act 1964* that is open is more than 25 km.
- (5) For the purposes of subregulation (4), a medical practitioner may rely on information provided by the registered nurse as to the patient's condition, the availability of other medical practitioners and the location of the nearest open pharmacy.
- (6) Within 72 hours of giving a starter pack instruction a medical practitioner must give to the registered nurse, or another registered nurse at the health service, signed, written confirmation of the instruction including —
 - (a) the name of the medical practitioner;

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- (b) the name of the registered nurse to whom the starter pack instruction was given;
 - (c) the name of the patient;
 - (d) the date and time when the instruction was given;
 - (e) details of the approved starter pack;
 - (f) any relevant directions for use that were to be given to the patient; and
 - (g) any other information that the medical practitioner considers relevant.
- (7) The person in charge of an approved health service must —
 - (a) keep all written confirmations given under subregulation (6) to registered nurses at the health service for at least 2 years; and
 - (b) produce them on demand to any person authorised under the Act to demand production of such records.
- (8) An approved starter pack must be labelled in English with —
 - (a) the words “Keep out of reach of children”;
 - (b) the name of the patient;
 - (c) the name and address of the health service;
 - (d) in relation to each poison in the approved starter pack —
 - (i) the approved name and strength or amount of the poison; or
 - (ii) if the brand name uniquely identifies the strength of the poison, that brand name;
 - (e) the total quantity of medication contained in the approved starter pack;
 - (f) the date on which the approved starter pack was given to the patient;
 - (g) any directions for use given by the medical practitioner;

- (h) the number referred to in subregulation (10)(f) identifying the relevant entry in the health service's Starter Pack Supply Book; and
 - (i) any relevant cautionary or advisory statements set out in Appendix K to the SUSDP.
- (9) The person in charge of an approved health service must —
 - (a) maintain a Starter Pack Supply Book for the health service consisting of —
 - (i) handwritten records in a bound book with sequentially numbered pages; or
 - (ii) records kept in another manner which has been specifically and individually approved in writing by the CEO for the purposes of this paragraph;
 - (b) keep the Starter Pack Supply Book for at least 2 years after the last entry is made in it; and
 - (c) produce the Starter Pack Supply Book on demand to any person authorised under the Act to demand production of such records.
- (10) Before giving an approved starter pack to a patient a registered nurse must record the following information in the health service's Starter Pack Supply Book —
 - (a) the name and address of the patient;
 - (b) in relation to each poison in the approved starter pack —
 - (i) the approved name and strength or amount of the poison; or
 - (ii) if the brand name uniquely identifies the strength of the poison, that brand name;
 - (c) the date and time at which the approved starter pack is to be given to the patient;
 - (d) the name of the medical practitioner;
 - (e) any directions for use given by the medical practitioner;
 - (f) a unique number identifying the entry in the Book; and

- (g) the registered nurse's name and signature.

*[Regulation 36AA inserted in Gazette 29 Jun 2001 p. 3115-18;
amended in Gazette 15 Dec 2006 p. 5630; 2 Oct 2007 p. 4965.]*

36AAB. Provision of “psychiatric emergency packs” by certain registered nurses

- (1) In this regulation —

approved name has the meaning given in regulation 35C;

Community Emergency Response Team means a service, provided by a public hospital, that —

- (a) is provided in the metropolitan region; and
- (b) responds to psychiatric emergencies in the community; and
- (c) is designated by the CEO for the purposes of this definition;

metropolitan region has the meaning given in section 4 of the *Planning and Development Act 2005*;

psychiatric emergency pack means a pack, approved by the CEO for the purposes of this regulation and prepared by a pharmaceutical chemist, containing a quantity of a poison included in Schedule 4 that —

- (a) if the poison is supplied in prepacked individual packs — is one individual standard pack; or
- (b) if the poison is a liquid — is the smallest pack of the poison available from the manufacturer; or
- (c) otherwise — does not exceed 3 days worth of medication of the poison;

Rural Community Mental Health Team means a service, provided by a public hospital, that —

- (a) is provided outside the metropolitan region; and
- (b) responds to psychiatric emergencies in the community; and

- (c) is approved by the CEO for the purposes of this definition;

team medical practitioner means a medical practitioner who is a member of a Community Emergency Response Team or a Rural Community Mental Health Team;

team psychiatrist means a psychiatrist who is a member of a Community Emergency Response Team or a Rural Community Mental Health Team;

team registered nurse means a registered nurse who is a member of a Community Emergency Response Team or a Rural Community Mental Health Team.

- (2) A team registered nurse may give a psychiatric emergency pack to a patient, other than an in-patient, if instructed to do so by a team psychiatrist or a team medical practitioner, who need not be present with the nurse at the time of giving the instruction.
- (3) The instruction may be given orally.
- (4) The psychiatrist or medical practitioner must not give the instruction unless satisfied that the patient is in need of urgent psychiatric intervention and it is not practical for the patient to obtain the medication contained in the pack in any other way.
- (5) For the purposes of subregulation (4), the psychiatrist or medical practitioner may rely on the information given by the nurse about the patient's condition.
- (6) Before giving the psychiatric emergency pack to the patient the nurse must —
- (a) ensure that the pack has been labelled in accordance with subregulation (9); and
 - (b) record in the Emergency Pack Supply Book the information required by subregulation (11).
- (7) Within 72 hours of giving the instruction the psychiatrist or medical practitioner must give the nurse, or another team

member, signed, written confirmation of the instruction including —

- (a) the name of the psychiatrist or medical practitioner; and
 - (b) the name of the nurse to whom the instruction was given; and
 - (c) the name of the patient; and
 - (d) the date and time when the instruction was given; and
 - (e) details of the psychiatric emergency pack; and
 - (f) any directions for use that were to be given to the patient; and
 - (g) any other information that the psychiatrist or medical practitioner considers relevant.
- (8) A person in charge of a Community Emergency Response Team or a Rural Community Mental Health Team must —
 - (a) keep all written confirmations given under subregulation (7) for at least 2 years; and
 - (b) produce them on demand to any person authorised under the Act to demand production of such records.
- (9) A psychiatric emergency pack must be labelled in English with —
 - (a) the words “keep out of reach of children”; and
 - (b) the name of the patient; and
 - (c) the name and address of the Community Emergency Response Team or the Rural Community Mental Health Team; and
 - (d) in relation to the poison in the psychiatric emergency pack —
 - (i) the approved name and strength or amount of the poison; or
 - (ii) if the brand name uniquely identifies the strength of the poison — that brand name;

- and
- (e) the total quantity of each medication contained in the psychiatric emergency pack; and
 - (f) the date on which the psychiatric emergency pack was given to the patient; and
 - (g) any directions for use given by the psychiatrist or medical practitioner; and
 - (h) the number referred to in subregulation (11)(f) identifying the relevant entry in the Emergency Pack Supply Book; and
 - (i) any relevant cautionary or advisory statements set out in Appendix K to the SUSDP.
- (10) A person in charge of a Community Emergency Response Team or a Rural Community Mental Health Team must —
- (a) maintain an Emergency Pack Supply Book for that Team consisting of handwritten records in a book with sequentially numbered pages; and
 - (b) keep the Emergency Pack Supply Book for at least 2 years after the last entry is made in it; and
 - (c) produce the Emergency Pack Supply Book on demand to any person authorised under the Act to demand production of such records.
- (11) The information to be recorded in the Emergency Pack Supply Book is —
- (a) the name and address of the patient; and
 - (b) in relation to the poison in the psychiatric emergency pack —
 - (i) the approved name and strength or amount of the poison; or
 - (ii) if the brand name uniquely identifies the strength of the poison — that brand name;
- and

- (c) the date and time at which the psychiatric emergency pack is to be given to the patient; and
- (d) the name of the psychiatrist or medical practitioner who gave the instruction; and
- (e) any directions for use given by the psychiatrist or medical practitioner; and
- (f) a unique number identifying the entry in the Book; and
- (g) the nurse's name and signature.

[Regulation 36AAB inserted in Gazette 2 Oct 2007 p. 4965-8.]

36A. Storage of substances included in Schedule 4

- (1) A pharmaceutical chemist to whom a substance included in Schedule 4 is supplied shall not store it, or expose or offer it for sale, in any portion of a pharmacy to which persons other than members of the staff of the pharmacy have access.
- (2) Subject to subregulation (3), a medical practitioner, dentist or veterinary surgeon to whom a substance included in Schedule 4 is supplied shall store it in a container, cupboard or room —
 - (a) at the medical practitioner's, dentist's or veterinary surgeon's usual place of practice;
 - (b) that is kept locked; and
 - (c) access to which is available only to the medical practitioner, dentist or veterinary surgeon and persons under his or her personal supervision.
- (3) A medical practitioner, dentist or veterinary surgeon may store substances included in Schedule 4 other than in accordance with subregulation (2) if —
 - (a) they are emergency supplies; and
 - (b) the medical practitioner, dentist or veterinary surgeon has them in his or her actual possession for the purpose of attending patients at places other than at his or her usual place of practice.

(4) In subregulation (3) —

emergency supplies means —

- (a) in the case of a medical practitioner — the substances described as “Emergency Drug (Doctor’s Bag) Supplies” in the document “Schedule of Pharmaceutical Benefits”, as published from time to time by the Commonwealth Government for the purposes of Part VII of the *National Health Act 1953* of the Commonwealth; or
- (b) in the case of a dentist or veterinary surgeon — the substances that are ordinarily carried by dentists or veterinary surgeons who are attending patients at places other than at their usual place of practice.

[Regulation 36A inserted in Gazette 19 Feb 1999 p. 555-6.]

36B. Record of supply or administration of substances included in Schedule 4

- (1) A medical practitioner, dentist or veterinary surgeon is to record in his or her client record cards every occasion on which he or she —
 - (a) supplies a substance included in Schedule 4 to a person; or
 - (b) administers a substance included in Schedule 4 to a person or animal.
- (2) A record required to be made under subregulation (1) is to include —
 - (a) the name, strength and quantity of the substance supplied or administered;
 - (b) the name and address of the person to whom the substance was supplied or administered, or of the owner of the animal to which the substance was administered; and

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- (c) the date on which the substance was supplied or administered.
- (3) A record required to be made under regulation (1) must be —
 - (a) kept for at least 2 years from the date on which the substance was supplied or administered; and
 - (b) made available for inspection on request by an authorised officer (other than an environmental health officer).

[Regulation 36B inserted in Gazette 19 Feb 1999 p. 556.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

37. Conditions for prescription of a poison included in Schedule 4

- (1) A prescription for a poison included in Schedule 4 shall comply with the following conditions —
 - (a) it shall include —
 - (i) the name and address of the prescriber; and
 - (ii) the name and address of the patient; and
 - (iii) the name and quantity of the substance; and
 - (iv) directions for use (if necessary); and
 - (v) the date on which it is issued; and
 - (vi) the maximum number of times it may be repeated, if any, and (where applicable) the intervals at which it may be repeated;
 - and
 - (b) it shall be issued in a manner provided for in subregulation (1A) or (1B); and
- [(ba) deleted]*
- (c) a prescription issued by a dentist shall be for dental purposes only and shall indicate that and a prescription issued by a veterinary surgeon shall be for veterinary use

- only and shall include the words “For veterinary use only” or “For animal treatment only”;
- (d) if a prescription contains an unusual dose the prescriber shall indicate that such a dose is intended by —
- (i) in the case of a prescription that is not issued electronically — underlining that part of the prescription and initialling the same in the margin; and
 - (ii) in the case of a prescription that is issued electronically — the means provided by the approved electronic prescribing system;
- (e) a prescription shall not bear the impression of a rubber stamp or other such contrivance in lieu of the written signature of the medical practitioner, nurse practitioner, dentist or veterinary surgeon by whom it has been written; and
- (f) a prescription shall not be written in cipher.
- (1A) A prescription that is issued electronically shall be issued via an approved electronic prescribing system.
- (1B) A prescription that is not issued electronically shall be either —
- (a) written in ink in the prescriber’s own handwriting; or
 - (b) processed on a computer program that —
 - (i) complies with the criteria specified in Appendix L; or
 - (ii) is recommended by the Poisons Advisory Committee and approved in writing by the CEO.
- The prescription shall be signed by the prescriber in his or her own handwriting.
- (2) With the written approval of the CEO a medical practitioner, nurse practitioner, dentist or veterinary surgeon may issue a typewritten prescription where the CEO is satisfied that by reason of physical infirmity the prescriber is unable to write

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legibly in his or her own handwriting but in that case the prescriber shall sign the prescription with his or her usual signature.

[Regulation 37 inserted in Gazette 19 Feb 1971 p. 519; amended in Gazette 21 Nov 1986 p. 4269; 5 Dec 1986 p. 4467; 17 Aug 1990 p. 4081; 26 Jul 1991 p. 3854; 7 Aug 1992 p. 3869; 26 May 1994 p. 2201; 19 Mar 1996 p. 1222; 15 Dec 2006 p. 5630; 7 Nov 2008 p. 4810-11; amended by Act No. 9 of 2003 s. 45.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

38. Dispensing poisons included in Schedule 4 in emergency cases

Where a medical practitioner, nurse practitioner, dentist or veterinary surgeon in a case of emergency orally or by telephone or telegram directs the dispensing of a poison included in Schedule 4, he shall forthwith write a prescription complying with the conditions prescribed in regulation 37, mark such prescription to show that it has been given as a confirmation of instructions given by him orally or by telephone or telegram, and despatch such prescription within 24 hours to the person to whom the instructions were given.

[Regulation 38 amended in Gazette 19 Mar 1996 p. 1222; amended by Act No. 9 of 2003 s. 46.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

[38A. Deleted in Gazette 17 Mar 1998 p. 1417.]

38AA. Administration of poisons included in Schedule 4 in hospital

- (1) Subject to subregulation (2) a person, other than a medical practitioner, nurse practitioner or a dentist, shall not administer a poison included in Schedule 4 to a patient in a hospital unless the administration of the poison is authorised in writing on the medication chart of the patient by a medical practitioner, nurse practitioner or a dentist.

- (2) A medical practitioner, nurse practitioner or dentist may verbally authorise the administration of a poison included in Schedule 4 and shall within 24 hours of so doing note such authorisation in writing on the medication chart of the patient.

[Regulation 38AA inserted in Gazette 28 May 1993 p. 2596; amended in Gazette 19 Mar 1996 p. 1222; amended by Act No. 9 of 2003 s. 47.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

[38B.] *Deleted in Gazette 24 Jun 1994 p. 2867.]*

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

38C. Clomiphene and cyclofenil

Clomiphene or cyclofenil or a substance containing clomiphene or cyclofenil and other substances specifically prepared to stimulate ovulation shall not be prescribed except —

- (a) by a gynaecologist or obstetrician;
- (b) by any other medical practitioner, if authorised in writing by the CEO; or
- (c) by a veterinary surgeon for the purpose of veterinary trials under the direction of a veterinary surgeon.

[Regulation 38C inserted in Gazette 24 Jun 1994 p. 2868; amended in Gazette 11 Apr 1997 p. 1829; 15 Dec 2006 p. 5630.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

38D. Etretinate or acitretin

- (1) Etretinate or acitretin or a substance containing etretinate or acitretin shall not be prescribed except by a physician or dermatologist.
- (1a) Where etretinate or acitretin or a substance containing etretinate or acitretin is supplied in accordance with a prescription under

subregulation (1) the supplier shall ensure that the container in which the etretinate or acitretin or the substance containing etretinate or acitretin is supplied, is labelled with a warning in the following words, or other words having the same effect —

“WARNING — CAUSES BIRTH DEFECTS”.

- (2) A physician or dermatologist who prescribes etretinate or acitretin or a substance containing etretinate or acitretin shall ensure that the possibility of pregnancy has been excluded prior to the commencement of the treatment and that the patient is informed that she must not become pregnant for a period of 24 months after completion of the treatment.

[Regulation 38D inserted in Gazette 8 Feb 1985 p. 519; amended in Gazette 31 May 1985 p. 1882; 23 May 1986 p. 1716; 2 Oct 1987 p. 3776; 27 May 1988 p. 1770; 11 Nov 1988 p. 4444; 2 Jun 1989 p. 1603; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 2 Sep 1994 p. 4533; 11 Apr 1997 p. 1829; 14 Sep 2001 p. 5074-5; 5 Oct 2004 p. 4309.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

38E. Prostaglandins

Cloprostenol, dinoprost, dinoprostone, fenprostalene, fluprostenol, prostianol or a substance containing any of those prostaglandins shall not be prescribed except —

- (a) by a veterinary surgeon for use in the treatment of animals; or
- (b) in the case of dinoprost or dinoprostone or a substance containing dinoprost or dinoprostone —
 - (i) by a physician, gynaecologist or obstetrician; or

- (ii) by any other medical practitioner, if authorised in writing by the CEO.

[Regulation 38E inserted in Gazette 2 Jun 1989 p. 1604; amended in Gazette 16 Apr 1992 p. 1635; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 11 Apr 1997 p. 1830; 15 Dec 2006 p. 5630-1.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

38F. Isotretinoin

- (1) Isotretinoin or a substance containing isotretinoin shall not be prescribed except by a physician or dermatologist.
- (1a) Where isotretinoin or a substance containing isotretinoin is supplied in accordance with a prescription under subregulation (1) the supplier shall ensure that the container in which the isotretinoin or the substance containing isotretinoin is supplied, is labelled with a warning in the following words, or other words having the same effect —
- “WARNING — CAUSES BIRTH DEFECTS”.
- (2) A physician or dermatologist who prescribes isotretinoin or a substance containing isotretinoin shall ensure that the possibility of pregnancy has been excluded prior to the commencement of the treatment and that the patient is informed that she must not become pregnant for a period of one month after completion of the treatment.

[Regulation 38F inserted in Gazette 31 May 1985 p. 1882; amended in Gazette 23 May 1986 p. 1716; 2 Oct 1987 p. 3776; 27 May 1988 p. 1770; 2 Jun 1989 p. 1604; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 11 Apr 1997 p. 1830; 14 Sep 2001 p. 5075; 5 Oct 2004 p. 4309.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

38G. Thalidomide for human use

- (1) Thalidomide or a substance containing thalidomide shall not be prescribed except by a physician or dermatologist.
- (2) Where thalidomide or a substance containing thalidomide is supplied in accordance with a prescription under subregulation (1) the supplier shall ensure that the container in which the thalidomide or the substance containing thalidomide is supplied, is labelled with a warning in the following words, or other words having the same effect —

“WARNING — CAUSES BIRTH DEFECTS”.
- (3) A physician or dermatologist who prescribes thalidomide or a substance containing thalidomide shall ensure that the possibility of pregnancy has been excluded prior to the commencement of treatment and that the patient is informed that she must not become pregnant for a period of one month after completion of treatment.

[Regulation 38G inserted in Gazette 26 Jul 1991 p. 3854; amended in Gazette 26 May 1994 p. 2201; 19 Mar 1996 p. 1223; 11 Apr 1997 p. 1830; 14 Sep 2001 p. 5075; 5 Oct 2004 p. 4310.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

38H. Chloramphenicol

Chloramphenicol or substances containing chloramphenicol shall not be prescribed except —

- (a) by a medical practitioner for human use; or
- (b) by a veterinary surgeon for use in or on an animal not used for meat, edible offal, egg or milk production.

[Regulation 38H inserted in Gazette 2 Jun 1989 p. 1604; amended in Gazette 24 Jun 1994 p. 2868; 11 Apr 1997 p. 1830-1.]

38I. Follicular stimulating hormone and luteinising hormone

Follicular stimulating hormone, luteinising hormone or a substance containing follicular stimulating hormone or luteinising hormone shall not be prescribed except —

- (a) by a physician, gynaecologist or obstetrician;
- (b) by any other medical practitioner, if authorised in writing by the CEO; or
- (c) by a veterinary surgeon for the purpose of veterinary trials under the direction of a veterinary surgeon.

[Regulation 38I inserted in Gazette 2 Jun 1989 p. 1604; amended in Gazette 11 Apr 1997 p. 1831; 15 Dec 2006 p. 5630-1.]

[38J. Deleted in Gazette 19 Mar 1996 p. 1223.]

38K. Carnidazole

Carnidazole or a substance containing carnidazole shall not be prescribed except by a veterinary surgeon for use in the treatment of pigeons.

[Regulation 38K inserted in Gazette 2 Jun 1989 p. 1604; amended in Gazette 11 Apr 1997 p. 1831.]

38L. Oxolinic acid

Oxolinic acid or any substance containing oxolinic acid shall not be prescribed except by a veterinary surgeon for use in the treatment of fish.

[Regulation 38L inserted in Gazette 13 Dec 1991 p. 6191; amended in Gazette 11 Apr 1997 p. 1831.]

38M. Clozapine

Clozapine or a substance containing clozapine shall not be prescribed except —

- (a) by a psychiatrist; or

- (b) by any other medical practitioner authorised in writing by the CEO.

[Regulation 38M inserted in Gazette 24 Jun 1994 p. 2868; amended in Gazette 19 Mar 1996 p. 1223; 11 Apr 1997 p. 1831; 27 Nov 1998 p. 6344; 15 Dec 2006 p. 5630-1.]

38N. Nitrofurantoin derivatives

The nitrofurantoin derivatives included in Schedule 4 and listed in the Table to this regulation, or a substance containing any of those poisons, shall not be prescribed except —

- (a) by a medical practitioner for human use; or
- (b) by a veterinary surgeon for use in the feeding or treatment of an animal not used for meat, edible offal, egg or milk production.

Table
Nitrofurantoin derivatives

Furazolidone
Nifursol
Nitrofurantoin
Nitrofurantoin
Nitrofurazone.

[Regulation 38N inserted in Gazette 24 Jun 1994 p. 2868; amended in Gazette 19 Mar 1996 p. 1223; 11 Apr 1997 p. 1831-2.]

38O. Bosentan for human use

- (1) Bosentan or a substance containing bosentan shall not be prescribed except —
 - (a) by a physician; or
 - (b) by any other medical practitioner authorised in writing by the CEO.

- (2) Where bosentan or a substance containing bosentan is supplied in accordance with a prescription under subregulation (1) the supplier shall ensure that the container in which the bosentan or the substance containing bosentan is supplied is labelled with a warning in the following words, or other words having the same effect —

“WARNING — CAUSES BIRTH DEFECTS”.

- (3) A physician, or other medical practitioner, who prescribes bosentan or a substance containing bosentan shall ensure that the possibility of pregnancy has been excluded prior to the commencement of treatment and that the patient is informed that she must not become pregnant during or for a period of 3 months after completion of treatment.

*[Regulation 38O inserted in Gazette 5 Oct 2004 p. 4310;
amended in Gazette 15 Dec 2006 p. 5630-1.]*

38P. Teriparatide for human use

Teriparatide or a substance containing teriparatide shall not be prescribed except —

- (a) by a physician, a rheumatologist, an immunologist, an endocrinologist or a geriatrician; or
- (b) by any other medical practitioner authorised in writing by the CEO.

*[Regulation 38P inserted in Gazette 5 Oct 2004 p. 4310;
amended in Gazette 15 Dec 2006 p. 5630-1.]*

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

39. Veterinary use of poisons included in Schedule 4

- (1) Notwithstanding the provisions of regulation 36 a pharmaceutical chemist is authorised to supply for veterinary use a poison included in Schedule 4 listed in Appendix H without a prescription where —

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- (a) the purchaser satisfies such pharmaceutical chemist that it is not reasonably practicable for him to obtain such a prescription;
- (b) the name and address of the purchaser, date of supply, form and quantity of poison supplied, species of animal and number of animals to be treated, and a descriptive name of the disease for which the animals are to be treated, are entered in a register of poisons;
- (c) the quantity of poisons supplied is not greater than is required to provide 72 hours of therapeutic treatment according to the directions for normal dosage with the poison, or in the case of a pre-packed proprietary brand the smallest size manufactured for sale of the proprietary brand which provides 72 hours treatment; and
- (d) the pharmaceutical chemist provides adequate written instructions for the use of the poison.

[(2) deleted]

[Regulation 39 inserted in Gazette 26 Aug 1977 p. 2966; amended in Gazette 2 Oct 1987 p. 3776; 19 Mar 1996 p. 1223-4.]

39A. Stockfeed manufacturers may sell poisons included in Schedule 4

- (1) Notwithstanding any other provision of these regulations a stockfeed manufacturer holding an appropriate permit under subregulation (3) may sell by retail to any person producing a written order therefor signed by a veterinary surgeon, a mixture of stockfeed with any poison included in Schedule 4 being an antibiotic or sulphonamide, in such quantity and of such composition as is specified in the order.
- (2) The signed order shall be cancelled by the stockfeed manufacturer and retained by him for not less than 2 years after the sale, and upon request shall be produced for inspection to an authorised officer.

- (3) A stockfeed manufacturer who wishes to sell by retail mixtures pursuant to subregulation (1) may apply to the CEO for, and at the discretion of the CEO be granted, a permit in Form 11AA in Appendix A, specifying the poisons included in Schedule 4 that may be contained in such mixtures, and any limits as to the quantity or composition of such mixtures that may be sold.
- (4) The provisions of section 23 of the Act do not apply to a sale by a stockfeed manufacturer pursuant to and in accordance with this regulation or to the preparation of a mixture of stockfeed for the purposes of such sale.

[Regulation 39A inserted in Gazette 5 Oct 1979 p. 3085; amended in Gazette 29 Jun 1984 p. 1784; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1224; 15 Dec 2006 p. 5630-1.]

39BA. Use of poisons included in Schedule 4 on certificated commercial vessels

- (1) The master of a certificated commercial vessel is authorised to procure and be in possession of any poison included in Schedule 4 that is necessary to complete the equipment of the vessel in order to comply with the requirements of the *Western Australian Marine Act 1982*.
- (2) The holder of an appropriate licence, or any other authorised person, may supply a poison included in Schedule 4 on receipt of a written order, signed by the master of the certificated commercial vessel, certifying that the poison is necessary to complete the equipment of the vessel in order to comply with the applicable requirements of subregulation (1).
- (3) The written order referred to in subregulation (2) must contain all of the following information —
 - (a) the date of the order;
 - (b) the name of the certificated commercial vessel;
 - (c) the machinery and hull number;

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- (d) the name, address and signature of the master of the vessel;
 - (e) the quantity, form and strength of the poison ordered.
- (4) The master of the certificated commercial vessel must ensure that —
 - (a) so far as is practicable, the poisons supplied under subregulation (2) are stored in a manner that prevents their theft, loss or unauthorised use; and
 - (b) a record is kept of all the poisons stored aboard the vessel.
- (5) When a medical practitioner authorises the administration of one of the poisons to a person on board the certificated commercial vessel, the master of the vessel must ensure that a record is kept of all of the following information —
 - (a) the date on which the poison was administered;
 - (b) the poison being administered, the strength of the poison and the quantity that has been administered;
 - (c) the name of the person to whom the poison has been administered;
 - (d) the name and address of the medical practitioner who authorised the administration of the poison.

[Regulation 39BA inserted in Gazette 12 Jun 2009 p. 2109-10.]

39BB. Use of poisons included in Schedule 4 on racing yachts

- (1) The owner of a racing yacht is authorised to procure and be in possession of any poison included in Schedule 4 that is necessary to complete the equipment of the yacht in order to comply with the requirements of the rules known as the “Racing Rules of Sailing” made by Yachting Australia Incorporated.
- (2) The holder of an appropriate licence, or any other authorised person, may supply a poison included in Schedule 4 on receipt of a written order, signed by the owner of the racing yacht, certifying that the poison is necessary to complete the

equipment of the yacht in order to comply with the applicable requirements of subregulation (1).

- (3) The written order referred to in subregulation (2) must contain all of the following information —
- (a) the date of the order;
 - (b) the name of the racing yacht;
 - (c) the registration number of the racing yacht;
 - (d) the name of the yacht club organising the race;
 - (e) the name, address and signature of the owner of the yacht;
 - (f) the quantity, form and strength of the poison ordered.
- (4) The owner of the racing yacht must ensure that —
- (a) so far as is practicable, the poisons supplied under subregulation (2) are stored in a manner that prevents their theft, loss or unauthorised use; and
 - (b) a record is kept of all the poisons stored aboard the yacht.
- (5) When a medical practitioner authorises the administration of one of the poisons to a person on board the racing yacht, the skipper of the yacht must ensure that a record is kept of all of the following information —
- (a) the date on which the poison was administered;
 - (b) the poison being administered, the strength of the poison and the quantity that has been administered;
 - (c) the name of the person to whom the poison has been administered;
 - (d) the name and address of the medical practitioner who authorised the administration of the poison.

[Regulation 39BB inserted in Gazette 12 Jun 2009 p. 2110-11.]

39B. Use of poisons included in Schedule 4 on ships and aircraft

- (1) The master of a ship other than a certificated commercial vessel or a racing yacht is authorised to procure and be in possession of any poison included in Schedule 4 that is necessary to complete the equipment of the ship in order to comply with the requirements of —
 - (a) if the ship is registered in Australia —
 - (i) section 125 of the *Navigation Act 1912* of the Commonwealth; or
 - (ii) the navigation authority of any State of Australia;
 - or
 - (b) if the ship is not registered in Australia —
 - (i) a law applying to ships in the country in which the ship is registered; or
 - (ii) the “*International Medical Guide for Ships*” (2nd. Edition), as published by the World Health Organization.
- (2) The holder of an appropriate licence, or any other authorised person, may supply a poison included in Schedule 4 on receipt of a written order, signed by the master of the ship and by the manager, or a person authorised in writing by the manager, of the ship’s agents in the State, certifying that the poison is necessary to complete the equipment of the ship in order to comply with the applicable requirements of subregulation (1).
- (3) The person in charge of an aircraft is authorised to be in possession of a poison included in Schedule 4, in a quantity that does not exceed the maximum permitted quantity, as specified by the Department of Transport of the Commonwealth, for the purposes of medical treatment on the aircraft.
- (4) The holder of an appropriate licence, or any other authorised person, may supply a poison included in Schedule 4 on receipt of a written order, signed by the manager, or a person authorised in writing by the manager, of the airline company or firm

responsible for the operation of the aircraft in the State, certifying that the poison is necessary for the purposes of medical treatment on aircraft.

[Regulation 39B inserted in Gazette 31 Dec 1993 p. 6884; amended in Gazette 19 Mar 1996 p. 1224; 12 Jun 2009 p. 2111.]

39C. Use of poisons included in Schedule 4 on ships carrying livestock

- (1) The master of a ship that is to carry livestock is authorised to procure and be in possession of any poison included in Schedule 4 that is necessary for compliance —
 - (a) by the exporter with the *Australian Livestock Export Standards — March 2001* (as amended from time to time); or
 - (b) by the master with order 18 of the *Marine Orders Part 43: Cargo and Cargo Handling — Livestock* (as amended from time to time) made under the *Navigation Act 1912* of the Commonwealth.
- (2) The holder of an appropriate licence or any other authorised person may supply a poison included in Schedule 4 to the master of a ship on receipt of a written order certifying that the master is authorised under subregulation (1) to procure and be in possession of the poison.
- (3) The written order must be signed by the master of the ship himself or herself and by the exporter of the livestock.
- (4) The master of a ship must store a poison supplied under subregulation (2) in a secure place on board the ship.
- (5) In this regulation —

livestock means livestock in relation to which an exporter has given a notice of intention to export under order 6 of the *Export Control (Animals) Orders as amended*, made under the *Export*

Control (Orders) Regulations 1982 in force under the *Export Control Act 1982* of the Commonwealth;

exporter means a person who holds a live-stock export licence under the *Australian Meat and Live-stock Industry Act 1997* of the Commonwealth, or a person authorised in writing by the licensee as the licensee's agent;

master of a ship includes, except in subregulation (3), a person authorised in writing by the master as the master's agent.

[Regulation 39C inserted in Gazette 4 Jan 2005 p. 3-4.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

40. Special authority to purchase poisons included in Schedule 4

- (1) Subject to subregulation (1aa), until in any particular case such authority is withdrawn —
- (a) a medical practitioner;
 - (aa) a nurse practitioner;
 - (b) a pharmaceutical chemist;
 - (c) a dentist;
 - (d) a veterinary surgeon;
 - (e) an analyst appointed under the *Health Act 1911*;
 - (f) the Director of Nursing of a hospital registered under the *Hospitals and Health Services Act 1927*;
 - (g) any other person authorised in writing by the CEO,

is authorised to procure, in accordance with subregulation (1a), a poison included in Schedule 4 to the extent that it is required for the purpose of his profession or employment, but such authority does not entitle any person to have in his possession any poison included in Schedule 4 other than in accordance with these regulations or in any quantity greater than is permitted by the CEO.

- (1aa) A medical practitioner is not authorised under subregulation (1) to procure a poison included in Schedule 4 and referred to in a regulation listed in the Table, unless the medical practitioner is authorised under that regulation to prescribe the poison.

Table

regulation 38C	regulation 38G
regulation 38D	regulation 38I
regulation 38E	regulation 38M
regulation 38F	regulation 38O
	regulation 38P

- (1a) A person authorised under subregulation (1) to procure a poison included in Schedule 4 shall, unless a record is made under regulation 41B in relation to the procurement of the poison, provide a written order to the person from whom he or she is attempting to procure the poison, setting out —
- (a) the name, address and signature of the authorised person;
 - (b) the date of the order; and
 - (c) the name and quantity of the poison.
- (2) A person who wishes to use any poison included in Schedule 4 being an antibiotic or sulphonamide for the preparation of mixtures for sale pursuant to regulation 39A, and who holds a permit under that regulation to sell such mixtures, is authorised to procure, use and be in possession of such poison included in Schedule 4 for the preparation of such mixtures.

[Regulation 40 amended in Gazette 5 Oct 1979 p. 3085; 29 Jun 1984 p. 1784; 8 Feb 1985 p. 519; 8 Jun 1990 p. 2627; 28 May 1993 p. 2596; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1225; 11 Apr 1997 p. 1832; 5 Oct 2004 p. 4311; 15 Dec 2006 p. 5630-1; amended by Act No. 9 of 2003 s. 48.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

40A. Delivery of a poison included in Schedule 4 on order

A person who sells or supplies a poison included in Schedule 4 under regulation 36(1), other than to the holder of a prescription under regulation 36(1)(b), may deliver that poison, or cause it to be delivered only —

- (a) to the person to whom he or she sold or supplied the poison; or
- (b) in accordance with the written directions of a person referred to in paragraph (a).

[Regulation 40A (formerly regulation 41) inserted in Gazette 8 Jun 1990 p. 2627; amended in Gazette 19 Mar 1996 p. 1225.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

Division 3 — General

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

41. Revocation notice in relation to poisons included in Schedule 6

The CEO may, by notice given to a person referred to in section 23(4) of the Act, revoke the authority conferred on that person by that section in relation to poisons included in Schedule 6, and that revocation may be —

- (a) total or subject to strict conditions;
- (b) made in respect of all or any poisons to which the authority relates; and
- (c) may be amended or revoked by a further notice.

[Regulation 41 inserted in Gazette 19 Mar 1996 p. 1225-6; amended in Gazette 15 Dec 2006 p. 5630-1.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

41A. Sale of poisons included in Schedule 7

- (1) A person who sells, by retail, any poisons included in Schedule 7 shall, in addition to any conditions and restrictions imposed by notice issued in accordance with these regulations, keep a record of sale by keeping and maintaining a register in accordance with this regulation.
- (2) A person recording a sale for the purposes of subregulation (1) shall, before delivering the poison to the purchaser, record in a register kept for that purpose particulars of —
 - (a) the date of sale;
 - (b) the name and address of the purchaser;
 - (c) the nature and quantity of the poison sold;
 - (d) the address to which the poison is to be delivered, if that address differs from the address recorded under paragraph (b); and
 - (e) the place of intended use,and obtain the signature of the purchaser to the entry in the register.
- (3) The register shall be kept in one of the following forms —
 - (a) a book with each recording written in ink;
 - (b) in a form of electronic means; or
 - (c) such other form as the CEO approves in writing.
- (4) A person keeping a register for the purposes of this regulation shall —
 - (a) keep that register for a period of at least 2 years at the licensed premises; and
 - (b) produce the register for inspection on demand by an authorised officer.

*[Regulation 41A inserted in Gazette 19 Mar 1996 p. 1226;
amended in Gazette 14 Sep 2001 p. 5076; 15 Dec 2006
p. 5630.]*

41AA. Standard for intramammary antibiotic preparations

A person shall not sell or supply any preparation for intramammary infusion in animals which contains any antibiotic substance unless it is packed in an applicator device specially designed for intramammary infusion and is suitably coloured with no less than 25 mg per dose of Brilliant Blue FCF so that the visual end point excludes 95% of excreted antibiotic.

[Regulation 41AA inserted in Gazette 17 Aug 1990 p. 4081.]

41AB. Camphor and naphthalene

A person shall not sell or supply 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 which prevents removal or ingestion of the contents during use.

[Regulation 41AB inserted in Gazette 26 Jul 1991 p. 3854.]

41B. Record of poisons included in Schedule 3, 4 or 7

- (1) Every person who holds a licence to procure, manufacture, or supply poisons included in Schedule 3, 4 or 7 by wholesale dealing shall, in relation to the supply of any such poison, keep an accurate record of —
 - (a) the day on which the poison was supplied;
 - (b) the quantity, form and strength of the poison supplied;
 - (c) the name and address of the person to whom it was supplied; and
 - (d) the reference number on the invoice or other document evidencing the supply,

and the record shall be made on the day of supply and shall be kept for not less than 2 years after that day.

- (2) A person referred to in subregulation (1) shall send to the CEO particulars in writing of any of the information required to be recorded and kept by that person under subregulation (1) —

- (a) within 7 days of being requested to do so where the information has been recorded within 2 months immediately before the request; and
- (b) otherwise within 28 days of being requested to do so.

[Regulation 41B inserted in Gazette 19 Dec 1986 p. 4874-5; amended in Gazette 27 May 1988 p. 1770; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1226; 15 Dec 2006 p. 5630.]

41C. Access to poisons included in Schedule 7

A substance included in Schedule 7 shall not be stored for retail sale in any area or in any manner that allows physical access to that substance by any person other than —

- (a) the owner of the business carried on on the premises where it is stored;
- (b) a person employed on the premises where it is stored; or
- (c) a person authorised to purchase substances included in Schedule 7 by notice given under section 24 of the Act.

[Regulation 41C inserted in Gazette 24 Jun 1994 p. 2868-9; amended in Gazette 19 Mar 1996 p. 1227.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

Part 6 — Drugs of addiction

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

Division 1 — General

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

42A. Interpretation

In this Part, a reference to prescribing or dispensing a drug of addiction is to be read as including a reference to prescribing or dispensing a preparation containing a drug of addiction.

[Regulation 42A inserted in Gazette 15 Nov 2005 p. 5603.]

42. Authority for prescribed persons to procure and have poisons included in Schedule 8

(1) Until in any particular case such authority is withdrawn —

- (a) a medical practitioner;
- (b) a pharmaceutical chemist employed in dispensing medicines at any public hospital or at a pharmacy for which a licence is held under regulation 5;
- [(c) deleted]*
- (d) a veterinary surgeon;
- (e) an analyst registered under the *Health Act 1911*;
- (f) a registered nurse employed in a public hospital (so far as the possession or use of such poison included in Schedule 8 is required in connection with its administration to a patient under the instruction of a medical practitioner); and
- (g) a person in possession of a permit granted by the CEO under these regulations,

is, subject to these regulations, hereby authorised to procure and be in possession of any poison included in Schedule 8 for the purpose of his profession or employment.

- (2) A person in respect of whom a prescription for a poison included in Schedule 8 is issued is hereby authorised to procure and have possession of the poison included in Schedule 8 to the extent specified in the prescription.
- (3) The authority under this regulation to procure and be in the possession of any poison included in Schedule 8 does not entitle the holder to procure or have in his possession any poison included in Schedule 8 in any quantity greater than is permitted by the CEO.
- (4) Until in any particular case such authority is withdrawn a dentist is, subject to these regulations and for the purpose of his profession, hereby authorised to procure and be in possession of the following poisons included in Schedule 8 in quantities not greater than those set out hereunder —

PETHIDINE in a form prepared for injection with a total pethidine content of 600 milligrams

PAPAVERETUM, in tablet form, with a total papaveretum content of 240 milligrams

CODEINE PHOSPHATE, in tablet form, with a total codeine phosphate content of 900 milligrams

METHADONE, in tablet form, with a total methadone content of 240 milligrams

MORPHINE, in a form prepared for injection, with a total morphine content of 180 milligrams

OXYCODONE, in tablet form, with a total oxycodone content of 120 milligrams

PENTAZOCINE, in a form prepared for injection, with a total pentazocine content of 360 milligrams.

[Regulation 42 amended in Gazette 9 Feb 1970 p. 370; 29 Jun 1984 p. 1784; 8 Feb 1985 p. 520; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1227; 27 Nov 1998 p. 6344; 15 Dec 2006 p. 5630; 7 Nov 2008 p. 4811-12.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

43. Authority for pharmacists to retail, compound and dispense poisons included in Schedule 8

- (1) Until in any particular case such authority is withdrawn, every pharmaceutical chemist holding a Pharmaceutical Chemist's licence to sell poisons under these regulations is hereby authorised, subject to the conditions, limitations and restrictions imposed by the CEO, to procure and to manufacture at his registered premises in the ordinary course of his retail business any preparation, admixture, or extract of any poison included in Schedule 8, and to carry on at his registered premises the business of dispensing or compounding any poison included in Schedule 8, and also of retailing and supplying a poison included in Schedule 8, but only to persons licensed or authorised under these regulations to be in possession of or to procure the poison included in Schedule 8.
- (2) The authority under this regulation does not in any way entitle the holder to procure, manufacture, sell, distribute, supply, or have in his possession any poison included in Schedule 8 in any quantity greater than is permitted by the CEO.

[Regulation 43 amended in Gazette 29 Jun 1984 p. 1784; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1227; 15 Dec 2006 p. 5630.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

43A. Revocation notice in relation to poisons included in Schedule 8 and specified drugs

The CEO may, by notice given to a person referred to in section 23(2) of the Act, revoke the authority conferred on that person by that section in relation to poisons included in Schedule 8 or specified drugs or both, and that revocation may be —

- (a) total or subject to strict conditions;
- (b) made in respect of all or any specified drugs or poisons to which the authority relates; and

- (c) may be amended or revoked by a further notice.

*[Regulation 43A inserted in Gazette 19 Mar 1996 p. 1227-8;
amended in Gazette 15 Dec 2006 p. 5630.]*

43B. Prescribed purposes (section 41(1))

For the purposes of section 41(1) of the Act —

- (a) analytical chemical analysis;
- (b) anaesthesia of exotic animals; and
- (c) training animals for the detection of substances included in Schedule 9 to the Act,

are purposes for which a specified person may be authorised under that subsection to manufacture, prepare, possess or use a specified substance included in Schedule 9 to the Act.

[Regulation 43B inserted in Gazette 1 Oct 1996 p. 5088.]

43C. Advertising of substances included in Schedule 8

A substance included in Schedule 8 shall not be advertised except in a publication that is normally sold or intended for sale or circulation only among —

- (a) persons of the kind referred to in section 23(2) of the Act; or
- (b) persons who are holders of a licence granted under section 24(1)(a), (b) or (c) of the Act.

[Regulation 43C inserted in Gazette 27 Nov 1998 p. 6344.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

44. Register of drugs of addiction

- (1) In this regulation —

authorised person means a person authorised to manufacture, distribute, sell or possess any drug of addiction, other than a person having possession of a drug of addiction by the authority

of a prescription issued by a medical practitioner, dentist or veterinary surgeon to the extent shown in the prescription.

- (2) An authorised person must maintain a register of the drugs of addiction manufactured, procured, used, supplied or kept by, or on behalf of, the person.
- (3) An authorised person is to record, or cause to be recorded, in the register, in relation to each transaction involving a drug of addiction —
 - (a) the name, quantity and form of the drug;
 - (b) the date of the transaction;
 - (c) the name and address of each other person or firm involved in the transaction;
 - (d) the name of the person who issued the prescription or order;
 - (e) the amount of the drug remaining on hand after the transaction;
 - (f) if the authorised person is a pharmaceutical chemist, the identifying number of the prescription; and
 - (g) if the authorised person is a manufacturer or distributor, an identifying number of the order or other authority on which the drug is supplied

and, if the register is maintained on paper, is to sign that entry in the register.

- (3a) An authorised person is to record, or cause to be recorded, in the Register the result of each inventory made by the authorised person under regulation 45 on the day on which the inventory is made.
- (4) The register must be maintained in such a way that at any time the amount of each drug of addiction manufactured, procured, used, supplied or kept by the authorised person is clearly apparent.
- (5) An authorised person must —

- (a) maintain a separate register for each location at which the person manufactures, procures, uses, supplies or keeps drugs of addiction; and
- (b) keep the register at that location.

[Regulation 44 inserted in Gazette 29 Feb 2000 p. 992-3; amended in Gazette 14 Sep 2001 p. 5076; 7 Nov 2008 p. 4812.]

44A. Destruction of drugs of addiction and poisons included in Schedule 8

- (1) Subject to subregulations (2) and (3) a person authorised to manufacture, distribute, procure, sell or possess a drug of addiction (other than a person who possesses a poison included in Schedule 8 under a prescription issued by a medical practitioner, dentist or veterinary surgeon) shall not wilfully destroy that drug of addiction.
- (2) Subject to regulation 31 a drug of addiction may be destroyed by —
 - (a) or under the personal supervision of a person declared to be an authorised officer for the purposes of this regulation by the Minister under section 52A of the Act; or
 - (b) a police officer acting under the *Misuse of Drugs Act 1981*.
- (3) Subject to regulation 31 a person referred to in subregulation (1), other than a person to whom subregulation (2) applies, who seeks to destroy a poison included in Schedule 8 shall carry out that destruction under the supervision of a witness selected, in accordance with subregulation (7), from any of the following categories —
 - (a) pharmaceutical chemists authorised to possess and supply poisons included in Schedule 8;
 - (b) medical practitioners authorised to supply poisons included in Schedule 8; and

(c) directors of nursing.

(4) A person who destroys poisons included in Schedule 8 must maintain a register of the poisons destroyed and record in it, at the time of each destruction —

- (a) the date of destruction;
- (b) the name, strength and quantity of the poison destroyed;
- (c) the reason for the destruction; and
- (d) the name of the witness to the destruction,

and, if the register is maintained on paper, is to sign, and cause the witness to sign, that entry in the register.

(5) A pharmaceutical chemist required to provide a monthly return under regulation 52C shall, as part of the return, provide details of the entries recorded in the register, maintained in accordance with subregulation (4), for the relevant period.

(6) Where the monthly return referred to in subregulation (5) is made —

- (a) on the original of the approved duplicate form, the details shall be entered by the person who destroyed the poison included in Schedule 8 and that person and the person who supervised the destruction shall each sign the entry;
- (b) on the original of the completed printout of the approved computerised recording system, the details shall be accompanied by the name of the person who destroyed the poison included in Schedule 8 and that of the witness who supervised the destruction of the poison.

(7) For the purposes of subregulation (3), a pharmaceutical chemist, authorised to possess and supply poisons included in Schedule 8 or Schedule 9, who wishes to destroy poisons included in Schedule 8 or Schedule 9 may have another pharmaceutical chemist authorised to possess and supply poisons included in Schedule 8 or Schedule 9 as a witness to that destruction, but

otherwise a witness shall not be a member of the same category as that of the person who seeks to destroy the poisons included in Schedule 8.

[Regulation 44A inserted in Gazette 1 Oct 1993 p. 5360-1; amended in Gazette 24 Jun 1994 p. 2869; 19 Sep 1995 p. 4383; 19 Mar 1996 p. 1228; 29 Feb 2000 p. 993-4; 7 Nov 2008 p. 4812.]

44B. Form of registers

- (1) A register kept for the purposes of regulation 44(2) or 44A(4) may be maintained on paper, electronically or in another approved manner.
- (1a) If a register is maintained on paper, all entries required to be made in the register are to be made in ink.
- (2) If a register is maintained other than on paper the information in the register must be recorded or stored in such a way that it —
 - (a) will remain in the form in which it was originally recorded or stored; and
 - (b) is capable of being reproduced in written form on paper.
- (3) The register must be maintained in a form and manner approved by the CEO.
- (4) An authorised person must make all the person's registers available for inspection on request by persons authorised under the Act to inspect registers.
- (5) Subject to subregulation (6) a person must not alter, obliterate or delete an entry in a register.
- (6) An authorised person may correct an error in a register —
 - (a) if the register is maintained on paper, by making a marginal or foot note and initialling and dating the note; or
 - (b) otherwise, in a manner approved by the CEO.

*[Regulation 44B inserted in Gazette 29 Feb 2000 p. 994;
amended in Gazette 14 Sep 2001 p. 5076; 15 Dec 2006
p. 5630.]*

44C. Control of access to electronic registers

- (1) In this regulation —

authorised person means the person who is required under regulation 44(2) or 44A(4) to maintain the register;

entry includes a note or alteration made in accordance with regulation 44B(6);

register means a register maintained electronically for the purposes of regulation 44(2) or 44A(4).

- (2) An authorised person must maintain the register in such a way that entries in the register cannot be deleted.
- (3) An authorised person must maintain the register in such a way that —
- (a) entries in the register cannot be made by any person who does not use an access code issued by the authorised person;
 - (b) an access code cannot be used other than in combination with a password known only by the person to whom the access code was issued;
 - (c) whenever a person makes an entry in the register the access code of that person is automatically recorded in the register; and
 - (d) the record of the access code cannot be changed.
- (4) The authorised person must keep a record of the access codes issued for the purposes of this regulation and the persons to whom they have been issued and must ensure that other persons do not have access to that record.
- (5) In any legal proceedings under this Act or the *Misuse of Drugs Act 1981*, if it is proved that the access code issued to a person

has been recorded in the register in respect of an entry, then in the absence of evidence to the contrary that person is taken to have made the entry.

[Regulation 44C inserted in Gazette 29 Feb 2000 p. 994-5; amended in Gazette 28 Jul 2009 p. 2980.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

45. Inventory of drugs of addiction

- (1) An inventory of drugs of addiction held in stock shall be made —
- (a) at intervals of not more than one month by every person required to keep a Register of Drugs of Addiction; and
 - (b) by a person who is about to relinquish control of drugs of addiction; and
 - (c) forthwith on assuming control by any person who assumes control of drugs of addiction,

and the result of that inventory is to be recorded in the Register in accordance with regulation 44(3a).

- (2) If such inventory of drugs of addiction in stock does not agree with the balance recorded in the Register, the person required to keep the Register shall immediately notify the CEO in writing of the discrepancy.

[Regulation 45 amended in Gazette 29 Jun 1984 p. 1784; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 14 Sep 2001 p. 5076; 15 Dec 2006 p. 5630.]

[46.] *Deleted in Gazette 29 Feb 2000 p. 995.]*

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

47. Records to be retained for 7 years and available on demand

- (1) All records, registers, prescription books, invoices and other documents relating to drugs of addiction, and transactions in regard thereto shall be kept by the person licensed or authorised to have drugs of addiction in his possession for not less than 7 years from the latest date on which such record, register, prescription book, invoice or other document was made or acted upon.
- (2) The records, registers, prescription books, invoices or other documents and stocks of drugs of addiction on hand shall be made available for inspection on demand by an authorised officer (other than an environmental health officer) and shall be accounted for, during the inspection, by the person licensed or authorised to have drugs of addiction in his possession.
- (3) In the event of a register being lost or destroyed the person to whom such register belongs shall upon becoming aware of the loss or destruction make and forward to the CEO a statutory declaration concerning that loss or destruction and shall immediately take stock of all drugs of addiction in his possession and enter particulars of those stocks in a new register in accordance with the requirements of these regulations.
- (4) A person authorised or licensed to procure and be in possession of a drug of addiction, on ceasing to be so authorised or licensed shall, if requested by the CEO, surrender any records, registers, prescription books, invoices or other documents and stocks of drugs of addiction that are in his possession to the CEO.
- (5) A person required by these regulations to make and keep records, registers, returns, prescription books, invoices and other documents relating to drugs of addiction shall not make any entry therein which is false or untrue in any particular.

- (6) The duplicate copy of the form or printout of the computerised recording system approved by the CEO for the purposes of regulation 52B is a record to be retained for the purposes of this regulation and, in the case of a transaction referred to in regulation 52(3)(h), it shall be kept at the place at which the poison was dispensed for at least one year from the date of the transaction.

[Regulation 47 amended in Gazette 23 Sep 1983 p. 3804; 29 Jun 1984 p. 1784; 31 Jan 1986 p. 332; 7 Aug 1987 p. 3083; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1229; 15 Dec 2006 p. 5630.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

48. Returns from manufacturers and wholesalers

- (1) Every person who is licensed under regulation 3 shall complete and forward to the CEO, every 7 days a form approved by the CEO for that purpose, reporting all transactions in poisons included in Schedule 8 made by him during that week.
- (2) The form referred to in subregulation (1) may be required by the CEO to be in a code approved by him from time to time and shall describe the composition, form, strength, size and quality of each poison included in Schedule 8 and identify the person from whom, or to whom a poison included in Schedule 8 has been obtained or supplied.

[Regulation 48 inserted in Gazette 23 Sep 1983 p. 3804; amended in Gazette 29 Jun 1984 p. 1784; 25 Jun 1993 p. 3080 and 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1229; 15 Dec 2006 p. 5630; 21 Apr 2009 p. 1359.]

49A. Use of poisons included in Schedule 8 on certificated commercial vessels

- (1) The master of a certificated commercial vessel is authorised to procure and be in possession of any poison included in Schedule 8 that is necessary to complete the equipment of the

vessel in order to comply with the requirements of the *Western Australian Marine Act 1982*.

- (2) The holder of an appropriate licence, or any other authorised person, may supply a poison included in Schedule 8 on receipt of a written order, signed by the master of the certificated commercial vessel, certifying that the poison is necessary to complete the equipment of the vessel in order to comply with the applicable requirements of subregulation (1).
- (3) The written order referred to in subregulation (2) must contain all of the following information —
 - (a) the date of the order;
 - (b) the name of the certificated commercial vessel;
 - (c) the machinery and hull number;
 - (d) the name, address and signature of the master of the vessel;
 - (e) the quantity, form and strength of the poison ordered.
- (4) The master of the certificated commercial vessel must ensure that —
 - (a) so far as is practicable, the poisons supplied under subregulation (2) are stored in a manner that prevents their theft, loss or unauthorised use; and
 - (b) a record is kept of all the poisons stored aboard the vessel.
- (5) When a medical practitioner authorises the administration of one of the poisons to a person on board the certificated commercial vessel, the master of the vessel must ensure that a record is kept of all of the following information —
 - (a) the date on which the poison was administered;
 - (b) the poison being administered, the strength of the poison and the quantity that has been administered;
 - (c) the name of the person to whom the poison has been administered;

- (d) the name and address of the medical practitioner who authorised the administration of the poison.

[Regulation 49A inserted in Gazette 12 Jun 2009 p. 2112-13.]

49B. Use of poisons included in Schedule 8 on racing yachts

- (1) The owner of a racing yacht is authorised to procure and be in possession of any poison included in Schedule 8 that is necessary to complete the equipment of the yacht in order to comply with the requirements of the rules known as the “Racing Rules of Sailing” made by Yachting Australia Incorporated.
- (2) The holder of an appropriate licence, or any other authorised person, may supply a poison included in Schedule 8 on receipt of a written order, signed by the owner of the racing yacht, certifying that the poison is necessary to complete the equipment of the yacht in order to comply with the applicable requirements of subregulation (1).
- (3) The written order referred to in subregulation (2) must contain all of the following information —
 - (a) the date of the order;
 - (b) the name of the racing yacht;
 - (c) the registration number of the racing yacht;
 - (d) the name of the yacht club organising the race;
 - (e) the name, address and signature of the owner of the yacht;
 - (f) the quantity, form and strength of the poison ordered.
- (4) The owner of the racing yacht must ensure that —
 - (a) so far as is practicable, the poisons supplied under subregulation (2) are stored in a manner that prevents their theft, loss or unauthorised use; and
 - (b) a record is kept of all the poisons stored aboard the yacht.

- (5) When a medical practitioner authorises the administration of one of the poisons to a person on board the racing yacht, the skipper of the yacht must ensure that a record is kept of all of the following information —
- (a) the date on which the poison was administered;
 - (b) the poison being administered, the strength of the poison and the quantity that has been administered;
 - (c) the name of the person to whom the poison has been administered;
 - (d) the name and address of the medical practitioner who authorised the administration of the poison.

[Regulation 49B inserted in Gazette 12 Jun 2009 p. 2113-14.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

49. Use of poisons included in Schedule 8 on ships and aircraft

- (1) The master of a ship other than a certificated commercial vessel or a racing yacht is authorised to procure and be in possession of any poison included in Schedule 8 that is necessary to complete the equipment of the ship in order to comply with the requirements of —
- (a) if the ship is registered in Australia —
 - (i) section 125 of the *Navigation Act 1912* of the Commonwealth; or
 - (ii) the navigation authority of any State of Australia;or
 - (b) if the ship is not registered in Australia —
 - (i) a law applying to ships in the country in which the ship is registered; or
 - (ii) the “*International Medical Guide for Ships*” (2nd. Edition), as published by the World Health Organization.

- (2) The holder of an appropriate licence, or any other authorised person, may supply a poison included in Schedule 8 on receipt of a written order, signed by the master of the ship and by the manager, or a person authorised in writing by the manager, of the ship's agents in the State, certifying that the poison included in Schedule 8 is necessary to complete the equipment of the ship in order to comply with the applicable requirements of subregulation (1).
- (3) The person in charge of an aircraft is authorised to be in possession of a poison included in Schedule 8, in a quantity that does not exceed the maximum permitted quantity specified by the Department of Transport of the Commonwealth, for the purposes of medical treatment on the aircraft.
- (4) The holder of an appropriate licence, or any other authorised person, may supply a poison included in Schedule 8 on receipt of a written order, signed by the manager, or a person authorised in writing by the manager, of the airline company or firm responsible for the operation of the aircraft in the State, certifying that the poison included in Schedule 8 is necessary for the purposes of medical treatment on aircraft.
- (5) Any person who supplies a poison included in Schedule 8 under this regulation shall, within 24 hours of so doing, report the details to the CEO or the officer in charge of the nearest police station.

[Regulation 49 inserted in Gazette 31 Dec 1993 p. 6884-5; amended in Gazette 26 May 1994 p. 2201; 19 Mar 1996 p. 1229; 15 Dec 2006 p. 5630; 12 Jun 2009 p. 2114.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

50. Used poisons included in Schedule 8 at hospitals

- (a) Where a Pharmaceutical Chemist is employed — The pharmaceutical chemist in charge of the pharmacy department of a hospital shall be responsible for ordering, storing and

issuing all poisons included in Schedule 8 in such hospital and for keeping records of poisons included in Schedule 8 as required by these regulations.

- (b) Where a Pharmaceutical Chemist is not employed — The director of nursing of a hospital or other person authorised by the CEO shall be responsible for ordering, issuing and storing all poisons included in Schedule 8 in such hospital and for keeping records of poisons included in Schedule 8 as required by these regulations.
- (c) Subject to paragraph (d), a person, other than a medical practitioner or dentist shall not administer a poison included in Schedule 8 to a patient in a hospital unless the administration of the poison is authorised in writing on the medication chart of the patient by a medical practitioner or a dentist.
- (d) A medical practitioner or dentist may verbally authorise the administration of a poison included in Schedule 8 and shall within 24 hours of so doing note such authorisation in writing on the medication chart of the patient.

[Regulation 50 amended in Gazette 29 Jun 1984 p. 1784; 28 May 1993 p. 2597; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1230; 15 Dec 2006 p. 5630.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

Division 2 — Supply and prescription

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

Subdivision 1 — Prescriptions generally

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

51. Prescriptions

- (1) A prescription for the supply of a drug of addiction shall comply with the following conditions —

- (a) it shall include —
 - (i) the name and address of the prescriber; and
 - (ii) the name, address and date of birth of the patient or, in the case of a prescription for veterinary use, the name and address of the person having the care of the animal for which the prescription is intended; and
 - (iii) the description and quantity of the drug to be dispensed; and
 - (iv) precise directions for the use of the drug, including the dose to be taken or administered and the frequency with which the dose is to be taken or administered; and
 - (v) the date when it was written; and
 - (vi) if the drug is to be dispensed more than once under the prescription — the maximum number of times it may be repeated and the intervals at which it may be dispensed;
- (b) it shall not prescribe more than one drug of addiction, or any other substance, but may prescribe the same drug in more than one form;
- (c) if issued by a dentist — it shall include the words “for dental treatment only” and if issued by a veterinary surgeon — it shall include the words “for animal treatment only”;
- (d) if it prescribes an unusual dose it shall indicate that such a dose was intended by —
 - (i) in the case of a prescription that is not issued electronically — that part of the prescription being underlined and initialled by the prescriber in the margin; and
 - (ii) in the case of a prescription that is issued electronically — the means provided by the approved electronic prescribing system;

(e) it shall be issued in a manner provided for in subregulation (1A) or (1B).

(1A) A prescription that is issued electronically shall be issued via an approved electronic prescribing system.

(1B) A prescription that is not issued electronically shall be either —

(a) written in ink in the prescriber's own handwriting; or

(b) processed on a computer program that —

(i) complies with the criteria specified in Appendix L; or

(ii) is recommended by the Poisons Advisory Committee and approved in writing by the CEO.

The prescription shall be signed by the prescriber in his or her own handwriting.

(2) With the written approval of the CEO a person authorised to prescribe drugs of addiction may issue a typewritten prescription where the CEO is satisfied that by reason of physical infirmity the prescriber is unable to write legibly in his or her own handwriting but in that case the prescriber shall sign the prescription with his or her usual signature.

[Regulation 51 inserted in Gazette 23 Sep 1983 p. 3804; amended in Gazette 29 Jun 1984 p. 1784; 31 Jan 1986 p. 332; 26 Jul 1991 p. 3855; 25 Jun 1993 p. 3080 and 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1230; 15 Nov 2005 p. 5603-4; 15 Dec 2006 p. 5630; 7 Nov 2008 p. 4812-13.]

Subdivision 2 — Supply and prescription to drug addicts

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

51A. Terms used

(1) In this Subdivision —

authorised prescriber means a medical practitioner who is designated by the CEO as an authorised prescriber under regulation 51C(1);

drug addict means a person who —

- (a) is under a state of periodic or chronic intoxication produced by consumption of a drug of addiction or any substitute; or
- (b) is under a desire or craving to take a drug of addiction or any substitute until he or she has so satisfied that desire or craving; or
- (c) is under a psychic or physical dependence to take a drug of addiction or any substitute; or
- (d) is listed in the register of information kept under the *Drugs of Addiction Notification Regulations 1980*;

pharmacotherapy means methadone or buprenorphine, or the salts of those substances, and any preparation or admixture containing those substances, or the salts of those substances;

pharmacy means a pharmacy registered under the *Pharmacy Act 1964*;

Policies Manual means the “Clinical policies and procedures for the use of methadone and buprenorphine in the treatment of opioid dependence”, published by the Drug and Alcohol Office Western Australia from time to time;

specialist prescriber means an authorised prescriber who is designated by the CEO as a specialist prescriber under regulation 51C(2).

- (2) In this Subdivision, a reference to prescribing a drug of addiction or a pharmacotherapy is a reference to writing, issuing or authorising a prescription or document prescribing the use, sale or supply of the drug of addiction or pharmacotherapy.

[Regulation 51A inserted in Gazette 21 Apr 2009 p. 1359-60.]

51AA. Disclosure by drug addict to medical practitioner

A drug addict must, when seeking to obtain from a medical practitioner or dentist —

- (a) a drug of addiction; or
- (b) a prescription or document prescribing the use, sale or supply of a drug of addiction,

disclose to the medical practitioner or dentist the fact that he or she is a drug addict.

[Regulation 51AA inserted in Gazette 12 Oct 1984 p. 3267; amended in Gazette 11 Apr 1997 p. 1832; 21 Apr 2009 p. 1360.]

51B. Prescription and supply in accordance with this Subdivision — general provision

- (1) A person must not prescribe or supply a drug of addiction for the treatment of a person who is a drug addict unless the person is authorised to do so under this Subdivision.
- (2) A person who is authorised under this Subdivision to prescribe or supply a drug of addiction for the treatment of a drug addict must do so in accordance with the Policies Manual, except to the extent to which an authorisation, designation or appointment of the person under this Subdivision is inconsistent with the manual.

[Regulation 51B inserted in Gazette 21 Apr 2009 p. 1361.]

51BA. Prescribing drugs of addiction for drug addicts other than for the treatment of drug addiction

- (1) A medical practitioner or dentist may administer a drug of addiction for the treatment of a person who is a drug addict.
- (2) A medical practitioner or dentist may prescribe or supply a drug of addiction for the treatment of a person who is a drug addict if the medical practitioner or dentist —

- (a) has been authorised by the CEO under this subregulation to do so for that drug addict; and
 - (b) does so in accordance with the authorisation.
- (3) Subregulations (1) and (2) do not authorise a medical practitioner or dentist to prescribe or supply a pharmacotherapy for the treatment of the drug addiction of a person who is a drug addict.

[Regulation 51BA inserted in Gazette 21 Apr 2009 p. 1361.]

51C. Designation of authorised prescribers and specialist prescribers

- (1) The CEO may designate a medical practitioner as an authorised prescriber for the purposes of this Subdivision.
- (2) The CEO may designate an authorised prescriber as a specialist prescriber for the purposes of this Subdivision.

[Regulation 51C inserted in Gazette 21 Apr 2009 p. 1361.]

51CA. Appointment of medical practitioner as authorised prescriber for a drug addict

- (1) The CEO may appoint an authorised prescriber to be the authorised prescriber for a person who is a drug addict.
- (2) The appointment as the authorised prescriber for a person is for the period specified in the instrument of appointment.
- (3) The instrument of appointment must be given to the authorised prescriber.

[Regulation 51CA inserted in Gazette 21 Apr 2009 p. 1362.]

51CB. Appointment of co-prescriber for a drug addict

- (1) A specialist prescriber who is the authorised prescriber for a person who is a drug addict may appoint a medical practitioner (who need not be an authorised prescriber) to be a co-prescriber for the person.

- (2) The appointment as a co-prescriber —
 - (a) is for the period specified in the instrument of appointment, which cannot be more than 12 months; and
 - (b) ceases on the earlier of —
 - (i) the end of the period of appointment; or
 - (ii) the specialist prescriber ceasing to be the authorised prescriber for the person.
- (3) The instrument of appointment must be given to the co-prescriber and a copy must be given to the CEO.

[Regulation 51CB inserted in Gazette 21 Apr 2009 p. 1362.]

51CC. Designations, authorisations and appointments — general rules

A designation, authorisation or appointment of a person under this Subdivision —

- (a) must be in writing; and
- (b) may be subject to conditions; and
- (c) may be amended, suspended or revoked at any time.

[Regulation 51CC inserted in Gazette 21 Apr 2009 p. 1362.]

51D. Prescribing pharmacotherapies for the treatment of the drug addiction of a drug addict — general rules

- (1) A medical practitioner may prescribe a pharmacotherapy for the treatment of the drug addiction of a person who is a drug addict if the medical practitioner —
 - (a) is an authorised prescriber; and
 - (b) is appointed as the authorised prescriber for the person; and
 - (c) does so in accordance with that appointment.

- (2) A medical practitioner may prescribe a pharmacotherapy for the treatment of the drug addiction of a person who is a drug addict if the medical practitioner —
- (a) is an authorised prescriber; and
 - (b) is a member of the same medical practice as the authorised prescriber appointed for the person; and
 - (c) has access to the medical records of the practice relating to the person; and
 - (d) does so in accordance with the appointment of the authorised prescriber for the person.
- (3) A medical practitioner may prescribe a pharmacotherapy for the treatment of the drug addiction of a person who is a drug addict if the medical practitioner —
- (a) is a co-prescriber for the person; and
 - (b) does so in accordance with —
 - (i) his or her appointment as a co-prescriber; and
 - (ii) the appointment of the authorised prescriber for the person.
- (4) A medical practitioner may prescribe a pharmacotherapy for the treatment of the drug addiction of a person who is a drug addict if the medical practitioner —
- (a) is a member of the same medical practice as a co-prescriber for the person; and
 - (b) is satisfied that the co-prescriber for the person is absent from the medical practice or is otherwise unable to prescribe a pharmacotherapy for the treatment of the drug addiction of the person; and
 - (c) has access to the medical records of the practice relating to the person; and
 - (d) does so in accordance with —
 - (i) the appointment of the co-prescriber for the person; and

- (ii) the appointment of the authorised prescriber for the person.

- (5) A prescription for the supply of a pharmacotherapy —
 - (a) under subregulation (3) — may not cover a period of more than 3 months; or
 - (b) under subregulation (4) — may not cover a period of more than one month.

[Regulation 51D inserted in Gazette 21 Apr 2009 p. 1362-3.]

51DA. Prescribing pharmacotherapies for the treatment of the drug addiction of a drug addict — in a hospital

- (1) A medical practitioner may prescribe a pharmacotherapy for the treatment of the drug addiction of a person who is a patient in a hospital and who is a drug addict if —
 - (a) an authorised prescriber is appointed for the person; and
 - (b) the medical practitioner is satisfied that it is safe to prescribe a pharmacotherapy for the person; and
 - (c) the medical practitioner does so in accordance with the appointment of the authorised prescriber for the person.
- (2) Subregulation (1) does not authorise the medical practitioner to prescribe a pharmacotherapy unless it will be administered to the person while the person is a patient in the hospital.
- (3) For the purposes of this regulation, a person is a patient in a hospital while the person is admitted as a patient to the hospital.
- (4) A prescription for the supply of a pharmacotherapy under this regulation may not cover a period of more than one month.

[Regulation 51DA inserted in Gazette 21 Apr 2009 p. 1364.]

51DB. Prescribing pharmacotherapies for the treatment of the drug addiction of a drug addict — in custody

- (1) A medical practitioner may prescribe a pharmacotherapy for the treatment of the drug addiction of a person who is in custody and who is a drug addict if —
 - (a) an authorised prescriber is appointed for the person; and
 - (b) the medical practitioner is satisfied that it is safe to prescribe a pharmacotherapy for the person; and
 - (c) the medical practitioner does so in accordance with the appointment of the authorised prescriber for the person.
- (2) Subregulation (1) does not authorise the medical practitioner to prescribe a pharmacotherapy unless it will be administered to the person while the person is in custody.
- (3) A prescription for the supply of a pharmacotherapy under this regulation may not cover a period of more than one month.

[Regulation 51DB inserted in Gazette 21 Apr 2009 p. 1364.]

51DC. Prescribing pharmacotherapies for the treatment of the drug addiction of a drug addict — interim prescriptions

- (1) A specialist prescriber may prescribe a pharmacotherapy for the treatment of the drug addiction of a person who is a drug addict if —
 - (a) an authorised prescriber is appointed for the person; and
 - (b) the specialist prescriber —
 - (i) is satisfied that the person is unable to obtain a prescription for a pharmacotherapy under regulation 51D, 51DA or 51DB; and
 - (ii) is satisfied that it is safe to prescribe a pharmacotherapy for the person; and
 - (iii) does so in accordance with the appointment (whether or not it has ceased) of the authorised prescriber for the person.

- (2) The specialist prescriber must, as soon as is practicable, notify the CEO, and (where relevant) the authorised prescriber for the person, of having prescribed a pharmacotherapy for a person under this regulation.
- (3) A prescription for the supply of a pharmacotherapy under this regulation may not cover a period of more than one month.

[Regulation 51DC inserted in Gazette 21 Apr 2009 p. 1365]

51E. Dispensing drugs of addiction from a pharmacy

A pharmaceutical chemist or an assistant under the direct personal supervision of a pharmaceutical chemist may dispense a drug of addiction, other than a pharmacotherapy, to a person who is a drug addict.

[Regulation 51E inserted in Gazette 21 Apr 2009 p. 1365.]

51EA. Dispensing pharmacotherapies from a pharmacy

- (1) The CEO may authorise the dispensing of pharmacotherapies at a pharmacy.
- (2) A pharmaceutical chemist or an assistant under the direct personal supervision of a pharmaceutical chemist may dispense a pharmacotherapy to a person who is a drug addict if the pharmaceutical chemist or assistant does so in accordance with an authorisation governing the dispensing of pharmacotherapies at the pharmacy.
- (3) Pharmacotherapies cannot be dispensed at a pharmacy unless there is an authorisation applying to the dispensing of pharmacotherapies at the pharmacy.

[Regulation 51EA inserted in Gazette 21 Apr 2009 p. 1365.]

Subdivision 2A — Supply and prescription of Schedule 8 poisons to persons other than drug addicts

[Heading inserted in Gazette 21 Apr 2009 p. 1366.]

51F. Treatment not to exceed 60 days unless authorised by CEO

- (1) A medical practitioner shall not write, issue or authorise a prescription or document prescribing the use, sale or supply of a poison included in Schedule 8, or supply a poison included in Schedule 8, for the treatment of a person, other than a drug addict, for a period in excess of 60 days, or for periods that in the aggregate over the preceding 12 months exceed 60 days, or for a course of treatment exceeding 60 days, unless he has first obtained written authorisation to do so from the CEO.
- (2) Where a medical practitioner has written, issued or authorised a prescription or document prescribing the use, sale or supply of a poison included in Schedule 8, for the treatment of a person other than a drug addict, or supplied a poison included in Schedule 8 for the treatment of a person, other than a drug addict, for a period of 60 days, or for periods that in the aggregate over the preceding 12 months exceed 60 days, or for a course of treatment exceeding 60 days, the medical practitioner shall not thereafter write, issue or authorise a prescription or document prescribing the use, sale or supply of a poison included in Schedule 8 in relation to that person or supply a poison included in Schedule 8 in relation to that person unless —
 - (a) the medical practitioner has first obtained written authorisation under this regulation to do so from the CEO; or
 - (b) the CEO has issued an authorisation under this regulation to do so in relation to that person and the authorisation is current.
- (3) Notwithstanding any authorisation referred to in subregulation (1) or (2) a medical practitioner shall not write, issue or authorise a prescription or document prescribing the use, sale or supply of methadone or buprenorphine for the treatment of a person or supply methadone or buprenorphine for the treatment of a person except for a person suffering from

intractable pain arising from a condition of health other than addiction to drugs.

- (4) In any authorisation issued for the purposes of subregulation (1) or (2) given with respect to a particular person the CEO may specify that any one or more of the conditions and restrictions set out below apply, namely —
- (a) that the prescription be issued by or the treatment be administered by a specified medical practitioner;
 - (b) that only a specified poison included in Schedule 8 be prescribed or used for treatment;
 - (c) that the type of the poison included in Schedule 8 specified be of the type specified;
 - (d) that the amount to be prescribed or used for treatment shall not exceed the amount specified;
 - (e) that the amount to be prescribed or used on any one day shall not exceed the amount specified;
 - (f) that the concentration to be prescribed shall not exceed the concentration specified;
 - (g) that the intervals between the issue of prescriptions or the administration of the poison included in Schedule 8 shall be such as are specified;
 - (h) that the prescription be supplied at the pharmacy specified;
 - (i) that the amount dispensed on a single prescription not exceed such amount as is specified;
 - (j) that the amount that may be supplied on any one day shall not exceed such amount as is specified.
- (5) An authorisation issued for the purposes of subregulation (1) or (2) is valid for such period as is specified unless revoked by the CEO before the expiration of that period.
- (6) A medical practitioner shall not write, issue or authorise a prescription or document prescribing the use, sale or supply of a

poison included in Schedule 8 or supply a poison included in Schedule 8 otherwise than in accordance with such conditions and restrictions as are specified.

- (7) A pharmaceutical chemist shall not sell or supply a poison included in Schedule 8 otherwise than in accordance with such conditions and restrictions as are specified pursuant to this regulation.
- (8) An authorisation issued prior to 1 October 1980 is valid until revoked by the CEO or until it expires whichever first occurs.

[Regulation 51F inserted in Gazette 3 Feb 1995 p. 342-3; amended in Gazette 19 Mar 1996 p. 1230-1; 11 Apr 1997 p. 1833; 16 Nov 2001 p. 5985; 15 Dec 2006 p. 5630 and 5631.]

Subdivision 3 — Supply and prescription of certain substances

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

51G. Interpretation

In this Subdivision —

authorised practitioner means a medical practitioner who holds an authorisation under regulation 51GAB;

stimulant means amphetamine, dexamphetamine, methylamphetamine, methylphenidate or phenmetrazine, or the salts of any of those substances and any preparation or admixture containing any of those substances, or the salts of any of those substances.

[Regulation 51G inserted in Gazette 12 Aug 2003 p. 3659.]

51GAA. When a medical practitioner may supply or prescribe a stimulant

A medical practitioner must not supply a stimulant or provide a prescription for a stimulant unless the medical practitioner —

- (a) is an authorised practitioner;

- (b) does so as a co-prescriber under regulation 51GAG;
- (c) does so in accordance with a special authorisation under regulation 51GAH; or
- (d) does so under regulation 51GAI.

[Regulation 51GAA inserted in Gazette 12 Aug 2003 p. 3659; amended in Gazette 21 Apr 2009 p. 1366.]

51GAB. Authorisation to supply or prescribe a stimulant

- (1) A medical practitioner may apply to the CEO for authorisation to supply a stimulant or to provide a prescription for a stimulant.
- (2) The application must be in a form approved by the CEO.
- (3) On receiving an application under subregulation (1) the CEO may grant the authorisation.
- (4) An authorisation remains in force until the applicant ceases to be a registered medical practitioner or the CEO revokes the authorisation.
- (5) The CEO may by notice in writing cancel or vary the terms of an authorisation at any time.

[Regulation 51GAB inserted in Gazette 12 Aug 2003 p. 3659-60; amended in Gazette 15 Dec 2006 p. 5630.]

51GAC. When an authorised practitioner may supply or prescribe a stimulant

An authorised practitioner must not supply a stimulant or provide a prescription for a stimulant unless the patient is diagnosed as having —

- (a) attention deficit hyperactivity disorder;
- (b) brain damage;
- (c) depression; or
- (d) narcolepsy.

[Regulation 51GAC inserted in Gazette 12 Aug 2003 p. 3660.]

51GAD. Treatment of attention deficit hyperactivity disorder with a stimulant

- (1) An authorised practitioner must not supply or prescribe a stimulant for treatment of attention deficit hyperactivity disorder to or for a patient who has not reached 2 years of age.
- (2) An authorised practitioner must not, without written permission from the CEO, supply or prescribe a stimulant for treatment of attention deficit hyperactivity disorder to or for a patient who has reached 2 years of age but has not reached 4 years of age.
- (3) An authorised practitioner must not supply or prescribe a stimulant for treatment of attention deficit hyperactivity disorder to or for a patient who has reached 4 years of age but has not reached 18 years of age unless the authorised practitioner is —
 - (a) a paediatrician;
 - (b) a paediatric neurologist; or
 - (c) a child and adolescent psychiatrist.
- (4) An authorised practitioner must not supply or prescribe a stimulant for treatment of attention deficit hyperactivity disorder to or for a patient who has reached 18 years but has not reached 25 years unless the authorised practitioner is —
 - (a) a neurologist or psychiatrist not referred to in subregulation (3); or
 - (b) an authorised practitioner referred to in subregulation (3) who was treating the patient for attention deficit hyperactivity disorder before the patient reached 18 years of age.
- (5) An authorised practitioner must not supply or prescribe a stimulant for treatment of attention deficit hyperactivity disorder to or for a patient who has reached 25 years unless the authorised practitioner is a neurologist or psychiatrist not referred to in subregulation (3).

- (6) An authorised practitioner must not, without written permission from the CEO, supply or prescribe a stimulant for treatment of attention deficit hyperactivity disorder to or for a patient who has a history of psychosis, bipolar disorder, or sustained significant substance abuse.

[Regulation 51GAD inserted in Gazette 12 Aug 2003 p. 3660-1; amended in Gazette 15 Dec 2006 p. 5630.]

51GAE. Dose for supply or prescription of a stimulant

- (1) If an authorised practitioner is treating a patient with a stimulant, the patient must be started on the lowest practicable dose that is then titrated according to the person's response.
- (2) An authorised practitioner must not, without written permission from the CEO, treat a patient with a dose greater than —
- (a) 1 mg/kg/day for dexamphetamine up to a maximum of 60 mg/day; and
 - (b) 2 mg/kg/day for methylphenidate up to a maximum of 120 mg/day.
- (3) If an authorised practitioner prescribes one or more stimulants for the same patient, the authorised practitioner must not, without written permission from the CEO, prescribe a total daily dosage exceeding 12 tablets/day for those stimulants.

[Regulation 51GAE inserted in Gazette 12 Aug 2003 p. 3661; amended in Gazette 15 Dec 2006 p. 5630.]

51GAF. Notification to CEO of supply or prescription of a stimulant

- (1) An authorised practitioner must notify the CEO as soon as practicable after —
- (a) a stimulant has been supplied to or prescribed for a patient by the authorised practitioner for the first time;
 - (b) there has been a change in —
 - (i) the dose of a stimulant supplied to or prescribed for a patient by the authorised practitioner;

- (ii) the type of stimulant supplied to or prescribed for a patient by the authorised practitioner;
 - (iii) the form of stimulant supplied to or prescribed for a patient by the authorised practitioner;
 - (iv) the name or residential address of a patient who is being treated with a stimulant by the authorised practitioner; or
 - (v) the co-prescribers (if any) of the authorised practitioner under regulation 51GAG;
- and
- (c) the supply or provision of prescriptions for a stimulant to a patient by the authorised practitioner has ceased.
- (2) The notification is to be in a form approved by the CEO.
 - (3) Upon receiving notification under subregulation (1)(a) or (b), the CEO may by notice to the authorised practitioner order that the treatment be cancelled or varied.
 - (4) An authorised practitioner receiving an order under subregulation (3) must comply with the order.

[Regulation 51GAF inserted in Gazette 12 Aug 2003 p. 3661-2; amended in Gazette 15 Dec 2006 p. 5630 and 5631.]

51GAG. Co-prescriber for supply or prescription of a stimulant

- (1) An authorised practitioner may nominate another medical practitioner to be a co-prescriber of a stimulant in a notification to the CEO under regulation 51GAF.
- (2) A co-prescriber may on the same conditions as the authorised practitioner supply a stimulant or provide a prescription for a stimulant to the patient who is the subject of the notification.

[Regulation 51GAG inserted in Gazette 12 Aug 2003 p. 3662; amended in Gazette 15 Dec 2006 p. 5630.]

51GAH. Special authorisation to supply or prescription of a stimulant

- (1) A medical practitioner may apply to the CEO for a special authorisation to supply or prescribe a stimulant to a particular patient in circumstances not set out in regulation 51GAC.
- (2) The application must be in a form approved by the CEO.
- (3) On an application under subregulation (1), the CEO may grant the special authorisation if the CEO considers that there are sound medical grounds for doing so.
- (4) The CEO may by notice in writing cancel or vary the terms of a special authorisation at any time.

[Regulation 51GAH inserted in Gazette 12 Aug 2003 p. 3662; amended in Gazette 15 Dec 2006 p. 5630.]

51GAI. Supply or prescription of a stimulant in a public hospital or prison

Where a person who is being treated with a stimulant under this Subdivision —

- (a) enters a public hospital for treatment as an in-patient; or
- (b) is placed in custody in a prison as defined in the *Prisons Act 1981*,

and needs to continue treatment with the stimulant while in that hospital or prison, a medical practitioner attached to the hospital or prison may supply the stimulant or provide a prescription for the stimulant on the same conditions that the medical practitioner who initiated the treatment would be able to.

[Regulation 51GAI inserted in Gazette 12 Aug 2003 p. 3662-3.]

51GA. Supply of dronabinol

A medical practitioner shall not supply, issue, write or authorise a prescription for delta-9-tetrahydrocannabinol (dronabinol) unless that practitioner has been authorised to do so by the

Secretary of the Commonwealth Department of Human Services and Health under section 19 of the *Therapeutic Goods Act 1989* of the Commonwealth.

[Regulation 51GA inserted in Gazette 19 Sep 1995 p. 4384.]

51GB. Supply of flunitrazepam

- (1) A medical practitioner shall not supply flunitrazepam or issue, write or authorise a prescription for flunitrazepam for a person unless that practitioner has been authorised in writing to do so in relation to that particular person by the CEO.
- (2) The CEO shall give the authorisation an identifying number (in this regulation called ***the HDWA Authorisation No.***).
- (3) In an authorisation given under subregulation (1), the CEO may specify that any one or more of the conditions and restrictions set out below apply, namely —
 - (a) that the prescription be issued by or the treatment be administered by the medical practitioner specified in the authorisation;
 - (b) that the amount of flunitrazepam to be prescribed or used for treatment shall not exceed the amount specified;
 - (c) that the amount of flunitrazepam to be prescribed or used on any one day shall not exceed the amount specified;
 - (d) that the concentration of flunitrazepam to be prescribed shall not exceed the concentration specified;
 - (e) that the intervals between the issue of prescriptions for flunitrazepam or the administration of flunitrazepam shall be such as are specified;
 - (f) that the prescription be supplied at the pharmacy specified;
 - (g) that the amount of flunitrazepam dispensed on a single prescription not exceed such amount as is specified;

- (h) that the amount of flunitrazepam that may be supplied on any one day shall not exceed such amount as is specified.
- (4) An authorisation issued for the purpose of subregulation (1) is valid for such period as is specified by the CEO unless revoked by the CEO, by notice in writing served on the practitioner, before the expiration of that period.
- (5) The CEO may at any time, by notice in writing served on the practitioner, amend the conditions and restrictions specified under subregulation (3).
- (6) A medical practitioner shall not supply flunitrazepam or issue, write or authorise a prescription for flunitrazepam contrary to any conditions and restrictions specified in the authorisation.
- (7) A medical practitioner who issues or writes a prescription for flunitrazepam shall write the HDWA Authorisation No. on the prescription after his or her signature using the following format —

“HDWA Authorisation No.”.
- (8) A pharmaceutical chemist shall not sell or supply flunitrazepam unless the HDWA Authorisation No. is written on the prescription for the flunitrazepam in accordance with subregulation (7).

[Regulation 51GB inserted in Gazette 26 May 1998 p. 2966; amended in Gazette 15 Dec 2006 p. 5630; 21 Apr 2009 p. 1366.]

51H. Dentists not to prescribe or supply certain drugs of addiction

- (1) A dentist shall not write, issue or authorise a prescription or document prescribing the use, sale or supply of a poison included in Schedule 8, or supply a poison included in Schedule 8, unless the poison is also included in the Commonwealth Schedule under the heading “Preparations

which may be prescribed by participating dental practitioners for dental treatment only”.

- (2) A dentist shall not write, issue or authorise a prescription or document prescribing the use, sale or supply of a poison included in Schedule 8, or supply a poison included in Schedule 8, for the treatment of a person for a period in excess of 7 days, or for periods that in the aggregate over the preceding 12 months exceed 60 days, unless the dentist has first obtained written authorisation to do so from the CEO.

- (3) In subregulation (1) —

Commonwealth Schedule means the document “Schedule of Pharmaceutical Benefits”, as published from time to time by the Commonwealth Government for the purposes of Part VII of the *National Health Act 1953* of the Commonwealth.

[Regulation 51H inserted in Gazette 11 Apr 1997 p. 1833; amended in Gazette 15 Dec 2006 p. 5630.]

[51J. Deleted in Gazette 12 Apr 1991 p. 1609.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

Division 3 — Dispensing and delivery

[Heading inserted in Gazette 12 Aug 2003 p. 3664.]

52. Dispensing drugs of addiction

- (1) Subject to the Act and these regulations a drug of addiction shall be dispensed or supplied only in accordance with a prescription complying with the requirements of the regulations.
- (2) A medical practitioner, pharmaceutical chemist, or veterinary surgeon or an assistant under the direct personal supervision of a medical practitioner, pharmaceutical chemist, or veterinary surgeon shall be the only person who shall dispense a drug of addiction.

- (3) The following conditions shall be observed by a person who dispenses a drug of addiction under a prescription —
- (a) the dispenser shall satisfy himself or herself —
 - (i) that the prescription is in accordance with the requirements of the Act;
 - (ii) that the person who issued the prescription is a medical practitioner, a dentist or a veterinary surgeon; and
 - (iii) in accordance with subregulation (3a), that the prescription was issued by the prescriber whose name appears on the prescription;
 - (b) the drug of addiction shall not be dispensed under the prescription more than the maximum number of times indicated by the prescription, or at intervals less than those indicated by the prescription;
 - (ba) on each occasion on which the drug of addiction is dispensed under the prescription the dispenser shall —
 - (i) in the case of a prescription that is not issued electronically — sign the prescription clearly in ink using his or her usual signature and clearly indicate the date on which the drug is dispensed; and
 - (ii) in the case of a prescription that is issued electronically — indicate that the drug of addiction was dispensed and the date on which it was dispensed using the means provided by the approved electronic prescribing system;
 - (bb) on the first occasion on which the drug of addiction is dispensed under the prescription, the dispenser shall —
 - (i) in the case of a prescription that is not issued electronically — stamp or otherwise mark the prescription clearly in ink with the name and address of the dispensary; and

- (ii) in the case of a prescription that is issued electronically — provide, in relation to the prescription, the name and address of the dispensary using the means provided by the approved electronic prescribing system;
- (c) where the drug of addiction is prescribed by a veterinary surgeon, the dispenser shall not dispense the drug of addiction on more than one occasion under that prescription;
- (d) where the dispenser dispenses less than the prescribed amount of the drug of addiction on a particular occasion and dispenses or intends to dispense the remainder on another occasion or occasions, the dispenser shall on each occasion on which part of the prescribed amount is dispensed —
 - (i) in the case of a prescription that is not issued electronically — note on the prescription clearly in ink the amount dispensed and the date on which it was dispensed; and
 - (ii) in the case of a prescription that is issued electronically — indicate, in relation to the prescription, the amount dispensed and the date on which it was dispensed using the means provided by the approved electronic prescribing system;
- (e) after dispensing the drug of addiction as directed by the prescription the dispenser shall —
 - (i) indicate, in relation to the prescription, the number of occasions remaining (if any) on which the drug of addiction is to be dispensed under the prescription; and
 - (ii) in the case of a prescription that is not issued electronically — retain, subject to subregulation (7), the prescription in safe custody at the dispensary;

- (f) in the case of a prescription that is not issued electronically — the dispenser shall write in ink, or stamp, the word “cancelled” across the prescription in legible letters if —
 - (i) the prescription does not clearly indicate the maximum number of occasions on which the drug of addiction is to be dispensed under the prescription;
 - (ii) the prescription does not clearly indicate the intervals at which the drug of addiction is to be dispensed under the prescription; or
 - (iii) the drug of addiction has already been dispensed on the maximum number of occasions on which it can lawfully be dispensed under the prescription;
- (fa) in the case of a prescription that is issued electronically — the dispenser shall indicate that the prescription is cancelled using the means provided by the approved electronic prescribing system if one or more of the conditions in paragraph (f) are met;
- (g) the dispenser shall enter, or cause to be entered, in the register maintained under regulation 44, a proper record of the transaction which record shall be made in such a way as to be easily understood;
- (h) before the drug of addiction is handed to the purchaser, the following particulars shall be recorded in accordance with regulation 52B —
 - (i) the prescription number;
 - (ii) the name, address and date of birth of the patient or, in the case of a prescription for veterinary use, the name and address of the person having the care of the animal for which the drug of addiction is prescribed;
 - (iii) a description of the drug of addiction;

- (iv) the quantity of the drug of addiction dispensed;
- (v) directions for the use of the drug of addiction;
- (vi) the date of the prescription;
- (vii) the name and address of the prescriber;
- (viii) in the case of a prescription that is not issued electronically — a note of the basis on which the dispenser is satisfied for the purposes of subregulation (3)(a)(iii) that the signature on the prescription is the signature of the prescriber whose name appears on the prescription;

[(j) deleted]

- (k) the label on the bottle or package containing the drug of addiction shall be marked with the prescription number referred to in paragraph (h); and

[(l) deleted]

- (m) subject to regulation 64, the drug of addiction so dispensed shall conform in quantity, description, composition, strength, form and every other material particular to the directions of the prescriber,

and in respect of a prescription prescribing a poison included in Schedule 8 issued under the *National Health Act 1953* or the *Repatriation Act 1920* of the Commonwealth a copy of such a prescription is deemed to be a prescription for the purposes of this regulation.

- (3a) For the purposes of subregulation (3)(a)(iii), if the prescription is not issued electronically, the dispenser shall orally ask the prescriber whose name appears on the prescription to verify that the prescriber issued the prescription, unless the dispenser is satisfied that the signature on the prescription is the signature of the prescriber on the basis that the dispenser is familiar with the signature of the prescriber and recognises the signature on the prescription as the prescriber's signature.

- (4) A person shall not dispense a drug of addiction under a prescription —
 - (a) that is more than 6 months old; or
 - (b) that —
 - (i) in the case of a prescription that is not issued electronically — is marked “cancelled”; or
 - (ii) in the case of a prescription that is issued electronically — is cancelled using the means provided by the approved electronic prescribing system.
- (5) A person shall not dispense a drug of addiction under a prescription which is illegible or defaced or which appears to have been altered or to be for the purpose of enabling some unauthorised person to obtain a drug of addiction, or which does not appear to be genuine.
- (6) If a pharmaceutical chemist is presented with or accesses a prescription which he or she suspects of being false in any particular he or she shall —
 - (a) in the case of a prescription that is not issued electronically — retain possession of the prescription for such reasonable period of time as will enable him or her to satisfy the requirements of paragraph (b); and
 - (b) in any case — make enquiries concerning the genuineness of the prescription, the identity of the person who issued it and the bona fides of the person wishing to have the drug dispensed under it.
- (6a) When a pharmaceutical chemist to whom a prescription is submitted for dispensing a drug of addiction is satisfied that the prescription is not in accordance with the requirements of the Act or regulations, he or she shall —
 - (a) in the case of a prescription that is not issued electronically —

- (i) mark on the prescription “cancelled”, the address of the dispensary and, in his or her own handwriting, the date and his or her usual signature; and
 - (ii) forward the prescription to the CEO; and
 - (iii) inform the CEO of the relevant circumstances and the reasons for his or her refusal to dispense the drug of addiction under the prescription;
- and
- (b) in the case of a prescription that is issued electronically —
 - (i) cancel the prescription using the means provided by the approved electronic prescribing system; and
 - (ii) inform the CEO that the prescription has been cancelled, and of the reasons for his or her refusal to dispense the drug of addiction under the prescription.
- (7) The dispenser of a drug of addiction may transfer a prescription that is not issued electronically into the safe custody of another person if the transfer is approved by the CEO under subregulation (7a).
- (7a) The CEO may, on the oral application of the dispenser, give approval for the dispenser to transfer the prescription to another person by whom the drug can be dispensed in accordance with these regulations.
- (8) A pharmaceutical chemist shall deliver up any document, prescription, authorisation or record relating to the sale or supply of a poison included in Schedule 8 upon request made by an authorised officer (other than an environmental health officer).

*[Regulation 52 amended in Gazette 29 Aug 1980 p. 3031;
23 Sep 1983 p. 3805-6; 29 Jun 1984 p. 1784; 31 Jan 1986
p. 332-3; 7 Aug 1987 p. 3038; 25 Jun 1993 p. 3085;
26 May 1994 p. 2201; 17 Mar 1995 p. 1026; 19 Mar 1996*

*p. 1231; 29 Feb 2000 p. 995; 15 Nov 2005 p. 5604-8;
15 Dec 2006 p. 5630; 7 Nov 2008 p. 4813-17.]*

52A. Movement of drugs of addiction in other circumstances

Any movement of stocks of drugs of addiction other than by prescription and other than supplies received from wholesale suppliers shall be recorded in the manner prescribed by regulation 52B.

*[Regulation 52A inserted in Gazette 31 Jan 1986 p. 333;
amended in Gazette 7 Aug 1987 p. 3083; 19 Mar 1996 p. 1231.]*

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

52B. Manner of recording details

- (1) The details required to be recorded under regulations 52(3)(h) and 52A shall be —
 - (a) entered on a duplicate form approved by the CEO; or
 - (b) entered in a computerised recording system approved by the CEO.
- (2) Where the details of a transaction referred to in regulation 52(3)(h) are entered —
 - (a) on an approved duplicate form, the details shall be entered and signed and dated by the person who actually dispensed the poison;
 - (b) in an approved computerised recording system, the details shall be accompanied by the name of the person who actually dispensed the poison and the date of the transaction.

*[Regulation 52B inserted in Gazette 7 Aug 1987 p. 3083;
amended in Gazette 25 Jun 1993 p. 3085; 26 May 1994 p. 2201;
19 Mar 1996 p. 1231; 15 Dec 2006 p. 5630.]*

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

52C. Returns to department

- (1) Every owner of a pharmacy which dispenses drugs of addiction shall return the original of the completed approved duplicate form or the original of the completed printout of the approved computerised recording system referred to in regulation 52B to the department monthly, by the 7th day of the following month, and where there have been no transactions in the month, the form or printout shall be returned showing the name and address of the pharmacy and marked "NIL".
- (2) Every computer printout returned shall bear the signature of a pharmaceutical chemist certifying the accuracy and completeness of the data recorded.

[Regulation 52C inserted in Gazette 7 Aug 1987 p. 3083.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

53. Dispensing poisons included in Schedule 8 in case of emergency

- (1) If a medical practitioner, dentist or veterinary surgeon in a case of emergency directs, orally or by telephone or other electronic means, the dispensing of a poison included in Schedule 8, he or she shall, within 24 hours, issue to the person by whom the poison was dispensed a prescription complying with regulation 51 that clearly indicates that it is in confirmation of the direction given by him or her under this subregulation.
- (2) A person by whom a poison included in Schedule 8 was dispensed in accordance with subregulation (1), shall where the prescription is not received by, or accessible via an approved electronic prescribing system to, him or her within 72 hours, immediately report the circumstances to the CEO.

[Regulation 53 amended in Gazette 23 Sep 1983 p. 3806; 27 May 1988 p. 1771; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1232; 15 Dec 2006 p. 5630-1; 7 Nov 2008 p. 4817.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

53A. Dispensing certain poisons included in Schedule 8

- (1) A person shall not dispense a prescription for or supply upon a prescription any of the following poisons included in Schedule 8, namely —

Amphetamine
Buprenorphine
Dexamphetamine
Dextromoramide
Flunitrazepam
Hydromorphone
Methadone
Methylamphetamine
Methylphenidate
Morphine
Oxycodone
Pethidine
Phenmetrazine

or the salts of any of those substances and any preparation or admixture containing any of those substances, or the salts of any of those substances, unless —

- (a) he or she is familiar with the prescriber's handwriting;
or
(b) he or she has verified with the purported prescriber that the prescription was issued by him or her; or
(c) the prescription is issued electronically via an approved electronic prescribing system.
- (2) Where a person cannot comply with subregulation (1), for good cause, he or she may dispense the prescription for, or supply upon the prescription, a quantity of the poison included in Schedule 8 sufficient to enable treatment at the rate prescribed for no more than 2 days.

*[Regulation 53A inserted in Gazette 23 Sep 1983 p. 3806;
amended in Gazette 19 Mar 1996 p. 1232; 26 May 1998
p. 2967; 16 Nov 2001 p. 5985; 13 Aug 2002 p. 4181;
12 Aug 2003 p. 3663; 7 Nov 2008 p. 4817-18.]*

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

54. Delivery of poisons included in Schedule 8 on order

- (1) Subject to regulation 53 and to subregulation (3) a poison included in Schedule 8 shall not be delivered to a person except —
 - (a) on the authority of a written order —
 - (i) legibly written in ink;
 - (ii) bearing on the face thereof —
 - (I) the date when it is written;
 - (II) the name and address of the person requiring it to be supplied;
 - (III) the quantity and description of the poison included in Schedule 8 to be supplied;
 - and
 - (iii) signed by a person licensed or otherwise authorised to procure or be in possession of the poison included in Schedule 8;
- or
- (b) on the authority of an order placed by telephone or telex, but such an order shall be confirmed by the person requiring the poisons to be supplied, by the signing and dating of the dispatch note or invoice delivered with the goods and the dispatch note or invoice shall be returned to the supplier within 7 days of the delivery or the supplier shall notify the CEO of the default.

- (2) A poison included in Schedule 8 shall not be delivered to any person not licensed, or otherwise authorised to be in possession of the poison included in Schedule 8, who purports to be sent by or on behalf of the person so licensed or authorised, unless the first-mentioned person produced an authority in writing signed by the person so licensed or authorised to receive the poison included in Schedule 8 on his or her behalf, and unless the person supplying the poison included in Schedule 8 is satisfied that the authority is genuine.
- (3) This regulation does not apply to medicines dispensed in pursuance of the foregoing regulations.

[Regulation 54 amended in Gazette 23 Sep 1983 p. 3807; 2 Jun 1989 p. 1605; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1232; 15 Dec 2006 p. 5630-1; 7 Nov 2008 p. 4818.]

54A. Packaging of drugs of addiction

A person forwarding for delivery a drug of addiction shall enclose the poison separately from goods of any other kind in a secure and sturdy package without exterior writing which might indicate the contents of the package and clearly address the package to the authorised person.

[Regulation 54A inserted in Gazette 23 Sep 1983 p. 3807; amended in Gazette 19 Mar 1996 p. 1232.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

55. Common carrier protected

A common carrier or his or her employee is hereby authorised to be in possession of any drug of addiction so far only as the possession is necessary for the transport of the drug of addiction in the ordinary course of business.

[Regulation 55 amended in Gazette 7 Nov 2008 p. 4818.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

Division 4 — Safe custody

[Heading inserted in Gazette 12 Aug 2003 p. 3665.]

56. Storing and securing drugs of addiction

- (1) A person who is —
- (a) authorised under regulation 42(1) or 42(4); or
 - (b) licensed under regulation 4,

and who is in possession of a drug or drugs of addiction in an amount that is less than or equal to the amount prescribed by regulation 56A, shall store the poison in a safe of a kind prescribed by clause 1 of Appendix M.

- (2) A person who is —
- (a) authorised under regulation 42(1); or
 - (b) licensed under regulation 4,

and who is in possession of a drug or drugs of addiction in an amount that is greater than the amount prescribed by regulation 56A, shall store the poison in a safe of a kind prescribed by clause 1 of Appendix M with the additional security requirements prescribed by clause 2 of that Appendix.

- (3) Subregulations (1) and (2) do not apply —
- (a) to a pharmaceutical chemist who is in possession of a drug or drugs of addiction in an amount that is less than or equal to the amount prescribed by regulation 56A for the purposes of his or her profession or employment who stores the poison in a safe —
 - (i) of a type that was prescribed by regulation 56A(2) or (3); and
 - (ii) that was in place and used by him or her, immediately before the commencement of the *Poisons Amendment Regulations (No. 2) 1993*¹;

- (aa) to a pharmaceutical chemist who is in possession of a drug or drugs of addiction in an amount that is greater than the amount prescribed by regulation 56A for the purposes of his or her profession or employment who stores the poison in a safe —
 - (i) of a type that was prescribed by regulation 56A(2) or (3); and
 - (ii) that was in place and used by him or her, immediately before the commencement of the *Poisons Amendment Regulations (No. 2) 1993*¹, if that safe complies with the additional security requirements prescribed by clause 2 of Appendix M;
- (b) to a person who has the written permission of the CEO to store a drug of addiction in a manner and with such security arrangements as are specified by the CEO and who stores and secures the drug of addiction in such manner;
- (c) to a person to whom regulation 52(2) applies where that person is in possession of a drug of addiction that he or she has prepared for supply, in accordance with a prescription; or
- (d) where a poison included in Schedule 8 in an amount that is no more than would reasonably be required for administration to a patient in an emergency is —
 - (i) transported by a medical practitioner, dentist or veterinary surgeon for the purpose of his or her profession or practice; or
 - (ii) otherwise in the possession of a medical practitioner, dentist or veterinary surgeon,if that medical practitioner, dentist or veterinary surgeon, takes reasonable precautions to protect the poison against theft or loss.

- (4) This regulation is subject to regulations 56E and 56G.

*[Regulation 56 inserted in Gazette 25 Jun 1993 p. 3081;
amended in Gazette 26 May 1994 p. 2201; 24 Jun 1994 p. 2869;
19 Mar 1996 p. 1232-3; 15 Dec 2006 p. 5630-1.]*

56A. Prescribed amount of poisons included in Schedule 8

- (1) For the purposes of regulations 56(1) and (2), the amount is —
- (a) 200 tablets or capsules, or tablets and capsules; or
 - (b) 20 ampoules; or
 - (c) 500 millilitres of liquid; or
 - (d) 7.5 grams,

of any poison included in Schedule 8.

- (2) A poison included in Schedule 8 in the form of a suppository shall not be included in the assessment of the amount under subregulation (1).

*[Regulation 56A inserted in Gazette 25 Jun 1993 p. 3082;
amended in Gazette 19 Mar 1996 p. 1233; 13 Aug 2002
p. 4181.]*

[56AA. Deleted in Gazette 25 Jun 1993 p. 3081.]

56B. Location of safe in premises

Where a person stores a drug of addiction in a safe in accordance with regulation 56(1) or (2), the person shall ensure that the safe is not in a part of the premises that is accessible to the public unless the person is present in that part of the premises when a member of the public is also present.

[Regulation 56B inserted in Gazette 25 Jun 1993 p. 3082.]

56C. Authorised persons to keep keys to safes

Where a person stores a drug of addiction in a safe in accordance with regulation 56(1), (2) or (3)(a), and the safe is of a kind that may be locked by a key, the person shall —

- (a) keep the key to the safe in his or her immediate and personal possession; or
- (b) ensure that the key to the safe is in the immediate and personal possession of a person who has been authorised by the CEO to have possession of the key.

[Regulation 56C inserted in Gazette 25 Jun 1993 p. 3082; amended in Gazette 26 May 1994 p. 2201; 15 Dec 2006 p. 5630-1.]

56D. Safes to be kept locked

- (1) A person who, under regulation 56C, is in possession of the key to a safe in which is stored a drug of addiction shall ensure that the safe is kept locked at all times except when items are being placed into, or being removed from, the safe.
- (2) Where a person stores a drug of addiction in a safe in accordance with regulation 56(1), (2) or (3)(a), and the safe is of a kind that may be locked by a combination lock, the person shall ensure that the safe is kept locked at all times except —
 - (a) when items are being placed into, or being removed from, the safe; or
 - (b) during the hours of business if the lock is in the view of the person, in which case and during which time the safe may be unlocked, but shall be closed.

[Regulation 56D inserted in Gazette 25 Jun 1993 p. 3082.]

56E. Pharmacist present on premises

A pharmaceutical chemist who is —

- (a) authorised to be, and is, in possession of a poison included in Schedule 8; and

(b) present on the pharmacy premises,

for the purpose of his or her profession or employment may, instead of storing the poison in accordance with regulation 56(1), (2) or (3)(a), as the case requires, store the drug in a poisons cupboard or in a lockable drawer.

[Regulation 56E inserted in Gazette 25 Jun 1993 p. 3083; amended in Gazette 19 Mar 1996 p. 1233.]

56F. Keys to, and locking of, poisons cupboards and lockable drawers

A pharmaceutical chemist referred to in regulation 56E shall —

- (a) keep in his or her immediate and personal possession the key to the poisons cupboard or lockable drawer, as the case may be; and
- (b) ensure that the poisons cupboard or lockable drawer, as the case may be, is kept locked at all times except when items are being placed into, or being removed from, the poisons cupboard or lockable drawer.

[Regulation 56F inserted in Gazette 25 Jun 1993 p. 3083.]

56G. Poisons included in Schedule 8 in hospital ward

A poison included in Schedule 8 may be stored in a hospital ward if the poison is stored in —

- (a) a lockable cupboard in the ward; or
- (b) in a lockable portion of a cupboard in the ward,

where the cupboard, or lockable portion of the cupboard, as the case may be, is used solely for the purpose of storing poisons included in Schedule 8.

[Regulation 56G inserted in Gazette 25 Jun 1993 p. 3083; amended in Gazette 19 Mar 1996 p. 1233.]

56H. Keys to, and locking of, cupboards in hospital wards

The registered nurse in charge of a ward in which a poison included in Schedule 8 is stored under regulation 56G shall —

- (a) keep in his or her immediate and personal possession the key to the cupboard or lockable portion of the cupboard, as the case may be; and
- (b) ensure that the cupboard or lockable portion of the cupboard, as the case may be, is kept locked at all times except when a poison included in Schedule 8 is being placed into, or removed from, the cupboard or lockable portion of the cupboard.

[Regulation 56H inserted in Gazette 25 Jun 1993 p. 3083; amended in Gazette 19 Mar 1996 p. 1234; 27 Nov 1998 p. 6344.]

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

Division 5 — Restrictions on supply

[Heading inserted in Gazette 12 Aug 2003 p. 3665.]

57. Labelling

- (1) A person shall not supply any drug of addiction unless the package or bottle containing the drug of addiction is plainly labelled or marked to show the quantity of such drug of addiction contained therein.
- (2) A person shall not supply any preparation or admixture containing any drug of addiction, unless the package or bottle containing that preparation or admixture is plainly labelled or marked to show the total quantity of such preparation or admixture in the package or bottle and the percentage or quantity of the drug of addiction contained therein, or in the case of tablets or other articles, the number of such tablets or articles in the package or bottle and the percentage or quantity of the drug of addiction contained in each tablet or article.

- (3) This regulation does not apply to any drug of addiction, preparation, or admixture dispensed in accordance with these regulations.

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

58. Improper prescribing or use of drugs of addiction

- (1) A medical practitioner, dentist or veterinary surgeon shall not knowingly give a prescription for a drug of addiction merely for purposes of addiction.
- (2) A medical practitioner, dentist or veterinary surgeon shall not knowingly supply or administer a drug of addiction merely for purposes of addiction.

*[Regulation 58 amended in Gazette 23 Sep 1983 p. 3807;
20 Mar 1987 p. 954.]*

[Headings deleted in Gazette 12 Aug 2003 p. 3663.]

Part 7 — Miscellaneous provisions

[Heading inserted in Gazette 12 Aug 2003 p. 3665.]

59. Names of persons from whom licence or authority withdrawn to be published

A decision of the CEO cancelling, suspending or revoking an authorisation, licence or permit conferred or issued under the Act or these regulations or any other decision of the CEO may be published in the *Government Gazette*.

*[Regulation 59 inserted in Gazette 29 Aug 1980 p. 3031;
amended in Gazette 29 Jun 1984 p. 1784; 25 Jun 1993 p. 3085;
26 May 1994 p. 2201; 15 Dec 2006 p. 5630-1.]*

[Heading deleted in Gazette 12 Aug 2003 p. 3663.]

[60-63. Deleted in Gazette 30 Dec 2004 p. 6943.]

64. Substitution of one brand of a drug for another

- (1) In this regulation —

approved name, in relation to a poison, means the name for the poison that is listed in the Australian Register of Therapeutic Goods, other than a brand of the poison;

Australian Register of Therapeutic Goods means the register of that name maintained under section 17 of the *Therapeutic Goods Act 1989* of the Commonwealth;

brand, in relation to a poison, means a name given to the poison by a manufacturer of it and listed in the Australian Register of Therapeutic Goods, other than its approved name.

- (2) If a prescription issued by a medical practitioner, nurse practitioner or a dentist prescribes a poison and describes the poison by its approved name, a person dispensing the prescription may dispense or supply any brand of the poison.
- (3) Except as provided by this regulation, if a prescription issued by a medical practitioner, nurse practitioner or a dentist prescribes

a poison and describes the poison by reference to a brand of it, a person dispensing the prescription must not dispense or supply the poison other than in accordance with the description in the prescription.

- (4) If a prescription issued by a medical practitioner, nurse practitioner or a dentist prescribes a poison and describes the poison by reference to a brand of it, a person dispensing the prescription may dispense or supply any brand of the poison, unless the prescription shows a contrary intention.
- (5) If a prescription issued by a medical practitioner or nurse practitioner in respect of a patient in a public hospital prescribes a poison and describes the poison by reference to a brand of it, a person dispensing the prescription may dispense or supply any brand of the poison, whether or not the prescription indicates a contrary intention.
- (6) For the purposes of this regulation, a contrary intention is shown on a prescription if it bears the words “No substitution” or words with a similar effect.

[Regulation 64 inserted in Gazette 17 Mar 1995 p. 1026-7; amended in Gazette 19 Mar 1996 p. 1234; 12 Aug 2003 p. 3663; amended by Act No. 9 of 2003 s. 49.]

65. Form of warrant (section 55A)

A warrant under section 55A of the Act is to be in the form of Form 15 in Appendix A.

[Regulation 65 inserted in Gazette 19 Mar 1996 p. 1234.]

Part 8 — Transitional provisions

[Heading inserted in Gazette 21 Apr 2009 p. 1366.]

Division 1 — Transitional provisions relating to the *Poisons Amendment Regulations (No. 2) 2009*

[Heading inserted in Gazette 21 Apr 2009 p. 1366.]

66. Terms used

In this Division —

commencement day means the day on which this Division comes into operation;

prescription means a prescription or document prescribing the use, sale or supply of a drug of addiction.

[Regulation 66 inserted in Gazette 21 Apr 2009 p. 1366.]

67. Authorisation to prescribe drugs of addiction

(1) This regulation applies to a person —

- (a) who was authorised under regulation 51B(1) (as in force before commencement day) in relation to a drug addict; and
- (b) whose authorisation (the ***old authorisation***) was in force immediately before commencement day.

(2) The person becomes, on commencement day, a person authorised by the CEO under regulation 51BA(2) for that drug addict on the same terms and conditions as, and (subject to these regulations) for the remainder of the term of, the old authorisation.

[Regulation 67 inserted in Gazette 21 Apr 2009 p. 1366-7.]

68. Authorisation to prescribe pharmacotherapies

(1) This regulation applies to a person —

- (a) who was authorised under regulation 51C (as in force before commencement day) in relation to a drug addict; and
 - (b) whose authorisation (the **old authorisation**) was in force immediately before commencement day.
- (2) The person becomes, on commencement day, a person appointed by the CEO under regulation 51CA(1) to be the authorised prescriber for that drug addict on the same terms and conditions as, and (subject to these regulations) for the remainder of the term of, the old authorisation.

[Regulation 68 inserted in Gazette 21 Apr 2009 p. 1367.]

69. Prescriptions

Nothing in regulations 51B to 51EA as inserted by the *Poisons Amendment Regulations (No. 2) 2009* (the **new provisions**), prevents a prescription that was written, issued or authorised before commencement day from being dealt with under these regulations as if it had been written, issued or authorised under the new provisions.

[Regulation 69 inserted in Gazette 21 Apr 2009 p. 1367.]

70. Dispensing drugs of addiction from a pharmacy

Regulation 51B (as inserted by the *Poisons Amendment Regulations (No. 2) 2009*) does not apply to or in respect of a pharmacy until the end of the 12 months after commencement day.

[Regulation 70 inserted in Gazette 21 Apr 2009 p. 1367.]

Appendix A

<i>Poisons Act 1964</i> <i>Poisons Regulations 1965, regulation 3</i> WHOLESALE'S LICENCE Form 1

This licence authorises the licensee to procure, manufacture and supply by wholesale dealing the poisons specified in this licence at or from the premises specified in this licence.

Licensee	Name
	Address

Poisons	The poisons included in —
	<input type="checkbox"/> Schedule 1 <input type="checkbox"/> Schedule 3 <input type="checkbox"/> Schedule 7
	<input type="checkbox"/> Schedule 2 <input type="checkbox"/> Schedule 4 <input type="checkbox"/> Schedule 8
to the <i>Poisons Act 1964</i>	

Manufacturing of poisons (regulation 3(3))	
Premises	
Qualified person	Name Qualifications

Supply of poisons (regulation 3(4))	
Premises	
Qualified person	Name Qualifications

Experienced person	Name Qualifications
---------------------------	------------------------

Other conditions

Duration of licence	Date of issue Date of expiry
----------------------------	---------------------------------

[Form 1 inserted in Gazette 14 Sep 2001 p. 5077.]

[Form 1A deleted in Gazette 19 Mar 1996 p. 1234.]

[Form 2 deleted in Gazette 14 Sep 2001 p. 5077.]

[Form 2A deleted in Gazette 19 Mar 1996 p. 1234.]

Form 3

Poisons Act 1964

PHARMACEUTICAL CHEMIST'S LICENCE TO SELL POISONS

This licence is granted to
and authorises that person to sell poisons at premises known as
..... and
(name of pharmacy)

situated at
.....

Dated at Perth 20.....

Valid until 30 June 20.....

.....

*[Form 3 amended in Gazette 7 Jun 1985 p. 1941; 27 May 1988
p. 1771; 14 Jun 1991 p. 2879; 16 Apr 1992 p. 1635; 16 Sep 1994
p. 4748.]*

[Forms 3A, 4 and 4A deleted in Gazette 19 Mar 1996 p. 1234.]

Form 5

Poisons Act 1964

**LICENCE TO SELL BY RETAIL POISONS INCLUDED IN
SCHEDULE 2**

This licence is granted to and authorises
that person to procure, and to sell by retail, on behalf of
the poisons included in Schedule 2 to the *Poisons Act 1964*, at premises situated
at

Dated at Perth 20.....

Valid until 30 June 20.....

.....
*[Form 5 amended in Gazette 7 Jun 1985 p. 1941; 23 May 1986
p. 1716; 27 May 1988 p. 1771; 14 Jun 1991 p. 2879; 16 Apr 1992
p. 1635; 19 Mar 1996 p. 1235.]*

[Form 5A deleted in Gazette 19 Mar 1996 p. 1235.]

Form 6

Poisons Act 1964

**LICENCE TO SELL BY RETAIL POISONS INCLUDED IN
SCHEDULE 7**

This licence is granted to and authorises
that person to procure, and sell by retail, on behalf of,
at premises situated at,
the following poisons included in Schedule 7 —

.....
.....

Subject to the following conditions —

.....
.....

Dated at Perth 20.....

Valid until 30 June 20.....

.....

*[Form 6 amended in Gazette 7 Jun 1985 p. 1941; 27 May 1988
p. 1771; 14 Jun 1991 p. 2879; 16 Apr 1992 p. 1635; 19 Mar 1996
p. 1235.]*

[Form 6A deleted in Gazette 19 Mar 1996 p. 1235.]

Form 6B

Poisons Act 1964

POISONS PERMIT (DISTRIBUTION OF SAMPLES)

This permit is granted to of
....., representative of, licensed
manufacturers of, or wholesale suppliers in, drugs containing poisons included
in Schedule 2, 3 or 4 to the *Poisons Act 1964*; and authorises that person to
procure samples of such drugs, other than drugs declared to be specified drugs
for the purposes of that Act, from

(Name of manufacturers or wholesale suppliers)

and supply them to persons authorised by regulation 8A of the *Poisons
Regulations 1965* (as amended) to receive them.

Dated at Perth20.....

Valid until 30 June 20.....

.....
*[Form 6B inserted in Gazette 22 Sep 1969 p. 2876; amended in
Gazette 17 Aug 1990 p. 4081; 12 Apr 1991 p. 1609; 14 Jun 1991
p. 2879; 16 Apr 1992 p. 1635; 19 Mar 1996 p. 1235.]*

[Form 6C deleted in Gazette 19 Mar 1996 p. 1235.]

Form 7

Poisons Act 1964

POISONS PERMIT (INDUSTRIAL)

This permit is granted to and
authorises that person to purchase on behalf of..... —

(a) the poisons included in Schedules to
the *Poisons Act 1964*;

(b) the following poisons —

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

This permit is issued subject to the following conditions —

(1) the poisons will be stored only at premises situated at

.....

(2) the poisons will not be resold;

(3) the poisons will be used only for the following purposes —

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

(4)

.....
.....

Dated at Perth 20.....

Valid until 30 June 20.....

.....

*[Form 7 amended in Gazette 7 Jun 1985 p. 1941; 27 May 1988
p. 1771; 14 Jun 1991 p. 2879; 16 Apr 1992 p. 1635; 19 Mar 1996
p. 1235.]*

[Form 7A deleted in Gazette 19 Mar 1996 p. 1235.]

Form 8

Poisons Act 1964

POISONS PERMIT (EDUCATIONAL, ADVISORY OR RESEARCH)

This permit is granted to and
authorises that person to purchase on behalf of..... —

(a) the poisons included in Schedules to
the *Poisons Act 1964*;

(b) the following poisons —

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

This permit is issued subject to the following conditions —

(1) the poisons will be stored only at premises situated at

.....

(2) the poisons will not be resold;

(3) the poisons will be used only for the following purposes —

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

(4)

.....
.....

Dated at Perth 20.....

Valid until 30 June 20.....

.....
CEO

*[Form 8 amended in Gazette 7 Jun 1985 p. 1941; 27 May 1988
p. 1771; 16 Apr 1992 p. 1635; 25 Jun 1993 p. 3085; 26 May 1994
p. 2201; 19 Mar 1996 p. 1235; 4 Apr 2006 p. 1406; 15 Dec 2006
p. 5630-1.]*

Form 8AA

Poisons Act 1964

POISONS PERMIT (HEALTH SERVICES)

This permit is granted to and
authorises that person to purchase on behalf of —

- (a) the poisons included in Schedules to
the *Poisons Act 1964*;
- (b) the following poisons —
.....
.....
.....

This permit is issued subject to the following conditions —

- (1) the poisons will be stored only at premises situated at
- (2) the poisons will not be resold;
- (3) the poisons will be used only for the following purposes —
.....
.....
.....
- (4)
.....
.....

Dated at Perth 20.....

Valid until 30 June 20.....

.....
CEO

*[Form 8AA inserted in Gazette 4 Apr 2006 p. 1407; amended in
Gazette 15 Dec 2006 p. 5630-1.]*

[Forms 9 and 9A deleted in Gazette 27 May 1988 p. 1771.]

[Form 10 deleted in Gazette 19 Mar 1996 p. 1236.]

[Forms 11 and 11A deleted in Gazette 2 Oct 1987 p. 3776.]

Form 11AA

Poisons Act 1964

STOCKFEED MANUFACTURER'S PERMIT

This permit is granted to and
authorises that person to sell by retail on behalf of
..... to any person producing the written
order of a veterinary surgeon such mixture containing the following poisons
included in Schedule 4 as may be specified in the order, and within the limits as
to quantity and composition set out in the order.

Poisons included in Schedule 4 to which this permit applies —

.....
.....

This permit is issued subject to the following conditions —

- (1) the mixture will be stored at and sold from premises situated at
.....
- (2)
.....
.....

Dated at Perth 20.....

Valid until 30 June 20

.....
*[Form 11AA inserted in Gazette 5 Oct 1979 p. 3085-6; amended in
Gazette 7 Jun 1985 p. 1941; 27 May 1988 p. 1771; 14 Jun 1991
p. 2879; 16 Apr 1992 p. 1635; 19 Mar 1996 p. 1236.]*

[Form 11AB deleted in Gazette 19 Mar 1996 p. 1236.]

[Form 12 deleted in Gazette 30 Dec 2004 p. 6943.]

Form 13

Poisons Act 1964

POISONS PERMIT (DEPARTMENTAL AND HOSPITAL)

This permit is granted to and
authorises that person to purchase on behalf of —

(a) the poisons included in Schedules to the
Poisons Act 1964;

(b) the following poisons —

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

This permit is issued subject to the following conditions —

(1) the poisons will be stored only at premises situated at

.....

(2) the poisons will not be resold unless the poisons referred to above
have been purchased on behalf of a public hospital;

(3) the poisons will be used only for the following purposes —

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

(4)

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

Dated at Perth 20.....

Valid until 30 June 20.....

.....
CEO

*[Form 13 inserted in Gazette 14 Jun 1967 p. 1582; amended in
Gazette 7 Jun 1985 p. 1941; 27 May 1988 p. 1771; 16 Apr 1992
p. 1635; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 1996
p. 1236; 15 Dec 2006 p. 5630-1.]*

Form 13A

[Reg. 10B]

Poisons Act 1964

(Section 41A)

LICENCE TO CULTIVATE ETC A PROHIBITED PLANT

This licence is granted to and
authorises that person to cultivate*/sell*/purchase*/have in the person's
possession* the following prohibited plants —

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

at premises situated at

subject to the following conditions —

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

Dated:

Valid until 30 June 20.....

.....
CEO

[* delete if not applicable]

*[Form 13A inserted in Gazette 23 Aug 1996 p. 4089; amended in
Gazette 15 Dec 2006 p. 5630-1.]*

Form 14

Poisons Act 1964

**APPLICATION FOR APPROVAL OF NEEDLE AND SYRINGE
PROGRAMME**

I of
hereby apply on behalf of
for the approval of the following needle and syringe programme —

.....
[specify precisely the activities, and the persons or

.....
class of persons conducting those activities, that

.....
constitute the programme]
.....

1. The programme will be conducted at

.....
[specify place or places]

2. The programme will be conducted at or between the following times —

.....
[specify times]

3. The coordinator of the programme will be —

.....
[specify name and address of coordinator]

.....
Signature of Coordinator

Date

.....
Signature of Applicant

[Form 14 inserted in Gazette 29 May 1994 p. 2200.]

Form 15

[Reg. 65]

Poisons Act 1964

(Section 55A)

WARRANT TO ENTER, SEARCH AND SEIZE

THIS IS A WARRANT authorising an authorised officer under the *Poisons Act 1964* to enter and search —

Place:	
Time: (specify hours or at any time)	

This warrant ceases to have effect:

Date:	
Time:	

I Justice of the Peace
ofam satisfied by complaint made on oath
that there are reasonable grounds for suspecting that —

- (a) an offence against the *Poisons Act 1964* has been, is being or is about to be committed; and
- (b) there is in or on the premises set out in this warrant, or in a part of those premises (being premises used as a residence) something relevant to the investigation of that offence,

and I authorise, an authorised officer, to exercise the entry, search and seizure powers set out in section 55(2) of the *Poisons Act 1964* in relation to the premises named in this warrant with such assistance, and by such force, as is reasonably necessary during the time referred to in this warrant.

.....
Signature of Justice of the Peace

.....
Date

(reverse of Form 15)

WARRANT INFORMATION

The authorised officer named in this warrant may, during the time the warrant is effective, exercise the following powers as set out in section 55(2) of the Act —

- (a) signal or direct the person in control of a vehicle or vessel —
 - (i) to stop the vehicle or vessel;
 - (ii) to move the vehicle or vessel to a place specified by the officer;
 - (iii) not to move the vehicle or vessel;
- (b) enter and search premises, vehicles or vessels using such force as is necessary to gain entry;
- (c) break open and search any package, container or other thing in or on premises, vehicles or vessels;
- (d) search all persons found in or on premises, vehicles or vessels;
- (e) take and remove a sample of anything in or on premises, vehicles or vessels;
- (f) seize anything reasonably suspected of being relevant to the investigation of an offence against this Act.

[Form 15 inserted in Gazette 19 Mar 1996 p. 1236-8.]

[Appendix B deleted in Gazette 1 Oct 1993 p. 5361.]

[Appendices C, D and E deleted in Gazette 11 Nov 1988 p. 4444.]

[Appendix F deleted in Gazette 1 Aug 1986 p. 2739.]

Appendix G

(reg 12)

[Heading inserted in Gazette 19 Mar 1996 p. 1238.]

Form No.	Description of Licence or Permit	Initial Fee (1 year) \$	Initial Fee (3 years) \$	Renewal (1 year) \$	Renewal (3 years) \$
1.	Wholesaler's Licence	600	850	175	425
[2.	<i>deleted]</i>				
3.	Pharmaceutical chemist's licence to sell poisons	100	200	75	175
5.	Licence to sell by retail, poisons included in Schedule 2 to the <i>Poisons Act 1964</i>	100	150	50	100
6.	Licence to sell by retail, poisons included in Schedule 7 to the <i>Poisons Act 1964</i>	200	300	75	175
6B.	Poisons permit (Distribution of samples)	100	150	50	100
7.	Poisons permit (Industrial) —				
	(a) for poisons other than those set out in this item	200	300	75	175
	(b) for any one or more of the poisons set out in this item	575	1275	425	1125
	• benzene;				
	• 4,4-diaminodiphenylmethane (Methylene dianiline);				
	• 4,4'-methylenebis(2-chloroaniline);				
8.	Poisons permit (Educational, advisory or research)	100	150	50	100
8AA.	Poisons permit (Health services)	200	300	75	175
11AA.	Stockfeed manufacturer's permit	200	300	75	175
13.	Poisons permit (Departmental and hospitals) —				
	(a) Departmental	100	150	50	100
	(b) Hospitals	No fee	No fee	No fee	No fee

[Appendix G inserted in Gazette 19 Mar 1996 p. 1238-9; amended in Gazette 11 Apr 1997 p. 1833-4; 14 Sep 2001 p. 5077; 4 Apr 2006 p. 1407.]

Appendix H

Schedule 4 substances referred to in regulation 39(1)

[Heading inserted in Gazette 8 Feb 1985 p. 520; amended in Gazette 19 Mar 1996 p. 1239.]

Except where otherwise stated, a substance in this Appendix does not include any derivative but does include any compound, preparation or admixture included in relation to that substance in Schedule 4. Where a method of application or of administration is stated in relation to a substance, the entry in this Appendix in relation to that substance applies only to compounds, preparation or admixtures of that substance which have been prepared for that method of application or administration —

Acepromazine Maleate.

Antihistamines.

Apomorphine.

Benzyl penicillin for parenteral injection.

Chlorpromazine (but not to be supplied for use on horses).

Procaine penicillin for parenteral injection.

Streptomycin.

[Appendix H inserted in Gazette 8 Feb 1985 p. 520 (erratum in Gazette 19 Apr 1985 p. 1409); amended in Gazette 19 Mar 1996 p. 1239.]

[Appendix I deleted in Gazette 23 May 1986 p. 1720.]

Appendix J

(reg. 35A)

Schedule 3 poison sales to be recorded

[Heading inserted in Gazette 20 Sep 1985 p. 3743.]

HYDROCORTISONE, when included in Schedule 3;

HYDROCORTISONE ACETATE, when included in Schedule 3.

PSEUDOEPHEDRINE, when included in Schedule 3.

[Appendix J inserted in Gazette 20 Sep 1985 p. 3743; amended in Gazette 23 May 1986 p. 1721; 23 Jan 1987 p. 187; 7 Aug 1987 p. 3084; 27 May 1988 p. 1771; 9 Dec 1988 p. 4825; 30 Nov 1990 p. 5908; 26 Jul 1991 p. 3855; 13 Dec 1991 p. 6191; 28 May 1993 p. 2597; 16 Sep 1994 p. 4749; 3 Feb 1995 p. 343; 19 Mar 1996 p. 1239; 24 Jul 2007 p. 3665.]

Appendix K

[r. 32B]

Criteria for electronic prescribing systems

[Heading inserted in Gazette 7 Nov 2008 p. 4818.]

The electronic prescribing system must be designed so that —

- (a) the system records each person who was given an access code, when it was given and (where relevant) when it was cancelled and each person who has a current access code, in a way that cannot be amended or erased; and
- (b) for each entry made in the system —
 - (i) a unique, sequential number is given to that entry; and
 - (ii) the time and date is recorded; and
 - (iii) the system identifier of the person whose access code was used to make the entry is recorded;and
- (c) the system requires that persons with access to it change their access code in accordance with standard industry practice; and
- (d) appropriate backup arrangements are in place; and
- (e) the system records the details of the administrator or each person who is an administrator of the system, and retains those details for 7 years after the person ceases to be an administrator; and
- (f) the system can generate appropriate reports from its records, for example —
 - (i) of persons with, or who were given, an access code;
 - (ii) of access to the system, or entries made in the system, during a certain period;
 - (iii) of entries made in the system during a certain period, sorted according to drug type, strength or dose or according to patient;
 - (iv) of corrections to entries made during a certain period;

and

(g) the records of the system can be printed.

[Appendix K inserted in Gazette 7 Nov 2008 p. 4818-19.]

Appendix L

(Regulations 37 and 51)

Specified criteria for the generation of prescriptions by computer

[Heading inserted in Gazette 26 Jul 1991 p. 3855.]

1. The computer system shall be designed so that —
 - (a) the prescription can be generated by the prescriber only;
 - (b) the prescription is printed on a form which is pre-printed with the name and address and contact telephone number of the prescriber OR which is pre-printed with at least the address and contact telephone number of the practice and the system individually prints the name of the prescriber at the foot of the prescription when the prescription is being generated;
 - (c) either a statement is printed on each prescription form indicating the total number of items prescribed on that form, or the area on the prescription form below the prescriber's signature is scored, hatched or otherwise marked to prevent any other item being printed in that area;
 - (d) the directions for use must be determined and included on each occasion by the prescriber;
 - (e) the particulars of any prescription issued are included in the clinical or prescription record of the person or animal for whom the prescription was generated;
 - (f) a number which uniquely identifies each prescription form is printed on the form which is related to the clinical or prescription record of the person or animal for whom that prescription was generated;
 - (g) the clinical or prescription record of the person or animal for whom the prescription was issued is preserved for at least one year from the date on which the prescription was generated and can be accessed when required.

[Clause 1 inserted in Gazette 26 Jul 1991 p. 3855.]

2. For prescriptions of a poison included in Schedule 8 or 9, the words, "The prescriber must write these prescription details in his or her own

handwriting” shall be printed by the system immediately below the computer-printed details, and the system shall allow space on the prescription for these handwritten details.

[Clause 2 inserted in Gazette 26 Jul 1991 p. 3855; amended in Gazette 19 Mar 1996 p. 1239.]

Appendix M

[Regulations 56(1) and (2)]

Safes and additional security for storing drugs of addiction

[Heading inserted in Gazette 25 Jun 1993 p. 3084.]

1. Safes

A safe for the storage of a drug of addiction shall be either —

(a) a free-standing safe as follows —

- (i) weighing at least 500 kilograms, but if the weight is less than 1 tonne, then the safe shall be securely bolted through a concrete floor by a person who is licensed under the *Security Agents Act 1976*⁴ as a security agent or guard to install safes;
- (ii) lockable by means of either a key or a combination lock;
- (iii) having a steel plate door at least 12 millimetres thick, with at least 2 locking bolts that are at least 25 millimetres thick; and
- (iv) having the manufacturer's recommendation that items with a total value of at least \$30,000 stored in the safe be eligible for insurance cover;

or

(b) an under-floor safe as follows —

- (i) embedded in concrete by a person who is licensed under the *Security Agents Act 1976*⁴ as a security agent or guard to install safes;
- (ii) lockable by means of a combination lock;
- (iii) having a heavy cast, high tensile steel lid that is secured at least 25 millimetres below a steel top plate; and

- (iv) having the manufacturer's recommendation that items with a total value of at least \$30,000 stored in the safe be eligible for insurance cover.

[Clause 1 inserted in Gazette 25 Jun 1993 p. 3084; amended in Gazette 24 Jun 1994 p. 2870.]

2. Additional security requirements

- (1) A drug or drugs of addiction in an amount greater than the amount prescribed by regulation 56A shall be protected by a detection device complying with the Australian Standard having the designation AS 2201.3 and entitled "Intruder alarm systems Part 3: Detection devices for internal use" published by the Standards Association of Australia⁵ including any amendment thereto made before the commencement of the *Poisons Amendment Regulations (No. 2) 1993*¹.
- (2) The detection device shall be able to detect the presence of a person who interferes, or attempts to interfere, with —
 - (a) the safe in which the poison is, or poisons are, stored;
 - (b) the detection device; or
 - (c) the device's alarm control panel.
- (3) The detection device and its alarm control panel shall be —
 - (a) monitored by a dedicated direct line; and
 - (b) installed in compliance with the Australian Standard having the designation AS 2201.1-1986 and entitled "Intruder alarm systems Part 1: Systems installed in client's premises", and by a person who is licensed under the *Security Agents Act 1976*⁴ as a security agent or guard to install that kind of device and alarm control panel.

[Clause 2 inserted in Gazette 25 Jun 1993 p. 3085; amended in Gazette 24 Jun 1994 p. 2870; 19 Mar 1996 p. 1239.]

Notes

- ¹ This is a compilation of the *Poisons Regulations 1965* and includes the amendments made by the other written laws referred to in the following table ⁶. The table also contains information about any reprint.

Compilation table

Citation	Gazettal	Commencement
<i>Poisons Act Regulations 1965</i> ⁷	29 Jun 1965 p. 1883-914	1 Jul 1965
Untitled regulations	10 Feb 1966 p. 410	10 Feb 1966
Untitled regulations	16 Nov 1966 p. 2935	16 Nov 1966
Untitled regulations	14 Jun 1967 p. 1582-3	14 Jun 1967
Untitled regulations	25 Oct 1967 p. 2962	25 Oct 1967
Untitled regulations	4 Jun 1968 p. 1694-5	4 Jun 1968
Untitled regulations	28 Nov 1968 p. 3457-8	28 Nov 1968
Untitled regulations	22 Sep 1969 p. 2874-6	22 Sep 1969
Untitled regulations	22 Sep 1969 p. 2877	22 Sep 1969
Untitled regulations	9 Feb 1970 p. 370	9 Feb 1970
Untitled regulations	12 Aug 1970 p. 2542-3	12 Aug 1970
Untitled regulations	11 Dec 1970 p. 3752	11 Dec 1970
Untitled regulations	12 Feb 1971 p. 425	12 Feb 1971
Untitled regulations	19 Feb 1971 p. 518-21	19 Feb 1971
Untitled regulations	26 May 1971 p. 1771-3	26 May 1971
Untitled regulations	7 Sep 1971 p. 3277-9	7 Sep 1971

Citation	Gazettal	Commencement
Untitled regulations	23 Dec 1971 p. 5318	23 Dec 1971
Reprint of the <i>Poisons Act Regulations 1965</i> authorised 12 Jul 1972 in <i>Gazette</i> 25 Jul 1972 p. 2755-99 (includes amendments listed above except those in <i>Gazette</i> 23 Dec 1971)		
Untitled regulations	22 Feb 1974 p. 553	22 Feb 1974
Untitled regulations	3 May 1974 p. 1434-5	3 May 1974
Untitled regulations	15 Apr 1976 p. 1183	15 Apr 1976
Untitled regulations	26 Aug 1977 p. 2966-73	26 Aug 1977
Untitled regulations	4 Nov 1977 p. 4087	4 Nov 1977
Untitled regulations	20 Oct 1978 p. 3760	20 Oct 1978
Untitled regulations	1 Jun 1979 p. 1437	1 Jul 1979
Untitled regulations	5 Oct 1979 p. 3085-6	5 Oct 1979
Untitled regulations	7 Dec 1979 p. 3799-805	7 Dec 1979
Untitled regulations	29 Aug 1980 p. 3027-31	1 Oct 1980 (see <i>Gazette</i> 29 Aug 1980 p. 3015)
<i>Poisons Act Amendment Regulations 1980</i>	7 Nov 1980 p. 3746	7 Nov 1980
Reprint of the <i>Poisons Act Regulations 1965</i> authorised 7 Sep 1981 in <i>Gazette</i> 15 Sep 1981 p. 3975-4029 (includes amendments listed above)		
<i>Poisons Act Amendment Regulations 1981</i>	6 Nov 1981 p. 4527	6 Nov 1981
<i>Poisons Amendment Regulations 1982</i>	16 Jul 1982 p. 2727-8	16 Jul 1982
<i>Poisons Amendment Regulations (No. 2) 1982</i>	24 Dec 1982 p. 4904	24 Dec 1982
<i>Poisons Amendment Regulations 1983</i>	28 Jan 1983 p. 341	28 Jan 1983

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Citation	Gazettal	Commencement
<i>Poisons Amendment Regulations (No. 2) 1983</i>	23 Sep 1983 p. 3803-7	23 Sep 1983
<i>Poisons Amendment Regulations 1984</i>	6 Apr 1984 p. 928 (erratum 13 Apr 1984 p. 1020)	6 Apr 1984
<i>Health Legislation Amendment Regulations 1984 r. 4</i>	29 Jun 1984 p. 1780-4	1 Jul 1984 (see r. 2)
<i>Poisons Amendment Regulations (No. 2) 1984</i>	12 Oct 1984 p. 3267	12 Oct 1984
<i>Poisons Amendment Regulations 1985</i>	8 Feb 1985 p. 519-20 (erratum 19 Apr 1985 p. 1409)	8 Feb 1985
<i>Poisons Amendment Regulations (No. 2) 1985</i>	8 Feb 1985 p. 520-1	8 Feb 1985
<i>Poisons Amendment Regulations (No. 3) 1985</i>	15 Mar 1985 p. 941-54 (erratum 29 Mar 1985 p. 1110)	15 Mar 1985
<i>Poisons Amendment Regulations (No. 5) 1985</i>	12 Apr 1985 p. 1285-6	1 Jul 1985 (see r. 2)
<i>Poisons Amendment Regulations (No. 6) 1985</i>	31 May 1985 p. 1882	31 May 1985
<i>Poisons Amendment Regulations (No. 4) 1985</i>	7 Jun 1985 p. 1941	7 Jun 1985
<i>Poisons Amendment Regulations (No. 6) 1985</i>	5 Jul 1985 p. 2392	5 Jul 1985
<i>Poisons Amendment Regulations (No. 8) 1985</i>	20 Sep 1985 p. 3743	20 Sep 1985
<i>Poisons Amendment Regulations 1986</i>	31 Jan 1986 p. 332-3	31 Jan 1986
<i>Poisons Amendment Regulations (No. 2) 1986</i>	28 Feb 1986 p. 616-17	28 Feb 1986
<i>Poisons Amendment Regulations (No. 3) 1986</i>	28 Feb 1986 p. 618	28 Feb 1986

Citation	Gazettal	Commencement
<i>Poisons Amendment Regulations (No. 4) 1986</i>	23 May 1986 p. 1716-20 (erratum 20 Jun 1986 p. 2049-54)	23 May 1986
<i>Poisons Amendment Regulations (No. 5) 1986</i>	23 May 1986 p. 1721 (erratum 30 May 1986 p. 1769)	23 May 1986
<i>Poisons Amendment Regulations (No. 7) 1986</i>	11 Jul 1986 p. 2339-40	15 Jul 1986 (see r. 2)
<i>Poisons Amendment Regulations (No. 6) 1986</i>	1 Aug 1986 p. 2739	1 Aug 1986
<i>Poisons Amendment Regulations (No. 8) 1986</i>	21 Nov 1986 p. 4269	21 Nov 1986
<i>Poisons Amendment Regulations (No. 9) 1986</i>	21 Nov 1986 p. 4270	21 Nov 1986
<i>Poisons Amendment Regulations (No. 10) 1986</i>	5 Dec 1986 p. 4466-7	5 Dec 1986
<i>Poisons Amendment Regulations (No. 12) 1986</i>	19 Dec 1986 p. 4874-5	19 Dec 1986
<i>Poisons Amendment Regulations 1987</i>	23 Jan 1987 p. 187	23 Jan 1987
<i>Poisons Amendment Regulations (No. 2) 1987</i>	20 Mar 1987 p. 954	20 Mar 1987
<i>Poisons Amendment Regulations (No. 3) 1987</i>	15 May 1987 p. 2121	15 May 1987
Reprint of the Poisons Regulations 1965 as at 22 Jul 1987 in Gazette 5 Aug 1987 p. 2987-3078 (includes amendments listed above)		
<i>Poisons Amendment Regulations (No. 4) 1987</i>	7 Aug 1987 p. 3083-4	7 Aug 1987
<i>Poisons Amendment Regulations (No. 5) 1987</i>	18 Sep 1987 p. 3596	18 Sep 1987
<i>Poisons Amendment Regulations (No. 6) 1987</i>	2 Oct 1987 p. 3776	2 Nov 1987 (see r. 2)
<i>Poisons Amendment Regulations (No. 2) 1988</i>	18 Mar 1988 p. 837	18 Mar 1988

Citation	Gazettal	Commencement
<i>Poisons Amendment Regulations 1988</i>	18 Mar 1988 p. 838-52	18 Mar 1988
<i>Poisons Amendment Regulations (No. 3) 1988</i>	27 May 1988 p. 1769-71	27 May 1988
<i>Poisons Amendment Regulations (No. 4) 1988</i>	11 Nov 1988 p. 4443-4	11 Nov 1988
<i>Poisons Amendment Regulations (No. 5) 1988</i>	9 Dec 1988 p. 4825	9 Dec 1988
<i>Poisons Amendment Regulations 1989</i>	2 Jun 1989 p. 1603-5	2 Jun 1989
<i>Poisons Amendment Regulations (No. 2) 1989</i>	16 Jun 1989 p. 1742	1 Jul 1989 (see r. 3)
<i>Poisons Amendment Regulations (No. 3) 1989</i>	25 Aug 1989 p. 2842	25 Aug 1989
<i>Poisons Amendment Regulations (No. 4) 1989</i>	25 Aug 1989 p. 2842	25 Aug 1989
<i>Poisons Amendment Regulations (No. 3) Amendment Regulations 1989</i>	6 Oct 1989 p. 3738	6 Oct 1989
<i>Poisons Amendment Regulations 1990</i>	8 Jun 1990 p. 2626-7	8 Jun 1990
<i>Poisons Amendment Regulations (No. 2) 1990</i>	22 Jun 1990 p. 3035	22 Jun 1990
<i>Poisons Amendment Regulations (No. 3) 1990</i>	17 Aug 1990 p. 4080-1	17 Aug 1990
<i>Poisons Amendment Regulations (No. 4) 1990</i>	23 Nov 1990 p. 5790-2	1 Jan 1991 (see r. 2)
<i>Poisons Amendment Regulations (No. 5) 1990</i>	30 Nov 1990 p. 5908	30 Nov 1990
<i>Poisons Amendment Regulations 1991</i>	12 Apr 1991 p. 1608-9	12 Apr 1991
<i>Poisons Amendment Regulations (No. 2) 1991</i>	14 Jun 1991 p. 2879	14 Jun 1991
<i>Poisons Amendment Regulations (No. 4) 1991</i>	28 Jun 1991 p. 3149	1 Jul 1991 (see r. 2)
<i>Poisons Amendment Regulations (No. 3) 1991</i>	26 Jul 1991 p. 3854-5	26 Jul 1991
<i>Poisons Amendment Regulations (No. 5) 1991</i>	13 Dec 1991 p. 6090-1	13 Dec 1991

Citation	Gazettal	Commencement
<i>Poisons Amendment Regulations 1992</i>	16 Apr 1992 p. 1634-5	16 Apr 1992
<i>Poisons Amendment Regulations (No. 2) 1992</i>	26 Jun 1992 p. 2700	1 Aug 1992 (see r. 2)
<i>Poisons Amendment Regulations (No. 4) 1992</i>	7 Aug 1992 p. 3864-6	7 Aug 1992
<i>Poisons Amendment Regulations (No. 3) 1992</i>	7 Aug 1992 p. 3868-9	7 Aug 1992
Reprint of the Poisons Regulations 1965 as at 7 Jan 1993 (includes amendments listed above)		
<i>Poisons Amendment Regulations 1993</i>	28 May 1993 p. 2595-7	28 May 1993
<i>Poisons Amendment Regulations (No. 2) 1993</i>	25 Jun 1993 p. 3078-85	25 Jun 1993
<i>Poisons Amendment Regulations (No. 3) 1993</i>	9 Jul 1993 p. 3329	1 Aug 1993 (see r. 2)
<i>Poisons Amendment Regulations (No. 4) 1993</i>	1 Oct 1993 p. 5360-1	1 Nov 1993 (see r. 2)
<i>Poisons Amendment Regulations (No. 5) 1993</i>	12 Nov 1993 p. 6146-7	12 Nov 1993
<i>Poisons Amendment Regulations (No. 7) 1993</i>	31 Dec 1993 p. 6883-5	31 Dec 1993
<i>Poisons Amendment Regulations 1994</i>	26 May 1994 p. 2195-201	26 May 1994
<i>Poisons Amendment Regulations (No. 3) 1994</i>	24 Jun 1994 p. 2854-5	1 Aug 1994 (see r. 2)
<i>Poisons Amendment Regulations (No. 2) 1994</i>	24 Jun 1994 p. 2864-70	24 Jun 1994
<i>Poisons Amendment Regulations (No. 5) 1994</i>	2 Sep 1994 p. 4532-3	2 Sep 1994
<i>Poisons Amendment Regulations (No. 6) 1994</i>	16 Sep 1994 p. 4748-9	16 Sep 1994
<i>Poisons Amendment Regulations (No. 7) 1994</i>	23 Dec 1994 p. 7076	23 Dec 1994
<i>Poisons Amendment Regulations (No. 9) 1994</i>	3 Feb 1995 p. 341-3	3 Feb 1995
<i>Poisons Amendment Regulations 1995</i>	17 Mar 1995 p. 1026-7	17 Mar 1995

Citation	Gazettal	Commencement
<i>Poisons Amendment Regulations (No. 2) 1995</i>	28 Apr 1995 p. 1466	28 Apr 1995
<i>Poisons Amendment Regulations (No. 3) 1995</i>	28 Apr 1995 p. 1466-7	1 Jun 1995 (see r. 2)
<i>Poisons Amendment Regulations (No. 4) 1995</i>	27 Jun 1995 p. 2550-1	1 Jul 1995 (see r. 2)
<i>Poisons Amendment Regulations (No. 6) 1996</i>	5 Sep 1995 p. 4162	5 Sep 1995
<i>Poisons Amendment Regulations (No. 5) 1995</i>	19 Sep 1995 p. 4382-4	19 Sep 1995
<i>Poisons Amendment Regulations 1996</i>	17 Jan 1996 p. 267	17 Jan 1996
<i>Poisons Amendment Regulations (No. 2) 1996</i>	19 Mar 1996 p. 1216-39	20 Mar 1996 (see r. 2 and <i>Gazette</i> 19 Mar 1996 p. 1203)
<i>Poisons Amendment Regulations (No. 4) 1996</i>	23 Aug 1996 p. 4088-9	23 Aug 1996
<i>Poisons Amendment Regulations (No. 5) 1996</i>	1 Oct 1996 p. 5088	1 Oct 1996
Reprint of the Poisons Regulations 1965 as at 4 Nov 1996 (includes amendments listed above) (correction in <i>Gazette</i> 29 Nov 1996 p. 6650)		
<i>Poisons Amendment Regulations 1997</i>	11 Apr 1997 p. 1828-34	11 Apr 1997
<i>Poisons Amendment Regulations 1998</i>	17 Mar 1998 p. 1417	17 Mar 1998
<i>Poisons Amendment Regulations (No. 2) 1998</i>	26 May 1998 p. 2966-7	19 Jun 1998 (see r. 2)
<i>Poisons Amendment Regulations (No. 3) 1998</i>	27 Nov 1998 p. 6343-4	27 Nov 1998
<i>Poisons Amendment Regulations 1999</i>	19 Feb 1999 p. 554-6	19 Feb 1999
<i>Poisons Amendment Regulations 2000</i>	29 Feb 2000 p. 992-5	29 Feb 2000
Reprint of the Poisons Regulations 1965 as at 12 May 2000 (includes amendments listed above)		
<i>Poisons Amendment Regulations 2001</i>	29 Jun 2001 p. 3115-18	29 Jun 2001
<i>Poisons Amendment Regulations (No. 2) 2001</i>	14 Aug 2001 p. 4253	14 Aug 2001

Citation	Gazettal	Commencement
<i>Poisons Amendment Regulations (No. 3) 2001</i> ³	14 Sep 2001 p. 5073-7	14 Sep 2001
<i>Poisons Amendment Regulations (No. 4) 2001</i>	16 Nov 2001 p. 5985	16 Nov 2001
<i>Poisons Amendment Regulations 2002</i>	13 Aug 2002 p. 4181	13 Aug 2002
Reprint 7: The Poisons Regulations 1965 as at 10 Jan 2003 (includes amendments listed above)		
<i>Nurses Amendment Act 2003</i> Pt. 3 Div. 5 assented to 9 Apr 2003 ⁸		9 Apr 2003 (see s. 2)
<i>Poisons Amendment Regulations 2003</i>	12 Aug 2003 p. 3658-65	12 Aug 2003
<i>Poisons Amendment Regulations 2004</i>	5 Oct 2004 p. 4309-11	5 Oct 2004
<i>Poisons Amendment Regulations (No. 3) 2004</i>	30 Dec 2004 p. 6943	1 Jan 2005 (see r. 2 and <i>Gazette</i> 31 Dec 2004 p. 7130)
<i>Poisons Amendment Regulations (No. 2) 2004</i>	4 Jan 2005 p. 3-4	4 Jan 2005
<i>Poisons Amendment Regulations 2005</i>	15 Nov 2005 p. 5602-8	1 Jan 2006 (see r. 2)
<i>Poisons Amendment Regulations 2006</i>	4 Apr 2006 p. 1406-7	4 Apr 2006
Reprint 8: The Poisons Regulations 1965 as at 5 May 2006 (includes amendments listed above)		
<i>Poisons Amendment Regulations (No. 2) 2006</i>	15 Dec 2006 p. 5629-31	15 Dec 2006
<i>Poisons Amendment Regulations (No. 2) 2007</i>	24 Jul 2007 p. 3663-5	r. 1 and 2: 24 Jul 2007 (see r. 2(a)); Regulations other than r. 1 and 2: 25 Jul 2007 (see r. 2(b))
<i>Poisons Amendment Regulations (No. 4) 2007</i>	2 Oct 2007 p. 4964-8	r. 1 and 2: 2 Oct 2007 (see r. 2(a)); Regulations other than r. 1 and 2: 3 Oct 2007 (see r. 2(b))
<i>Poisons Amendment Regulations (No. 2) 2008</i>	7 Nov 2008 p. 4805-19	r. 1 and 2: 7 Nov 2008 (see r. 2(a)); Regulations other than r. 1 and 2: 8 Nov 2008 (see r. 2(b))

Citation	Gazettal	Commencement
<i>Poisons Amendment Regulations (No. 2) 2009</i>	21 Apr 2009 p. 1359-67	r. 1 and 2: 21 Apr 2009 (see r. 2(a)); Regulations other than r. 1 and 2: 22 Apr 2009 (see r. 2(b))
<i>Poisons Amendment Regulations (No. 4) 2009</i>	12 Jun 2009 p. 2109-14	r. 1 and 2: 12 Jun 2009 (see r. 2(a)); Regulations other than r. 1 and 2: 13 Jun 2009 (see r. 2(b))
<i>Poisons Amendment Regulations (No. 5) 2009</i>	28 Jul 2009 p. 2979-80	r. 1 and 2: 28 Jul 2009 (see r. 2(a)); Regulations other than r. 1 and 2: 29 Jul 2009 (see r. 2(b))

² Repealed by the *Mental Health Act 1981* which was repealed by the *Mental Health Act 1996*.

³ The *Poisons Amendment Regulations (No. 3) 2001* r. 4(2) reads as follows:

“

(2) A licence issued under regulation 4 of the *Poisons Regulations 1965* and in force immediately before the day on which this regulation commences, continues in force on and after that day, as if it were a licence issued under regulation 3 of those regulations as amended by this regulation.

”.

⁴ Repealed by the *Security and Related Activities (Control) Act 1996*.

⁵ The Standards Association of Australia has changed its corporate status and its name. It is now Standards Australia International Limited (ACN 087 326 690). It also trades as Standards Australia

⁶ Renumbering of regulation 41 to regulation 40A effected by amendment in *Gazette* 19 March 1996 p. 1225.

⁷ Now known as the *Poisons Regulations 1965*; citation amended (see note to r. 1).

⁸ The *Nurses Amendment Act 2003* s. 50 reads as follows:

“

50. Existing power to amend regulations unaffected

Nothing in this Division prevents any of the *Poisons Regulations 1965* from being amended in accordance with the *Poisons Act 1964*.

”.

