Western Australia

Poisons Regulations 1965

Reprinted as at 12 May 2000

Reprinted under the *Reprints Act 1984* as at 12 May 2000

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Defined Terms

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Poisons Act 1964

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1. Citation

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

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

2. Interpretation

In these regulations unless the context requires otherwise —

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

"approved needle and syringe programme" means a needle and syringe programme that has been approved by the Commissioner of Health;

"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 means supplying the medicine or poison on and in accordance with a prescription duly given by a medical practitioner, a dentist or a veterinary surgeon;

"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;

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

"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 Commissioner of Health 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 Commissioner of Health;

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

"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 Commissioner of Health 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 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*.

[Regulation 2 amended in Gazette 23 September 1983 p.3803; 29 June 1984 p.1784; 28 February 1986 p.618; 5 December 1986 p.4467; 27 May 1988 p.1769; 25 August 1989 p.2842 (as amended in Gazette 6 October 1989 p.3738); 8 June 1990 p.2626; 23 November 1990 p.5791; 12 April 1991 p.1608; 7 August 1992 p.3868; 25 June 1993 pp.3078-9; 26 May 1994 p.2197; 24 June 1994 p.2865; 2 September 1994 p.4533; 23 December 1994 p.7076; 28 April 1995 p.1466; 28 April 1995 pp.1466-7; 5 September 1995 p.4162; 19 September 1995 p.4383; 17 January 1996 p.267; 19 March 1996 pp.1216-17; 11 April 1997 p.1829; 27 November 1998 p.6343.]

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 March 1996 p.1217.]

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 P 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 Appendix P of the SUSDP.

[Regulation 2A inserted in Gazette 12 November 1993 pp.6146-7; amended in Gazette 19 September 1995 p.4383; 19 March 1996 p.1217.]

3. Licence to procure etc. poisons

(1) A licence to procure, manufacture and supply by wholesale dealing poisons (other than drugs of addiction) shall authorise the licensee to procure, manufacture and supply (according to the endorsement thereon) by wholesale dealing substances as specified in the licence from the premises described in the licence, and shall be in the form of Form 1 in Appendix A.

(2) In addition to any other conditions required under these regulations the licence shall be subject to the following conditions —

(a) the manufacture shall be carried out —

(i) by a qualified person whose name appears on the licence; or

(ii) by an experienced person acting under the personal supervision of a qualified person whose name appears on the licence;

and

(b) the supply shall be carried out —

(i) by a qualified person whose name appears on the licence; or

(ii) by an experienced person whose name appears on the licence,

but where the person whose name appears on the licence ceases to be employed or is unable to exercise the necessary supervision, the Commissioner of Health may authorise, in writing, another person who holds the required qualifications to act in his stead.

[Regulation 3 inserted in Gazette 7 August 1992 pp.3868-9; amended in Gazette 26 May 1994 p.2201.]

4. Licence to procure etc. drugs of addiction

(1) A licence to procure, manufacture and supply by wholesale dealing drugs of addiction shall authorise the licensee to procure, manufacture, and supply by wholesale dealing drugs of addiction on or from the premises described in the licence, and shall be in the Form 2 in Appendix A.

(2) In addition to any other conditions required by these regulations the licence shall be subject to the following conditions —

(a) the manufacture shall be carried out —

(i) by a qualified person whose name appears on the licence; or

(ii) by an experienced person acting under the personal supervision of a qualified person whose name appears on the licence;

(b) the supply shall be carried out —

(i) by a qualified person whose name appears on the licence; or

(ii) by an experienced person whose name appears on the licence,

but should the person whose name appears on the licence cease employment or be unable to exercise the necessary supervision,

the Commissioner of Health may authorise, in writing, some other person having the required qualification to act in his stead.

[Regulation 4 amended in Gazette 29 June 1984 p.1784; 25 June 1993 p.3085; 26 May 1994 p.2201.]

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.

*[**6.** Repealed in Gazette 19 March 1996 p.1217.]*

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 March 1996 p.1217.]

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.

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 Commissioner of Health in writing of the fact and deliver up therewith his permit to the Commissioner of Health and the Commissioner of Health 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 Commissioner of Health, 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 Commissioner of Health a detailer shall submit all records of samples received and delivered and shall make an account of those samples to the Commissioner of Health 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 September 1969 pp.2874-6; amended in Gazette 29 June 1984 p.1784; 12 April 1991 p.1608; 16 April 1992 p.1634; 7 August 1992 p.3865; 25 June 1993 pp.3079 and 3085; 26 May 1994 p.2201; 19 March 1996 p.1218.]

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 March 1996 p.1218.]

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 March 1996 p.1218.]

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 within the meaning of the *Hospitals and Health Services Act 1927*.

[Regulation 10A inserted in Gazette 14 June 1967 p.1582; amended in Gazette 19 March 1996 p.1219.]

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 August 1996 p.4089.]

11. Commissioner of Health may designate remote area nursing posts

(1) The Commissioner of Health may, in writing, designate a remote area site to be a remote area nursing post for the purposes of these regulations.

(2) The Commissioner of Health may amend or withdraw a designation under subregulation (1), in writing, at any time.

[Regulation 11 inserted in Gazette 24 June 1994 p.2865.]

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 Commissioner of Health an application in such form as may be approved by the Commissioner of Health 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 Commissioner of Health 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 March 1996 p.1219.]

12A. Approval of needle and syringe programme

(1) A person may apply to the Commissioner of Health 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 Commissioner of Health 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 Commissioner of Health;

(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 Commissioner of Health is not to approve a needle and syringe programme unless the Commissioner of Health 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 pp.2197-8.]

12B. Copy of approval to be provided

Where the Commissioner of Health approves a needle and syringe programme, the Commissioner of Health 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.]

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 Commissioner of Health before 30 June in each year an annual report on the needle and syringe programme; and

(d) report to the Commissioner of Health any irregularities that occur in the conduct of the programme.

[Regulation 12C inserted in Gazette 26 May 1994 p.2198.]

12D. Requirements relating to programme

(1) Where the Commissioner of Health approves a needle and syringe programme, the Commissioner of Health 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.]

12E. Direction to person

(1) Where the Commissioner of Health 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 Commissioner of Health 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.]

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 Commissioner of Health and the Commissioner of Police.

[Regulation 12F inserted in Gazette 26 May 1994 p.2199.]

Licences and permits — General conditions

*[**13, 14.** Repealed in Gazette 19 March 1996 p.1219.]*

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 Commissioner of Health.

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

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 November 1986 p.4270; 24 June 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 Commissioner of Health, 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 Commissioner of Health.

[Regulation 17 amended in Gazette 29 June 1984 p.1784; 25 June 1993 p.3085; 26 May 1994 p.2201.]

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.

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 November 1990 p.5791; amended in Gazette 24 June 1994 p.2865; 19 March 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 Commissioner of Health.

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

[Regulation 19AA inserted in Gazette 23 November 1990 p.5791; amended in Gazette 26 May 1994 p.2201; 19 March 1996 pp.1219-20.]

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 March 1996 p.1220.]

*[**20.** Repealed in Gazette 23 November 1990 p.5792.]*

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, 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, registered nurse at a remote area nursing post, or dentist;

(v) the name and address of the pharmacy, or medical or dental surgery, 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, registered nurse at a remote area nursing post, pharmaceutical chemist or dentist; and

(vii) the total quantity contained;

(b) a pharmaceutical chemist, medical 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 August 1992 pp.3865-6; amended in Gazette 24 June 1994 pp.2865-6; 19 March 1996 p.1220.]

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 July 1986 p.2339; amended in Gazette 19 March 1988 p.838; 24 June 1994 p.2866; 19 March 1996 p.1220.]

*[**22-24**. Repealed in Gazette 23 November 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 Commissioner of Health.

[Regulation 24A inserted in Gazette 17 August 1990 p.4081; amended in Gazette 26 May 1994 p.2201; 19 March 1996 p.1220.]

Containers and labels — General

25. Commissioner of Health may approve container or label

The Commissioner of Health 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 June 1984 p.1784; 25 June 1993 p.3085; 26 May 1994 p.2201.]

26. Commissioner of Health may suspend use of container or label

The Commissioner of Health 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 June 1984 p.1784; 25 June 1993 p.3085; 26 May 1994 p.2201.]

*[**27.** Repealed in Gazette 23 November 1990 p.5792.]*

*[**27AA, 27A.** Repealed in Gazette 24 June 1994 p.2866.]*

*[**28.** Repealed in Gazette 23 November 1990 p.5792.]*

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

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 August 1986 p.2739; 28 May 1993 p.2595; 19 March 1996 p.1220.]

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.

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 March 1996 p.1220.]

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 November 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 P 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 P of the SUSDP.

[Regulation 33B inserted in Gazette 12 April 1991 p.1608; amended in Gazette 24 June 1994 pp.2866-7; 16 September 1994 p.4748; 19 September 1995 p.4383.]

*[**34, 34A, 34B, 34C.** Repealed in Gazette 23 May 1986 p.1716.]*

*[**34D.** Repealed in Gazette 19 March 1996 p.1220.]*

Restrictions on retail sale of Schedule poisons

[Heading amended in Gazette 24 June 1994 p.2867.]

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 February 1985 p.521; amended in Gazette 19 March 1996 p.1220.]

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

[(1) repealed]

(1a) A substance included in Schedule 3 shall not be sold or supplied by retail except under the personal supervision of a pharmaceutical chemist.

(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.

(2) Before a substance referred to in Appendix J is delivered to a purchaser on a sale by retail, the pharmaceutical chemist or graduate trainee in pharmacy making the sale shall —

(a) record, in ink, in the prescription book referred to in regulation 36(3)(c), the following particulars —

(i) the date of sale;

(ii) the name and address of the purchaser and, where the person for whom the substance is intended is not the purchaser, the name and address of the person for whom the substance is intended; and

(iii) the name and quantity of the substance supplied,

and the entry in the prescription book shall be given a unique identification number or letter;

(b) label the product with —

(i) the name and address of the pharmacy; and

(ii) the unique identifying number or letter allocated in accordance with paragraph (a).

(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 November 1968 p.3458; amended in Gazette 20 September 1985 p.3743; 29 August 1990 p.3028; 30 November 1990 p.5908; 13 December 1991 p.6190; 19 March 1996 p.1221.]

*[**35AA.** Repealed in Gazette 11 April 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 August 1980 p.3028; amended in Gazette 19 March 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 September 1983 p.3803; amended in Gazette 2 October 1987 p.3776; 19 March 1996 p.1221; 27 November 1998 pp.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 February 1999 p.555.]

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 holder of a prescription written by a medical 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 Commissioner of Health; 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, 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 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 thereon, and on each occasion upon which it is dispensed the prescription shall be stamped or marked to show clearly the date upon which it is dispensed and the name and address of the pharmacy at which it is dispensed;

(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 thereon, shall write in ink, stamp or mark in legible letters across such prescription the word "cancelled";

(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 Commissioner of Health 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) marked "cancelled"; or

(ii) more than 12 months old;

(e) a prescription which is illegible or defaced 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 to whom a prescription referred to in paragraph (e) is presented shall retain the prescription and forthwith inform the Commissioner of Health of the relevant circumstances and the reasons for his refusal to dispense the prescription.

(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

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

[Regulation 36 amended in Gazette 19 February 1971 pp.518-19; 29 August 1980 p.3028; 29 June 1984 p.1784; 5 July 1985 p.2392; 7 August 1987 p.3038; 18 September 1987 p.3596; 2 June 1989 p.1603; 3 June 1990 p.2626; 16 April 1992 p.1634; 25 June 1993 p.3085; 26 May 1994 p.2201; 24 June 1994 p.2867; 19 March 1996 pp.1221-2.]

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 February 1999 pp.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

(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 February 1999 p.556.]

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 show in a clearly legible and indelible manner —

(i) the name and address of prescriber;

(ii) the name and address of the patient;

(b) subject to paragraph (ba) there shall be written in ink in the prescriber's own handwriting —

[(i) deleted]

(ii) the name and quantity of the substance;

(iii) direction for use, if necessary;

(iv) the date on which it is written;

(v) the maximum number of times it may be repeated, if any, and (where applicable) the intervals at which it may be repeated; and

(vi) the signature of the prescriber;

(ba) where a prescription is processed on a computer which —

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

(ii) is recommended by the Poisons Advisory Committee and approved in writing by the Executive Director, Public Health,

the prescription shall contain —

(iii) the information required under paragraph (b)(ii) to (v), in a form generated by the computer;

(iv) the endorsement "Issued under the *Poisons Regulations 1965* (Regulation 37(1)(ba))"; and

(v) the signature of the prescriber in his or her own handwriting;

(c) a prescription written by a dentist shall be for dental purposes only and shall be marked as such and a prescription written by a veterinary surgeon shall be for veterinary use only and shall be marked "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 underlining that part of the prescription and initialling the same in margin;

(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, dentist or veterinary surgeon by whom it has been written; and

(f) a prescription shall not be written in cipher.

(2) With the written approval of the Commissioner of Health a medical practitioner, dentist or veterinary surgeon may issue a typewritten prescription where the Commissioner of Health 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 37 inserted in Gazette 19 February 1971 p.519; amended in Gazette 21 November 1986 p.4269; 5 December 1986 p.4467; 17 August 1990 p.4081; 26 July 1991 p.3854; 7 August 1992 p.3869; 26 May 1994 p.2201; 19 March 1996 p.1222.]

38. Dispensing poisons included in Schedule 4 in emergency cases

Where a medical 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 March 1996 p.1222.]

*[**38A.** Repealed in Gazette 17 March 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 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 or a dentist.

(2) A medical 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 March 1996 p.1222.]

*[**38B.** Repealed in Gazette 24 June 1994 p.2867.]*

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 Commissioner of Health; 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 June 1994 p.2868; amended in Gazette 11 April 1997 p.1829.]

38D. Etretinate or acetretin

(1) Etretinate or acetretin or a substance containing etretinate or acetretin shall not be prescribed except by a physician or dermatologist.

(1a) Where etretinate or acetretin or a substance containing etretinate or acetretin is supplied in accordance with a prescription under subregulation (1) the supplier shall —

(a) when supplying the patient or the agent of the patient with the etretinate or acetretin or the substance containing etretinate or acetretin, provide that person with a leaflet approved by the Commissioner of Health setting out the hazards associated with the use of etretinate or acetretin; and

(b) ensure that the container in which the etretinate or acetretin or the substance containing etretinate or acetretin is supplied is labelled with a statement as follows —

"WARNING — CAUSES BIRTH DEFECTS".

(2) A physician or dermatologist who prescribes etretinate or acetretin or a substance containing etretinate or acetretin 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 February 1985 p.519; amended in Gazette 31 May 1985 p.1882; 23 May 1986 p.1716; 2 October 1987 p.3776; 27 May 1988 p.1770; 11 November 1988 p.4444; 2 June 1989 p.1603; 25 June 1993 p.3085; 26 May 1994 p.2201; 2 September 1994 p.4533; 11 April 1997 p.1829.]

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 Commissioner of Health.

[Regulation 38E inserted in Gazette 2 June 1989 p.1604; amended in Gazette 16 April 1992 p.1635; 25 June 1993 p.3085; 26 May 1994 p.2201; 11 April 1997 p.1830.]

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 —

(a) when supplying the isotretinoin or the substance containing isotretinoin to the patient or the agent of the patient, provide that person with a leaflet approved by the Commissioner of Health setting out the hazards associated with the use of isotretinoin; and

(b) ensure that the container in which the isotretinoin or the substance containing isotretinoin is supplied is labelled with a statement as follows —

"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 October 1987 p.3776; 27 May 1988 p.1770; 2 June 1989 p.1604; 25 June 1993 p.3085; 26 May 1994 p.2201; 11 April 1997 p.1830.]

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 —

(a) when supplying the thalidomide or the substance containing thalidomide to the patient or the agent of the patient provide that person with a leaflet approved by

the Commissioner of Health setting out the hazards associated with the use of thalidomide; and

(b) ensure that the container in which the thalidomide or the substance containing thalidomide is supplied is labelled "WARNING — CAUSES BIRTH DEFECTS DO NOT USE IF PREGNANT OR LIKELY TO BECOME PREGNANT".

(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 July 1991 p.3854; amended in Gazette 26 May 1994 p.2201; 19 March 1996 p.1223; 11 April 1997 p.1830.]

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 June 1989 p.1604; amended in Gazette 24 June 1994 p.2868; 11 April 1997 pp.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 Commissioner of Health; 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 June 1989 p.1604; amended in Gazette 11 April 1997 p.1831.]

*[**38J.** Repealed in Gazette 19 March 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 June 1989 p.1604; amended in Gazette 11 April 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 December 1991 p.6191; amended in Gazette 11 April 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 Commissioner of Health.

[Regulation 38M inserted in Gazette 24 June 1994 p.2868; amended in Gazette 19 March 1996 p.1223; 11 April 1997 p.1831; 27 November 1998 p.6344.]

38N. Nitrofuran derivatives

The nitrofuran 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

NITROFURAN DERIVATIVES
Furazolidone
Nifursol
Nitrofuran
Nitrofurantoin
Nitrofurazone.

[Regulation 38N inserted in Gazette 24 June 1994 p.2868; amended in Gazette 19 March 1996 p.1223; 11 April 1997 pp.1831-2.]

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 —

(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) repealed]

[Regulation 39 inserted in Gazette 26 August 1977 p.2966; amended in Gazette 2 October 1987 p.3776; 19 March 1996 pp.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 Commissioner of Health for, and at the discretion of the Commissioner of Health 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 October 1979 p.3085; amended in Gazette 29 June 1984 p.1784; 25 June 1993 p.3085; 26 May 1994 p.2201; 19 March 1996 p.1224.]

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

(1) The master of a ship 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 December 1993 p.6884; amended in Gazette 19 March 1996 p.1224.]

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;

(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 Commissioner of Health,

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 Commissioner of Health.

(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 to this subregulation, 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	

(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 October 1979 p.3085; 29 June 1984 p.1784; 8 February 1985 p.519; 8 June 1990 p.2627; 28 May 1993 p.2596; 25 June 1993 p.3085; 26 May 1994 p.2201; 19 March 1996 p.1225; 11 April 1997 p.1832.]

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 [3] (formerly regulation 41) inserted in Gazette 8 June 1990 p.2627; amended in Gazette 19 March 1996 p.1225.]

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

The Commissioner of Health 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 March 1996 pp.1225-6.]

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, occupation 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 and purpose 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; or

(b) in a form of electronic means.

(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 March 1996 p.1226.]

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 August 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 July 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 Commissioner of Health 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 December 1986 pp.4874-5; amended in Gazette 27 May 1988 p.1770; 25 June 1993 p.3085; 26 May 1994 p.2201; 19 March 1996 p.1226.]

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 June 1994 pp.2868-9; amended in Gazette 19 March 1996 p.1227.]

Drugs of addiction

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 Commissioner of Health 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 to whom a prescription for a poison included in Schedule 8 has been given 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 Commissioner of Health.

(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 February 1970 p.370; 29 June 1984 p.1784; 8 February 1985 p.520; 25 June 1993 p.3085; 26 May 1994 p.2201; 19 March 1996 p.1227; 27 November 1998 p.6344.]

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 Commissioner of Health, 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 Commissioner of Health.

[Regulation 43 amended in Gazette 29 June 1984 p.1784; 25 June 1993 p.3085; 26 May 1994 p.2201; 19 March 1996 p.1227.]

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

The Commissioner of Health 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 March 1996 pp.1227-8.]

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 October 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 November 1998 p.6344.]

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 from 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 wrote 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.

(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 February 2000 pp.992-3.]

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 from 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 October 1993 pp.5360-1; amended in Gazette 24 June 1994 p.2869; 19 September 1995 p.4383; 19 March 1996 p.1228; 29 February 2000 pp.993-4.]

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.

(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 Commissioner of Health.

(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 Commissioner for Health.

[Regulation 44B inserted in Gazette 29 February 2000 p.994.]

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 proof to the contrary that person is taken to have made the entry.

[Regulation 44C inserted in Gazette 29 February 2000 pp.994-5.]

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.

(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 Commissioner of Health in writing of the discrepancy.

[Regulation 45 amended in Gazette 29 June 1984 p.1784; 25 June 1993 p.3085; 26 May 1994 p.2201.]

*[**46.** Repealed in Gazette 29 February 2000 p.995.]*

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 Commissioner of Health 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 Commissioner of Health, surrender any records, registers, prescription books, invoices or other documents and stocks of drugs of addiction that are in his possession to the Commissioner of Health.

(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 Commissioner of Health 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 September 1983 p.3804; 29 June 1984 p.1784; 31 January 1986 p.332; 7 August 1987 p.3083; 25 June 1993 p.3085; 26 May 1994 p.2201; 19 March 1996 p.1229.]

48. Returns from manufacturers and wholesalers

(1) Every person who is licensed under regulation 4 shall complete and forward to the Commissioner of Health, every 7 days a form approved by the Commissioner of Health 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 Commissioner of Health 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 September 1983 p.3804; amended in Gazette 29 June 1984 p.1784; 25 June 1993 pp.3080 and 3085; 26 May 1994 p.2201; 19 March 1996 p.1229.]

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

(1) The master of a ship 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 Commissioner of Health or the officer in charge of the nearest police station.

[Regulation 49 inserted in Gazette 31 December 1993 pp.6884-5; amended in Gazette 26 May 1994 p.2201; 19 March 1996 p.1229.]

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 Commissioner of Health 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 June 1984 p.1784; 28 May 1993 p.2597; 25 June 1993 p.3085; 26 May 1994 p.2201; 19 March 1996 p.1230.]

51. Prescriptions

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

(a) the prescription shall bear on its face, legibly printed or written in ink the name and address of the prescriber;

(b) subject to paragraph (ba) the prescription shall bear on its face, legibly written in ink in the handwriting of the prescriber —

(i) the date when it is written;

(ii) the signature of the prescriber;

(iii) the name and full address of the patient or, in the case of a prescription for veterinary use, the name and full address of the person having the care of the animal for which it is intended;

(iv) the description and quantity of the poison or preparation containing the poison to be dispensed;

(v) adequate directions for use, including where applicable, the dose to be taken or administered;

(vi) where it is to be dispensed more than once, the maximum number of times it may be repeated and the intervals at which it may be dispensed;

(vii) the words 'for animal treatment only' if it is written by a veterinary surgeon;

(viii) the words 'for dental treatment only' if it is written by a dentist;

(ix) where it contains an unusual dose, an indication that such is intended, by underlining that part of the prescription and initialling the same in the margin;

(ba) where a prescription is processed on a computer which —

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

(ii) is recommended by the Poisons Advisory Committee and approved in writing by the Executive Director, Public Health,

the prescription shall contain —

(iii) the information required under paragraph (b)(i), (iii), (vii) and (viii) in a form generated by the computer;

(iv) the endorsement "Issued under the *Poisons Regulations 1965* (Regulation 51(1)(ba))"; and

(v) the signature of the prescriber in his or her own handwriting;

and

(c) the prescription shall not bear the impression of a rubber stamp or other such contrivance in lieu of the written signature of the medical practitioner, dentist or veterinary surgeon by whom it has been issued.

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

[Regulation 51 inserted in Gazette 23 September 1983 p.3804; amended in Gazette 29 June 1984 p.1784; 31 January 1986 p.332; 26 July 1991 p.3855; 25 June 1993 pp.3080 and 3085; 26 May 1994 p.2201; 19 March 1996 p.1230.]

51A. Definition of "drug addict"

For the purposes of regulations 51AA to 51G —

"drug addict" means a person who is —

(a) under a state of periodic or chronic intoxication produced by consumption of a drug of addiction or any substitute therefor;

(b) under a desire or craving to take a drug of addiction or any substitute therefor until he has so satisfied that desire or craving;

(c) under a psychic or physical dependence to take a drug of addiction or any substitute therefor; or

(d) listed in the register of information kept under the *Drugs of Addiction Notification Regulations 1980.*

[Regulation 51A inserted in Gazette 29 August 1980 p.3028; amended in Gazette 12 October 1984 p.3267; 12 April 1991 p.1608.]

51AA. Disclosure by drug addict to medical practitioner

A drug addict shall, 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 is a drug addict.

[Regulation 51AA inserted in Gazette 12 October 1984 p.3267; amended in Gazette 11 April 1997 p.1832.]

51B. Drug addicts: medical practitioner or dentist not to prescribe or supply drugs of addiction without written authorisation

(1) A medical practitioner or dentist shall not write, issue or authorise a prescription or document prescribing the use, sale or supply of a drug of addiction, or supply a drug of addiction, for the treatment of a person —

(a) who is a drug addict; or

(b) who has been named as a drug addict by the Commissioner of Health by notice forwarded to the medical practitioner or dentist,

unless the medical practitioner or dentist has first obtained written authorisation to do so from the Commissioner of Health.

(2) In this regulation —

"drug of addiction" includes methadone only if prescribed or supplied by a dentist.

[Regulation 51B inserted in Gazette 11 April 1997 p.1832.]

51C. Authorisation of Commissioner of Health required for medical practitioner to prescribe methadone for drug addict

A medical practitioner shall not write, issue or authorise a prescription or document prescribing the use, sale or supply of methadone, or supply methadone, for the treatment of a person who is —

(a) a drug addict; or

(b) a person who has been named as a drug addict by the Commissioner of Health by notice forwarded to the medical practitioner,

unless the medical practitioner has —

(c) notified the Commissioner of Health of the condition of health of that person in accordance with the *Drugs of Addiction Notification Regulations 1980* as in force under the *Health Act 1911* from time to time; and

(d) received written authorisation to do so from the Commissioner of Health.

[Regulation 51C inserted in Gazette 29 August 1980 p.3029; amended in Gazette 29 June 1984 p.1784; 25 June 1993 p.3085; 26 May 1994 p.2201; 11 April 1997 p.1832.]

51D. Assessment of drug addict for treatment purposes

(1) Before an authorisation is issued by the Commissioner of Health for the treatment of a drug addict with methadone the drug addict in relation to whom the treatment is to be authorised, prescribed or used shall be assessed for such treatment by —

(a) a medical practitioner approved by the Commissioner of Health;

[(b) and (c) deleted]

(d) a psychiatrist in the course of treating that drug addict at a psychiatric unit of a hospital that is approved of as a teaching hospital as defined in the *Hospitals and Health Services Act 1927*; or

(e) a medical officer attached to a regional hospital established under the *Hospitals and Health Services Act 1927* who is approved of by the Commissioner of Health.

(2) A person who makes an assessment for the purposes of subregulation (1) shall specify in the assessment —

(a) the maximum daily dose not to be exceeded in the treatment in relation to the drug addict with respect to whom the assessment is made; and

(b) the maximum period of the treatment,

and shall sign the assessment in his usual signature.

[Regulation 51D inserted in Gazette 29 August 1980 p.3029; amended in Gazette 29 June 1984 p.1784; 27 May 1988 p.1771; 12 April 1991 p.1609; 25 June 1993 p.3085; 26 May 1994 p.2201; 19 March 1996 p.1230; 29 February 2000 p.995.]

51E. Conditions on treatment of drug addict

(1) In an authorisation given with respect to the treatment of a particular drug addict with methadone the Commissioner of Health 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 treatment administered by, a specified medical practitioner;

(b) that the type of methadone prescribed or administered be of the type specified;

(c) that the amount to be prescribed or used for treatment shall not exceed the amount specified;

(d) that the amount to be prescribed or used on any one day shall not exceed the amount specified;

(e) that the concentration to be prescribed or used shall not exceed the concentration specified;

(f) that the intervals between the issue of prescriptions or the administration of the treatment shall be such as are specified;

(g) that the prescription be supplied at the pharmacy or institution specified;

(h) that the amount dispensed on a single prescription form shall not exceed such amount as is specified;

(i) the amount that may be supplied on any one day shall not exceed such amount as is specified.

(2) Subject to subregulation (3) an authorisation under subregulation (1) is valid for a period of 12 months from the date of its issue or such earlier date (if any) as is specified.

(3) The Commissioner of Health may at any time revoke an authorisation or if the period has not expired vary the period for which the authorisation is valid.

(4) A medical practitioner shall not write, issue or authorise a prescription or document prescribing the use, sale or supply of methadone or supply methadone contrary to such conditions and restrictions as are specified.

(5) A pharmaceutical chemist shall not sell or supply methadone otherwise than in accordance with such conditions and restrictions as are specified.

(6) An authorisation issued under these regulations prior to 1 October 1980 is valid until it is revoked by the Commissioner of Health or until it expires whichever first occurs.

[Regulation 51E inserted in Gazette 29 August 1980 p.3029; amended in Gazette 29 June 1984 p.1784; 12 April 1991 p.1609; 25 June 1993 p.3085; 26 May 1994 p.2201; 19 March 1996 p.1230.]

51F. Treatment not to exceed 60 days unless authorised by Commissioner of Health

(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 Commissioner of Health.

(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 Commissioner of Health; or

(b) the Commissioner of Health 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 for the treatment of a person or

supply methadone 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 Commissioner of Health 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 Commissioner of Health 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 Commissioner of Health or until it expires whichever first occurs.

[Regulation 51F inserted in Gazette 3 February 1995 pp.342-3; amended in Gazette 19 March 1996 pp.1230-1; 11 April 1997 p.1833.]

51G. Medical practitioner not to supply certain drugs

(1) Notwithstanding regulations 51B to 51F, a medical practitioner shall neither supply any of the following substances nor issue, write or authorise a prescription for any of the following substances —

(a) amphetamine;

(b) dexamphetamine;

(c) methylamphetamine;

(d) methylphenidate;

(e) phenmetrazine;

(f) the salts of any of those poisons included in Schedule 8; or

(g) a preparation or admixture containing any of those poisons included in Schedule 8 or their salts,

unless subregulation (2) applies or he is authorised under subregulation (3) or, in the case of methylphenidate, subregulation (4).

(2) Subregulation (1) does not apply to the oral use of dexamphetamine or methylphenidate for therapeutic trials of up to 30 days when these are initiated by a paediatrician, paediatric neurologist, or paediatric psychiatrist.

(3) The Commissioner of Health may authorise a medical practitioner to supply any substance referred to in subregulation (1) or to issue, write or authorise a prescription for any such substance to treat a person who has —

(a) narcolepsy;

(b) brain damage;

(c) in the case of a person who is less than 18 years of age, a behavioural disorder;

(d) depression where the patient is either medically ill or elderly and —

(i) is unresponsive to; or

(ii) unable to tolerate,

standard treatments or other antidepressant drugs where treatment with the substance has been recommended by a psychiatrist;

(e) depression that has been —

(i) well-documented; and

(ii) resistant to a series of standard treatment courses,

where treatment with the substance has been recommended by a psychiatrist;

(f) depression where the patient is terminally ill and —

(i) is unresponsive to; or

(ii) unable to tolerate,

standard treatments or other antidepressant drugs where treatment with the substance is for no more than 30 days; or

(g) in the case of a person of 18 years of age or more, attention deficit disorder where treatment with the substance has been assessed and recommended in accordance with guidelines approved by the Commissioner of Health.

(4) The Commissioner of Health may authorise a medical practitioner to supply methylphenidate or to issue, write or authorise a prescription for methylphenidate for the continued treatment of a person who, before the coming into operation of this regulation, had been approved by the department to be treated with methylphenidate.

(5) The Commissioner of Health may revoke or amend an authority granted under subregulation (3) or (4).

[Regulation 51G inserted in Gazette 12 April 1991 p.1609; amended in Gazette 16 April 1992 p.1635; 25 June 1993 pp.3080 and 3085; 26 May 1994 p.2201; 3 February 1995 p.343; 19 March 1996 p.1231.]

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 September 1995 p.4384.]

51GB. Supply of flunitrazepam

(1) Notwithstanding regulations 51B to 51F, 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 Commissioner of Health.

(2) The Commissioner of Health shall give the authorisation an identifying number (in this regulation called **"the HDWA Authorisation No."**).

(3) In an authorisation given under subregulation (1), the Commissioner of Health 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 Commissioner of Health unless revoked by the Commissioner, by notice in writing served on the practitioner, before the expiration of that period.

(5) The Commissioner of Health 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.]

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 Commissioner of Health.

(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 April 1997 p.1833.]

*[**51J.** Repealed in Gazette 12 April 1991 p.1609.]*

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 persons dispensing prescriptions referred to in this regulation —

(a) the person to whom a prescription is submitted for dispensing shall satisfy himself —

(i) that the prescription is in accordance with the requirements of the Act; and

(ii) that the person who signed the prescription is a medical practitioner, a dentist or a veterinary surgeon duly registered within the State;

(b) the prescription shall not be dispensed more than the maximum number of times indicated thereon, or at intervals less than those indicated therein, and on each occasion at the time at which it is dispensed it shall be marked in ink, by writing in the hand of the dispensing pharmacist, to show clearly his usual signature, the date upon which it is dispensed, and marked or stamped with the name and address of the pharmacy at which it is dispensed;

(c) a prescription written by a veterinary surgeon shall be dispensed once only;

(d) a prescription shall be dispensed once only where the prescription directs the dispensing of 2 or more items as separate articles;

(e) subject to subregulation (7) —

(i) where a prescription is produced to him and the prescription prescribes no more than one occasion on which it is to be dispensed, the person dispensing the prescription shall retain the prescription in safe custody after having dispensed it;

(ii) where a prescription is produced to him and the prescription prescribes more than one occasion on which it is to be dispensed, the person dispensing the prescription shall, after having dispensed it as directed in the prescription, mark the prescription with the number of occasions remaining to be dispensed and return it to the person producing it but if there remain no more occasions on which it is to be dispensed shall, after having dispensed it as directed in the

prescription, retain the prescription in safe custody;

(f) the person who dispenses a prescription which does not clearly indicate the maximum number of times such prescription is to be dispensed or the intervals at which it is to be repeated, or which has reached the last occasion upon which it can be lawfully dispensed according to the maximum indicated thereon, shall write in ink, stamp, or mark in legible letters across such prescription the word "cancelled";

(g) the person who dispenses a prescription 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, details of the transaction, including —

(i) prescription number;

(ii) name and address of patient;

(iii) poison description;

(iv) quantity of the poison;

(v) directions for use;

(vi) date of the prescription; and

(vii) the name and address of the person who wrote the prescription,

shall be recorded in the manner prescribed by regulation 52B;

[(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.

(4) A prescription marked "cancelled" or that is more than 6 months old shall not be dispensed.

(5) A prescription which is illegible or defaced or which appears to be for the purpose of enabling some unauthorised person to obtain a drug of addiction, or which does not appear to be genuine, shall not be dispensed.

(6) A pharmaceutical chemist shall retain possession of any prescription prescribing a drug of addiction presented to him for dispensing and which he suspects of being false in any particular and hold the prescription for such reasonable period as will enable him to satisfy himself as to its genuineness and make enquiries concerning the bona fides of the person by whom it is presented or the identity of the individual by whom such prescription purports to have been written.

(6a) When a pharmaceutical chemist to whom a prescription is submitted for dispensing is satisfied that the prescription is not in accordance with the requirements of the Act or regulations, he shall cancel it and endorse upon its face in ink in his own handwriting the date and his usual signature, together with the address of the dispensary either stamped or written and forward it to the Commissioner of Health and inform the Commissioner of Health of the relevant circumstances and the reasons for his refusal to dispense the prescription.

[(7) repealed]

(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 August 1980 p.3031; 23 September 1983 pp.3805-6; 29 June 1984 p.1784; 31 January 1986 pp.332-3; 7 August 1987 p.3038; 25 June 1993 p.3085; 26 May 1994 p.2201; 17 March 1995 p.1026; 19 March 1996 p.1231; 29 February 2000 p.995.]

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 January 1986 p.333; amended in Gazette 7 August 1987 p.3083; 19 March 1996 p.1231.]

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 Commissioner of Health; or

(b) entered in a computerised recording system approved by the Commissioner of Health.

(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 August 1987 p.3083; amended in Gazette 25 June 1993 p.3085; 26 May 1994 p.2201; 19 March 1996 p.1231.]

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 August 1987 p.3083.]

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

(1) Where a medical 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 8, he shall forthwith write a prescription complying with the conditions prescribed in regulation 51 mark such prescription so as to show clearly that it is in confirmation of the directions given by him orally or by telephone or telegram, and dispatch such prescription within 24 hours to the person by whom the poison included in Schedule 8 was dispensed.

(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 him within 72 hours, immediately report the circumstances to the Commissioner of Health.

[Regulation 53 amended in Gazette 23 September 1983 p.3806; 27 May 1988 p.1771; 25 June 1993 p.3085; 26 May 1994 p.2201; 19 March 1996 p.1232.]

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,

Dextromoramide
Flunitrazepam
Hydromorphone
Methadone
Morphine
Pethidine

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 is familiar with the prescriber's handwriting; or

(b) he has verified with the purported prescriber that the prescription was written by him.

(2) Where a person cannot comply with subregulation (1), for good cause, he 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 September 1983 p.3806; amended in Gazette 19 March 1996 p.1232; 26 May 1998 p.2967.]

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 Commissioner of Health 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 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 September 1983 p.3807; 2 June 1989 p.1605; 25 June 1993 p.3085; 26 May 1994 p.2201; 19 March 1996 p.1232.]

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 September 1983 p.3807; amended in Gazette 19 March 1996 p.1232.]

55. Common carrier protected

A common carrier or his 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.

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 Commissioner of Health to store a drug of addiction in a manner and with such security arrangements as are specified by the Commissioner of Health 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 June 1993 p.3081; amended in Gazette 26 May 1994 p.2201; 24 June 1994 p.2869; 19 March 1996 pp.1232-3.]

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) 1 litre or less of methadone syrup that has been supplied by the Western Australian Alcohol and Drug Authority established under the *Alcohol and Drug Authority Act 1974*; or

(b) a suppository,

shall not be included in the assessment of the amount under subregulation (1).

[Regulation 56A inserted in Gazette 25 June 1993 p.3082; amended in Gazette 19 March 1996 p.1233.]

*[**56AA.** Repealed in Gazette 25 June 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 June 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 Commissioner of Health to have possession of the key.

[Regulation 56C inserted in Gazette 25 June 1993 p.3082; amended in Gazette 26 May 1994 p.2201.]

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 June 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 June 1993 p.3083; amended in Gazette 19 March 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 June 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 June 1993 p.3083; amended in Gazette 19 March 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 June 1993 p.3083; amended in Gazette 19 March 1996 p.1234; 27 November 1998 p.6344.]

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.

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 September 1983 p.3807; 20 March 1987 p.954.]

Miscellaneous

[Heading inserted in Gazette 17 March 1995 p.1026.]

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

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

[Regulation 59 inserted in Gazette 29 August 1980 p.3031; amended in Gazette 29 June 1984 p.1784; 25 June 1993 p.3085; 26 May 1994 p.2201.]

60. Appeals

(1) Any person desirous of appealing under the provisions of section 29 of the Act shall lodge with the clerk of petty sessions of the court of petty sessions held nearest to the place of business of the appellant notice of appeal in the Form 12 in Appendix A.

(2) A copy of the notice shall be served on the Commissioner of Health within 7 days after lodging the notice with the clerk of petty sessions.

(3) On proof by affidavit to the satisfaction of the magistrate that the notice has been duly served, the magistrate shall cause to be sent to the parties written notice of a date and time for the hearing of the appeal, which date shall not be less than 14 clear days from the service of the notice.

[Regulation 60 amended in Gazette 29 June 1984 p.1784; 25 June 1993 p.3085; 26 May 1994 p.2201.]

61. Parties to appeal failing to attend

If either party to the appeal neglects to appear personally or by counsel or solicitor on the date and at the time fixed for hearing, the magistrate may —

(a) where the appellant fails to appear, dismiss the appeal;

(b) where the Commissioner of Health fails to appear, hear the appeal or adjourn it to some other date.

[Regulation 61 amended in Gazette 29 June 1984 p.1784; 25 June 1993 p.3085; 26 May 1994 p.2201.]

62. Costs of appeal

On the hearing and determination of the appeal the magistrate may make such order as to costs to be paid by either party to the appeal as he may think just.

63. Rules of evidence to apply at appeal

On the hearing of the appeal, it shall proceed according to the procedure and rules of evidence applicable in the court of petty sessions.

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 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 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 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 in respect of a patient in a public hospital (as defined in the *Hospitals and Health Services Act 1927*) 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 March 1995 pp.1026-7; amended in Gazette 19 March 1996 p.1234.]

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 March 1996 p.1234.]

Appendix A

Form 1

Poisons Act 1964

LICENCE TO PROCURE, MANUFACTURE AND SUPPLY POISONS (OTHER THAN POISONS INCLUDED IN SCHEDULE 8) BY WHOLESALE DEALING

This licence is granted to ..... and authorises that person to procure, manufacture and supply by wholesale dealing on behalf of ..... the poisons included in Schedules *1, 2, 3, 4, or 7 to the *Poisons Act 1964*.

Subject to the following conditions —

1. The poisons will be manufactured at premises situated at ....
   (a) under the personal supervision of ..... who holds the qualification ..... (or)
   (b) under the direction of ..... who holds the qualification ..... and under the personal supervision of ..... who is an experienced person within the meaning of the regulations (or)
   (c) ....
2. The poisons will be supplied from premises situated at ....
   (a) under the personal supervision of ..... who holds the qualification ..... (or)
   (b) under the direction of ..... who holds the qualification ..... and under the personal supervision of ..... who is an experienced person within the meaning of the regulations (or)
   (c) ....

3. (a) .....

(b) .....

Dated at Perth ..... 19.....

Valid until 30 June 19.....

.....

* Strike out whichever is not applicable.

[Form 1A deleted]

Form 2

Poisons Act 1964

LICENCE TO PROCURE, MANUFACTURE AND SUPPLY BY WHOLESALE DEALING POISONS INCLUDED IN SCHEDULE 8

This licence is granted to ..... and authorises that person to procure, manufacture and supply by wholesale dealing on behalf of ..... the following poisons included in Schedule 8 ....

Subject to the following conditions —

1. The poisons included in Schedule 8 will be manufactured at premises situated at ....
   (a) under the personal supervision of ..... who holds the qualification ..... (or)
   (b) under the direction of ..... who holds the qualification ..... and under the personal supervision of ..... who is an experienced person within the meaning of the regulations.
2. The poisons included in Schedule 8 will be supplied from premises situated at ....
   (a) under the personal supervision of ..... who holds the qualification ..... (or)
   (b) under the direction of ..... who holds the qualification ..... and under the personal supervision of ..... who is an experienced person within the meaning of the regulations.
3. (a) .....
   (b) .....

Dated at Perth ..... 19.....

Valid until 30 June 19.....

.....

[Form 2A deleted]

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 ..... 19.....
Valid until 30 June 19.....

.....

[Forms 3A, 4 and 4A deleted]

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 ..... 19.....

Valid until 30 June 19.....

.....

[Form 5A deleted]

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 ..... 19.....

Valid until 30 June 19.....

.....

———————

[Form 6A deleted]

Appendix A

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 Perth .....19.....

Valid until 30 June 19.....

.....

[Form 6C deleted]

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 ..... 19.....

Valid until 30 June 19.....

.....

[Form 7A deleted]

Form 8

Poisons Act 1964

POISONS PERMIT (EDUCATIONAL, RESEARCH OR 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 ..... 19.....

Valid until 30 June 19.....

.....
Commissioner of Health

———————

[Forms 8A, 9, 9A, 10, 11, 11A deleted]

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 ..... 19.....

Valid until 30 June 19 .....

.....

[Form 11AB deleted]

Appendix A

Form 12

Poisons Act 1964

NOTICE OF APPEAL UNDER SECTION 29

IN the court of petty sessions

at .....

BETWEEN

..... Appellant

and

..... Respondent

TAKE NOTICE that pursuant to the provisions of section 29 of the *Poisons Act 1964*, I intend to appeal to the magistrate of the abovenamed court against your (a) .....on the ..... day of ..... 19.....
(b) .....
.....
.....

Dated this ..... day of ..... 19.....

.....
Appellant

To the Commissioner of Health

And to .....

(a) State whether refusal, cancellation, order, etc.

(b) Set out particulars of the decision from which you are appealing.

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 ..... 19.....

Valid until 30 June 19.....

.....
Commissioner of Health

Appendix A

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 19.....

.....
Commissioner of Health

[* delete if not applicable]

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

Appendix A

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 of .....am 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.

[Appendix A amended in Gazette 14 June 1967 pp.1582-3; 22 September 1969 p.2876; 3 May 1974 p.1435; 5 October 1979 pp.3085-6; 7 June 1985 p.1941; 23 May 1986 p.1716; 15 May 1987 p.2121; 2 October 1987 p.3776; 27 May 1988 p.1771; 2 June 1989 p.1605; 17 August 1990 p.4081; 12 April 1991 p.1609; 14 June 1991 p.2879; 16 April 1992 p.1635; 25 June 1993 p.3085; 26 May 1994 pp.2200 and 2201; 24 June 1994 p.2869; 16 September 1994 pp.4748-9; 27 June 1995 p.2550; 19 March 1996 pp.1234-8; 23 August 1996 p.4089.]

[Appendix B repealed in Gazette 1 October 1993 p.5361.]

[Appendices C, D, E repealed in Gazette 11 November 1988 p.4444.]

[Appendix F repealed in Gazette 1 August 1986 p.2739.]

Appendix G

(reg 12)

Form No.	*Description of Licence or Permit*	*Initial Fee (1 year) $*	*Initial Fee (3 years) $*	*Renewal (1 year) $*	*Renewal (3 years) $*
1.	Licence to procure, manufacture and supply poisons (other than poisons included in Schedule 8) by wholesale dealing	600	850	175	425
2.	Licence to procure, manufacture and supply by wholesale dealing poisons included in Schedule 8 ...	600	850	175	425
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 *Poisons Act 1964*	100	150	50	100
6.	Licence to sell by retail, poisons included in Schedule 7 to the *Poisons Act 1964*	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 (Research or health services)	100	150	50	100
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 March 1996 pp.1238-9; amended in Gazette 11 April 1997 pp.1833-4.]

Appendix H

SCHEDULE 4 SUBSTANCES REFERRED TO IN REGULATION 39(1)

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 February 1985 p.520; (erratum in Gazette 19 April 1985 p.1409); amended in Gazette 19 March 1996 p.1239.]

[Appendix I repealed in Gazette 23 May 1986 p.1720.]

Appendix J

(reg. 35A)

SCHEDULE 3 POISON SALES TO BE RECORDED

HYDROCORTISONE, when included in Schedule 3;

HYDROCORTISONE ACETATE, when included in Schedule 3.

NICOTINE, when included in Schedule 3.

[Appendix J inserted in Gazette 20 September 1985 p.3743; amended in Gazette 23 May 1986 p.1721; 23 January 1987 p.187; 7 August 1987 p.3084; 27 May 1988 p.1771; 9 December 1988 p.4825; 30 November 1990 p.5908; 26 July 1991 p.3855; 13 December 1991 p.6191; 28 May 1993 p.2597; 16 September 1994 p.4749; 3 February 1995 p.343; 19 March 1996 p.1239.]

[Appendix K deleted in Gazette 19 March 1996 p.1239.]

Appendix L

(Regulations 37 and 51)

SPECIFIED CRITERIA FOR THE GENERATION OF PRESCRIPTIONS BY COMPUTER

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.
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.

[Appendix L inserted in Gazette 26 July 1991 p.3855; amended in Gazette 19 March 1996 p.1239.]

Appendix M

[Regulations 56(1) and (2)]

SAFES AND ADDITIONAL SECURITY FOR STORING DRUGS OF ADDICTION

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.

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 Australia 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.

[Appendix M inserted in Gazette 25 June 1993 pp.3084-5; amended in Gazette 24 June 1994 p.2870; 19 March 1996 p.1239.]

Notes

[1] This reprint is a compilation as at 12 May 2000 of the *Poisons Regulations 1965* and includes the amendments included in the reprint as at 4 November 1996 and the amendments effected by the other regulations referred to in the following Table.

Table of Regulations

Citation	Gazettal	Commencement	Miscellaneous
Poisons Act Regulations 1965	29 June 1965 pp.1883-914	1 July 1965	Short title subsequently amended (see note under regulation 1)
(Regulations effecting amendments in the previous reprint are not referred to in this Table)			Previous reprint as at 4 November 1996
Poisons Amendment Regulations 1997	11 April 1997 pp.1828-34	11 April 1997	
Poisons Amendment Regulations 1998	17 March 1998 p.1417	17 March 1998	
Poisons Amendment Regulations (No. 2) 1998	26 May 1998 pp.2966-7	19 June 1998 (see regulation 2)	
Poisons Amendment Regulations (No. 3) 1998	27 November 1998 pp.6343-4	27 November 1998	
Poisons Amendment Regulations 1999	19 February 1999 pp.554-6	19 February 1999	
Poisons Amendment Regulations 2000	29 February 2000 pp.992-5	29 February 2000	

[2] Repealed by the *Mental Health Act 1981* (No. 51 of 1981) which was repealed by the *Mental Health Act 1996* (No. 69 of 1996).

[3] Renumbering of regulation 41 to regulation 40A effected by amendment in *Gazette* 19 March 1996 p.1225.

[4] Repealed by the *Security and Related Activities (Control) Act 1996* (No. 27 of 1996).

Defined Terms

[This is a list of terms defined and the provisions where they are defined. The list is not part of the law.]

Defined Term	Provision(s)
animal	2
approved name	35C(4), 64(1)
approved needle and syringe programme	2
Australian Register of Therapeutic Goods	35C(4), 64(1)
authorised person	44(1), 44C(1)
brand name	35C(4)
brand	64(1)
child	2
Commonwealth Schedule	51H(3)
coordinator	2
dermatologist	2
direction	2
director of nursing	2
dispense	2
distribute	2
distributor	2
dosage unit	2
drug addict	51A
drug of addiction	51B(2)
emergency supplies	36A(4)
entry	44C(1)
experienced person	2
external	2
gynaecologist	2
height	21A(4)
immediate container	2
immediate wrapper	2
manufacture	2
manufacturer	2
Medical Board	2
obstetrician	2
permit	2
personal supervision	2
physician	2
poisons cupboard	2
proprietary preparation	8A(16)
psychiatrist	2
qualified person	2
quarter	2

Defined Terms

By Authority: JOHN A. STRIJK, Government Printer