Western Australia

**Poisons Regulations 1965** 

# Western Australia

# **Poisons Regulations 1965**

# **Contents**

1.	Citation	2
2.	Interpretation	2
2AA.	Prescribed office (section 64B)	6
2A.	Exemptions	6
P	art 2 — Licences and permits	
	Division 1 — General	
3.	Wholesaler's licences and permits	8
5.	Pharmaceutical chemist's licence to sell poisons	9
7.	Retailer's licence to sell poisons specified in	
	Schedule 2 to the Act	9
8.	Retailer's licence to sell poisons included in	
	Schedule 7 to the Act	10
8A.	Poisons permit (Distribution of samples)	10
9.	Poisons permit (Industrial)	14
10.	Poisons permit (Educational, advisory or research)	14
10AA.	Poisons permit (Health services)	14
10A.	Poisons permit (Departmental and hospital)	15
10B.	Licence to cultivate prohibited plants	15
11.	Commissioner of Health may designate remote	
	area nursing posts	15
11 <b>A</b> .	Commissioner of Health may designate areas for	
	the purposes of section 23 of the Act	16
12.	Application for licence or permit (sections 24 and	
	25)	17
	Division 2 — Needle and syringe programme	
12A.	Approval of needle and syringe programme	17

As at 04 Apr 2006 Version 07-h0-04
Extract from www.slp.wa.gov.au, see that website for further information page i

# Contents

12B.	Copy of approval to be provided	18
12C.	Duties of coordinator	18
12D.	Requirements relating to programme	19
12E.	Direction to person	19
12F.	Requirements relating to used hypodermic needles	
	and syringes	20
	Division 3 — Restrictions and obligations	
15.	Restriction to issue of licence or permit	20
16.	Sale of poison only by licensee	20
17.	Licence or permit not transferable	21
18.	Licensee to display licence	21
I	Part 3 — Containers and labels	
	Division 1 — Containers	
19.	Adoption of SUSDP for containers and labels	22
19AA.	Certain containers prohibited	22
19A.	Food etc. containers to be distinguishable from	
	poison containers	23
	Division 2 — Labels	
21.	Labels on medicines or preparations	23
21A.	Appendix K container must have appropriate label	26
24A.	Carcinogenicity and teratogenicity warnings to be	27
	approved	21
2.5	Division 3 — General	
25.	Commissioner of Health may approve container or	27
26.	label Commissioner of Health may suspend use of	21
20.	container or label	27
_		27
ŀ	Part 4 — Storage, disposal and loss or	
	theft of poisons	
30.	Storage of substances other than those specified in	
	regulation 56	29
31.	Disposal of poisons	29
32.	Notification of loss or theft of poison	29
I	Part 5 — Sale, supply and use of	

poisons

		Contents
D	Division 1 — Restrictions	
33.	Poison not to be sold to persons under 16 years	30
33A.	Restrictions applying to veterinary preparations	30
33B.	Adoption of SUSDP for certain paints	30
35.	Restrictions on retail sale of substances included in	
	Schedule 2	31
35A.	Restrictions on retail sale of substances included in	
	Schedule 3	31
35B.	Storage of substances included in Schedule 3	33
35C.	Advertising of substances included in Schedule 3	33
35D.	Advertising of substances included in Schedule 4	34
D	Division 2 — Schedule 4 poisons	
	<del>-</del>	25
36.	Supply of poisons included in Schedule 4	35
36AA.	Provision of "approved starter packs" by registered	39
36A.	nurses Storage of substances included in Schodule 4	39 42
36A.	Storage of substances included in Schedule 4	42
30D.	Record of supply or administration of substances included in Schedule 4	44
37.	Conditions for prescription of a poison included in	44
37.	Schedule 4	44
38.	Dispensing poisons included in Schedule 4 in	44
36.	* * * * * *	46
38AA.	emergency cases Administration of poisons included in Schedule 4	40
JOAA.	in hospital	47
38C.	Clomiphene and cyclofenil	47
38D.	Etretinate or acitretin	48
38E.	Prostaglandins	49
38F.	Isotretinoin	49
38G.	Thalidomide for human use	50
38H.	Chloramphenicol	50
38I.	Follicular stimulating hormone and luteinising	20
501.	hormone	51
38K.	Carnidazole	51
38L.	Oxolinic acid	51
38M.	Clozapine	52
38N.	Nitrofuran derivatives	52
38O.	Bosentan for human use	53
38P.	Teriparatide for human use	53
39.	Veterinary use of poisons included in Schedule 4	54

As at 04 Apr 2006 Version 07-h0-04 Extract from www.slp.wa.gov.au, see that website for further information page iii

# Contents

39A.	Stockfeed manufacturers may sell poisons included in Schedule 4	54
39B.	Use of poisons included in Schedule 4 on ships and aircraft	55
39C.	Use of poisons included in Schedule 4 on ships carrying livestock	56
40.	Special authority to purchase poisons included in Schedule 4	58
40A.	Delivery of a poison included in Schedule 4 on order	59
D	vivision 3 — General	
41.	Revocation notice in relation to poisons included in Schedule 6	60
41A.	Sale of poisons included in Schedule 7	60
41AA.	Standard for intramammary antibiotic preparations	61
41AB.	Camphor and naphthalene	61
41B.	Record of poisons included in Schedule 3, 4 or 7	62
41C.	Access to poisons included in Schedule 7	62
P	art 6 — Drugs of addiction	
	Division 1 — General	
42A.	Interpretation	64
42.	Authority for prescribed persons to procure and	
	have poisons included in Schedule 8	64
43.	Authority for pharmacists to retail, compound and	
	dispense poisons included in Schedule 8	66
43A.	Revocation notice in relation to poisons included in	
	Schedule 8 and specified drugs	67
43B.	Prescribed purposes (section 41(1))	67
43C.	Advertising of substances included in Schedule 8	67
44.	Register of drugs of addiction	68
44A.	Destruction of drugs of addiction and poisons	<i>(</i> 0
44D	included in Schedule 8	69
44B.	Form of registers	71 72
44C. 45.	Control of access to electronic registers	
45. 47.	Inventory of drugs of addiction	73
4/.	Records to be retained for 7 years and available on	
	demand	7/
48.	demand Returns from manufacturers and wholesalers	74 75

		Contents
49.	Use of poisons included in Schedule 8 on ships and	<b>5.</b> 5
50	aircraft	75 77
50.	Used poisons included in Schedule 8 at hospitals	77
	Division 2 — Supply and prescription	
	Subdivision 1 — Prescriptions generally	
51.	Prescriptions	78
	Subdivision 2 — Supply and prescription to drug addicts	
51A.	Definition of "drug addict"	80
51AA.	Disclosure by drug addict to medical practitioner	80
51B.	Drug addicts: medical practitioner or dentist not to	
	prescribe or supply drugs of addiction without	
<b>.</b>	written authorisation	81
51C.	Authorisation of Commissioner of Health required	
	for medical practitioner to prescribe methadone or	0.1
51D.	buprenorphine for drug addict	81
51D. 51E.	Assessment of drug addict for treatment purposes	82 83
51E. 51F.	Conditions on treatment of drug addict Treatment not to exceed 60 days unless authorised	0.3
JII.	by Commissioner of Health	84
	•	04
	Subdivision 3 — Supply and prescription of certain substances	
51G.	Interpretation	87
	When a medical practitioner may supply or	07
	prescribe a stimulant	87
51GAB.	Authorisation to supply or prescribe a stimulant	88
	When an authorised practitioner may supply or	
	prescribe a stimulant	88
51GAD.	Treatment of attention deficit hyperactivity	
	disorder with a stimulant	89
	Dose for supply or prescription of a stimulant	90
51GAF.	Notification to Commissioner of Health of supply	0.0
<b>51010</b>	or prescription of a stimulant	90
51GAG.	Co-prescriber for supply or prescription of a	0.1
FICALL	stimulant	91
JIGAH.	Special authorisation to supply or prescription of a stimulant	92
51GAI.	Supply or prescription of a stimulant in a public	92
JIOAI.	hospital or prison	92
51GA.	Supply of dronabinol	92
JIGA.	Supply of dronaoinoi	92

As at 04 Apr 2006 Version 07-h0-04 Extract from www.slp.wa.gov.au, see that website for further information page v

# Contents

51GB.	Supply of flunitrazepam	93
51H.	Dentists not to prescribe or supply certain drugs of addiction	94
		94
<i>5</i> 0	Division 3 — Dispensing and delivery	0.5
52.	Dispensing drugs of addiction	95
52A.	Movement of drugs of addiction in other	100
52B.	circumstances Manner of recording details	100 100
52Б. 52С.	Manner of recording details Returns to department	100
52C. 53.	Dispensing poisons included in Schedule 8 in case	101
33.	of emergency	101
53A.	Dispensing certain poisons included in Schedule 8	101
54.	Delivery of poisons included in Schedule 8 on	102
51.	order	103
54A.	Packaging of drugs of addiction	104
55.	Common carrier protected	105
	Division 4 — Safe custody	
56.	Storing and securing drugs of addiction	105
56A.	Prescribed amount of poisons included in	103
0 01 1.	Schedule 8	107
56B.	Location of safe in premises	107
56C.	Authorised persons to keep keys to safes	108
56D.	Safes to be kept locked	108
56E.	Pharmacist present on premises	108
56F.	Keys to, and locking of, poisons cupboards and	
	lockable drawers	109
56G.	Poisons included in Schedule 8 in hospital ward	109
56H.	Keys to, and locking of, cupboards in hospital	
	wards	110
	Division 5 — Restrictions on supply	
57.	Labelling	110
58.	Improper prescribing or use of drugs of addiction	111
F	Part 7 — Miscellaneous provisions	
59.	Names of persons from whom licence or authority	
33.	withdrawn to be published	112
64.	Substitution of one brand of a drug for another	112
65.	Form of warrant (section 55A)	113
00.	Total of mariant (Section 2011)	115

Appendix A

Contents

136

	Appendix G	
	Appendix H	
	Appendix J	
	Appendix L	
	1. 2.	132 132
	Appendix M	
1. 2.	Safes Additional security requirements	134 135
	Notes	

Compilation table

As at 04 Apr 2006 Version 07-h0-04 Extract from www.slp.wa.gov.au, see that website for further information page vii

# Western Australia

Poisons Act 1964

# **Poisons Regulations 1965**

Preliminary

r. 1

# Part 1 — Preliminary

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

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

#### 1. Citation

These regulations may be cited as the *Poisons* Regulations 1965 <sup>1</sup>.

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

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

#### 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
  - to be in charge of a hospital; or
  - to a remote area nursing post;
- "dispense", in relation to a medicine or a poison —

Version 07-h0-04 As at 04 Apr 2006 page 2

- (a) means supply the medicine or poison on and in accordance with a prescription duly given by a medical practitioner, a nurse practitioner, a dentist or a veterinary surgeon; and
- in relation to a drug of addiction, has a meaning affected by regulation 42A;
- "distributor" means a person who imports, sells or otherwise supplies a poison;
- "dosage unit" means an individual dose of a poison and includes a tablet, capsule, cachet, single dose powder, or a single dose sachet of powders or granules;
- "experienced person" means a person who for at least 5 years has been employed in the manufacture, handling or selling of poisons;
- "external" in relation to the use of a poison, means application in the ears, eyes or nose, or to a body surface other than in the mouth, rectum, vagina, urethra or other body orifice;
- "gynaecologist" means a medical practitioner who has qualifications recognised by the Medical Board as appropriate to a specialist in gynaecology;
- "immediate container" includes any form of container in which a poison is directly packed, but does not include any such container intended for consumption or any immediate wrapper;
- "immediate wrapper" means metal foil, plastic foil, waxed paper, or any other such material not intended for consumption, when used as the first wrapper for a dosage unit or dressing;
- "manufacture" includes the processes of packing and repacking, refining manipulating and mixing any poison;
- "manufacturer" means a person who manufactures, produces, or packs a poison;
- "Medical Board" means the Medical Board established under section 4 of the Medical Act 1894;

- "obstetrician" means a medical practitioner who has qualifications recognised by the Medical Board as appropriate to a specialist in obstetrics;
- "permit" means a permit granted pursuant to the Act;
- "personal supervision" means close and continuous control requiring the actual presence of the person exercising the supervision;
- "physician" means a medical practitioner who has qualifications recognised by the Medical Board as appropriate to a specialist in general medicine;
- "poisons cupboard" means a substantially made cupboard provided with an effective locking device and, except in the case of a cupboard used for the storage of a drug of addiction, having the word "Poison" conspicuously painted on the outside of the cupboard;
- "prescribe", in relation to a drug of addiction, has a meaning affected by regulation 42A;
- **"psychiatrist"** means a medical practitioner whose name is contained in a register under section 89(1) of the *Mental Health Act 1962* <sup>2</sup>:
- "public hospital" means a public hospital as defined in section 2(1) of the *Hospitals and Health Services Act 1927*;
- "qualified person" means
  - (a) a medical practitioner, pharmaceutical chemist, dentist, veterinary surgeon;
  - (b) a person who is the holder of a degree approved by the 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

page 4 Version 07-h0-04 As at 04 Apr 2006

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, nurse practitioner or dentist, or by a registered nurse when acting under the direction of a medical practitioner, or the administration of any substance specified in any of the Schedules to the Act to an animal under the direct personal supervision or under the direction of a veterinary surgeon, shall not be deemed to be supplying within the meaning of these regulations;
- "SUSDP" has the meaning given in clause 1(1) of Appendix A to the Act:

### r. 2AA

"the Act" means the Poisons Act 1964.

[Regulation 2 amended in Gazette 23 Sep 1983 p. 3803; 29 Jun 1984 p. 1784; 28 Feb 1986 p. 618; 5 Dec 1986 p. 4467; 27 May 1988 p. 1769; 25 Aug 1989 p. 2842 (as amended in Gazette 6 Oct 1989 p. 3738); 8 Jun 1990 p. 2626; 23 Nov 1990 p. 5791; 12 Apr 1991 p. 1608; 7 Aug 1992 p. 3868; 25 Jun 1993 p. 3078-9; 26 May 1994 p. 2197; 24 Jun 1994 p. 2865; 2 Sep 1994 p. 4533; 23 Dec 1994 p. 7076; 28 Apr 1995 p. 1466; 28 Apr 1995 p. 1466-7; 5 Sep 1995 p. 4162; 19 Sep 1995 p. 4383; 17 Jan 1996 p. 267; 19 Mar 1996 p. 1216-17; 11 Apr 1997 p. 1829; 27 Nov 1998 p. 6343; by No. 9 of 2003 s. 41; 12 Aug 2003 p. 3658; 15 Nov 2005 p. 5603.1

#### Prescribed office (section 64B) 2AA.

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

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

#### 2A. **Exemptions**

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

- 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;
- poisons in a product listed in Appendix A to the SUSDP; (b)
- (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,

Version 07-h0-04 As at 04 Apr 2006 page 6

Second or Third Schedule of Appendix I to the SUSDP, if—

- the proportion of the poison is less than the (i) proportion specified in those schedules; or
- the proportion of the poison is within the limits (ii) specified in those schedules and the container is labelled in accordance with the provisions of Part 2 of the SUSDP.

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

r. 3

# Part 2 — Licences and permits

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

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

### Division 1 — General

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

#### **3.** Wholesaler's licences and permits

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

**Division 1** 

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

In this regulation — (6)

"specified" means specified in a wholesaler's licence.

[Regulation 3 inserted in Gazette 14 Sep 2001 <sup>3</sup> p. 5073-4.]

**[4.** Repealed in Gazette 14 Sep 2001 p. 5073.]

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

#### Pharmaceutical chemist's licence to sell poisons **5.**

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

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

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

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

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

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

[Regulation 7 amended in Gazette 23 May 1986 p. 1716; 19 Mar 1996 p. 1217.1

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

r. 8

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

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

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

#### 8A. **Poisons permit (Distribution of samples)**

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

and the holder of a permit shall, for the purposes of these regulations, be known as a detailer.

A permit under this regulation shall contain the name and (3) address of the detailer and the name of each manufacturer or wholesale supplier whom he represents.

Version 07-h0-04 As at 04 Apr 2006 page 10

- Where a detailer ceases to represent a manufacturer or (4) wholesale supplier named in his permit
  - 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;
  - the detailer shall return to the manufacturer or wholesale (b) 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
  - 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.
- A detailer shall not supply a sample to any person who is not (5)
  - a medical practitioner; (a)
  - (b) a veterinary surgeon;
  - (c) a dentist; or
  - a pharmacist.
- (6) A detailer shall not procure, carry or supply a sample
  - in the case of an oral contraceptive, for more than 2 months use: or
  - 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.

- r. 8A
  - (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
  - more than 100 samples of any single proprietary preparation; or
  - samples of more than 5 different proprietary (b) preparations,

to be kept at that address at any one time.

- A detailer shall not supply a sample unless (13)
  - he has received a signed request from a person to whom he is authorised in accordance with subregulation (5) to supply the sample; and
  - immediately upon supplying the sample, he signs and (b) 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.
- Upon receiving a written request from the Commissioner of (15)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 the rapeutic use boxed or wrapped in a single sample package;
  - "sample" means a sample package containing a poison intended for the rapeutic use included in Schedule 2, 3 or 4.

**Division 1** General

r. 9

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

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

### 9. Poisons permit (Industrial)

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

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

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

### 10. Poisons permit (Educational, advisory or research)

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

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

### 10AA. Poisons permit (Health services)

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

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

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

#### 10A. Poisons permit (Departmental and hospital)

- This permit shall authorise the holder to purchase from a (1) 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.
- This permit may be granted only to (2)
  - a department or instrumentality of the State or of the Commonwealth: and
  - a public hospital. (b)

[Regulation 10A inserted in Gazette 14 Jun 1967 p. 1582; amended in Gazette 19 Mar 1996 p. 1219; 12 Aug 2003 p. 3658.7

#### 10B. Licence to cultivate prohibited plants

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

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

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

#### Commissioner of Health may designate remote area nursing 11. 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 Jun 1994 p. 2865.]

Version 07-h0-04 As at 04 Apr 2006 page 15 **Division 1** General

r. 11A

# 11A. Commissioner of Health may designate areas for the purposes of section 23 of the Act

- (1) The Commissioner of Health may, in writing, designate an area for the purposes of section 23(2)(e) of the Act.
- (2) The Commissioner of Health may amend or withdraw a designation under subregulation (1), in writing, at any time, subject to subregulation (4).
- (3) The Commissioner of Health may not designate an area under subsection (1) until after receiving
  - (a) written advice with respect to the proposal to designate the area from the officer of the department who is principally responsible for providing advice on matters related to nursing; and
  - (b) clinical protocols for the proposed area approved in writing by
    - (i) the officer referred to in paragraph (a);
    - (ii) the person holding or acting in the office of Executive Director, Personal Health Services in the department; and
    - (iii) the person holding or acting in the office known as Executive Director, Population Health, or if there is no such office at the relevant time, the office of Executive Director, Public Health and Scientific Support Services in the department.
- (4) The Commissioner of Health may not amend or withdraw a designation under this section until after receiving written advice with respect to the proposed action from the officer of the department who is principally responsible for providing advice on matters related to nursing.

[Regulation 11A inserted by No. 9 of 2003 s. 42.]

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

Division 2

#### **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.
- An applicant under this regulation must indicate in the (2) 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.
- The Commissioner of Health may only grant an application and (5) issue a licence or permit, or renew a licence or permit, if the application under this regulation is accompanied by the appropriate fee set out in Appendix G.

[Regulation 12 inserted in Gazette 19 Mar 1996 p. 1219.]

### Division 2 — Needle and syringe programme

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

#### 12A. Approval of needle and syringe programme

- A person may apply to the Commissioner of Health for the (1) approval of a needle and syringe programme.
- An application referred to in subregulation (1) shall (2)
  - be in the form of Form 14 in Appendix A; and
  - (b) nominate a person to be the coordinator of the programme.

Part 2 Licences and permits

**Division 2** Needle and syringe programme

r. 12B

- (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 p. 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 —

page 18 Version 07-h0-04 As at 04 Apr 2006

Division 2

- maintain a register of all persons who participate in the (a) 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;
- submit to the Commissioner of Health before 30 June in (c) each year an annual report on the needle and syringe programme; and
- report to the Commissioner of Health any irregularities (d) that occur in the conduct of the programme.

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

#### 12D. Requirements relating to programme

- Where the Commissioner of Health approves a needle and syringe (1) programme, the Commissioner of Health may specify in the approval a requirement that the programme only be conducted
  - at a specified place or specified places; or
  - between specified times. (b)
- (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.
- A person shall not contravene a direction under (2) subregulation (1).

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

Part 2 Licences and permits **Division 3** Restrictions and obligations

r. 12F

#### 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.
- For the purposes of subregulation (1), a hypodermic syringe or a (2) 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.]

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

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

### Division 3 — Restrictions and obligations

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

#### 15. Restriction to issue of licence or permit

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

[Regulation 15 amended in Gazette 29 Jun 1984 p. 1784; 25 Jun 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.

**Division 3** 

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

#### 17. Licence or permit not transferable

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

### Provided that —

- a 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;
- the holder of a licence or permit who ceases to carry on (b) 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 Jun 1984 p. 1784; 25 Jun 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.

r. 19

### Part 3 — Containers and labels

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

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

### **Division 1 — Containers**

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

### 19. Adoption of SUSDP for containers and labels

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

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

### 19AA. Certain containers prohibited

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

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 Nov 1990 p. 5791; amended in Gazette 26 May 1994 p. 2201; 19 Mar 1996 p. 1219-20.7

#### 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 —

- 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
- of a like description to that prescribed for a container in (b) which a poison intended for external use may be sold.

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

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

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

### **Division 2 — Labels**

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

#### 21. Labels on medicines or preparations

- (1) Notwithstanding regulation 19, a medicine or preparation containing any poison dispensed or supplied in the course of the professional practice of
  - a pharmaceutical chemist, medical practitioner, nurse practitioner, registered nurse at a remote area nursing post, or dentist, for human internal use shall comply

Version 07-h0-04 As at 04 Apr 2006 page 23 r. 21

with that regulation if it is labelled in the English language with —

- (i) the words "Keep out of reach of children";
- (ii) the name and strength or amount of each poison in the preparation, or the trade name and strength of the preparation (unless the trade name also uniquely identifies the strength, in which case only the trade name need be given);
- (iii) the name of the patient;
- (iv) a date of dispensing or supply, and a number identifying the prescription or supply which corresponds to
  - (I) the entry in the Prescription Book referred to in regulation 36(3)(c), in the case of a pharmaceutical chemist; or
  - (II) the patient's records, in the case of a medical practitioner, nurse practitioner, registered nurse at a remote area nursing post, or dentist;
- (v) the name and address of the pharmacy, or medical or dental surgery, or area designated under section 23(2)(e) of the Act, or remote area nursing post, from which it is supplied;
- (vi) the instructions given on the prescription, if dispensed by a pharmaceutical chemist, or directions for use, if supplied by a medical practitioner, nurse practitioner, registered nurse at a remote area nursing post, pharmaceutical chemist or dentist; and
- (vii) the total quantity contained;
- (b) a pharmaceutical chemist, medical practitioner, nurse practitioner, registered nurse at a remote area nursing post or dentist, for human external use shall comply with that regulation if it is labelled in accordance with

page 24 Version 07-h0-04 As at 04 Apr 2006

- 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
  - 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);
  - the owner's surname and the species of animal; (iii)
  - instructions for the use of that medicine or (iv) preparation;
  - (v) a date of dispensing, and a number identifying the prescription or supply which corresponds to
    - the entry in the Prescription Book referred to in regulation 36(3)(c), in the case of a pharmaceutical chemist; or
    - the patient's records, in the case of a (II)veterinary surgeon;
  - (vi) the name and address of the pharmacy, or veterinary practice, from which it is supplied;
  - the words "For veterinary use only" or "For (vii) animal treatment only", together with the words "For external use only" if the medicine or preparation is not prepared for internal use; and
  - the total quantity contained. (viii)
- (2) Subregulations (1)(a) and (b) do not apply to a medicine or preparation (containing a poison) labelled in accordance with regulation 19, if it is supplied by a medical practitioner for the purposes of therapeutic treatment of a patient over a period of not more than 3 days.

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

### 21A. Appendix K container must have appropriate label

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

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

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

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

"height" means the height of capital letters or lower case letters having an ascender or a descender.

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

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

#### 24A. Carcinogenicity and teratogenicity warnings to be approved

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

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

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

### Division 3 — General

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

#### 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 Jun 1984 p. 1784; 25 Jun 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 Jun 1984 p. 1784; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201.]

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

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

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

# Poisons Regulations 1965

Part 3 Containers and labels

**Division 3** General

r. 26

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

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

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

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

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

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

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

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

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

#### 31. Disposal of poisons

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

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

#### 32. Notification of loss or theft of poison

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

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

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

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

### **Division 1** — Restrictions

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

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

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

### 33A. Restrictions applying to veterinary preparations

A person shall not —

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

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

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

### 33B. Adoption of SUSDP for certain paints

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

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

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

*[34.* Repealed in Gazette 23 May 1986 p. 1716.]

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

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

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

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

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

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

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

on the premises where it is stored.

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

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

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

- $\int (1)$ repealed]
- A substance included in Schedule 3 shall not be sold or supplied (1a) by retail except under the personal supervision of a pharmaceutical chemist.
- A pharmaceutical chemist shall not store in any part of the retail (1b)area of premises any of the substances referred to in Appendix J.
- A substance referred to in Appendix J shall only be sold or (1c)supplied by direct, personal sale by a pharmaceutical chemist or

**Division 1** Restrictions

r. 35B

- 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 Nov 1968 p. 3458; amended in Gazette 20 Sep 1985 p. 3743; 29 Aug 1990 p. 3028; 30 Nov 1990 p. 5908; 13 Dec 1991 p. 6190; 19 Mar 1996 p. 1221.]

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

#### 35B. Storage of substances included in Schedule 3

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

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

#### 35C. Advertising of substances included in Schedule 3

- Subject to subregulations (2) and (3), a substance included in (1) 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.
- A substance included in Schedule 3 may be advertised if the (3) substance is in a pregnancy testing kit.
- (4) In this regulation —
  - "approved name", in relation to a poison, means the name for the poison that is listed in the Australian Register of Therapeutic Goods, other than a brand name of the poison;
  - "Australian Register of Therapeutic Goods" means the register of that name maintained under section 17 of the Therapeutic Goods Act 1989 of the Commonwealth;
  - "brand name", in relation to a poison, means a name given to the poison by a manufacturer of it and listed in the Australian Register of Therapeutic Goods, other than its approved name.

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

As at 04 Apr 2006 Version 07-h0-04 page 33 Poisons Regulations 1965

Part 5 Sale, supply and use of poisons

**Division 1** Restrictions

r. 35D

### 35D. Advertising of substances included in Schedule 4

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

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

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

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

## Division 2 — Schedule 4 poisons

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

#### **36.** Supply of poisons included in Schedule 4

- 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
    - is satisfied that the person to whom the poison is sold or supplied is authorised under regulation 40(1) to procure the poison; and
    - receives from that person a written order in (ii) accordance with regulation 40(1a) or makes a record under regulation 41B;
  - the person to whom the poison is sold or supplied is the (b) holder of a prescription written by a medical practitioner, nurse practitioner, dentist or veterinary surgeon prescribing the poison according to the requirements of these regulations;
  - 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 —
    - 3 days medication of the poison; or
    - where the poison is supplied in prepacked (ii) 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
  - in accordance with regulation 36(1)(c)(i);

- for the treatment of an acute medical condition in (ii) 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, nurse practitioner, pharmaceutical chemist, or veterinary surgeon or an assistant under the direct personal supervision of a medical practitioner, nurse practitioner, pharmaceutical chemist, or veterinary surgeon shall be the only person who shall dispense a poison included in Schedule 4.
- The following conditions shall be observed by persons (3) dispensing such prescriptions
  - the prescription shall not be dispensed more than the (a) 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;
  - the person who dispenses a prescription which does not (b) 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";
  - for the purposes of this paragraph (c)(i)

- (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;
- microfilm, microfiche, or any other photographic (III) 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;

before the poison is handed to the purchaser the (ii) 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;

- in the event of the dispensing of a repeated prescription (iii) 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;
- the label on the bottle or package containing the poison (iv) shall be marked with the identifying letter or number of the prescription as appearing in the Prescription Book; and

**Division 2** Schedule 4 poisons

r. 36AA

- 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
  - marked "cancelled": or
  - (ii) more than 12 months old;
- 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;
- 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.
- The following conditions shall be observed by persons supplying **(4)** poisons included in Schedule 4 under subregulation (1)(d) –
  - 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 Feb 1971 p. 518-19; 29 Aug 1980 p. 3028; 29 Jun 1984 p. 1784; 5 Jul 1985 p. 2392; 7 Aug 1987 p. 3038; 18 Sep 1987 p. 3596; 2 Jun 1989 p. 1603; 3 Jun 1990 p. 2626; 16 Apr 1992 p. 1634; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 24 Jun 1994 p. 2867; 19 Mar 1996 p. 1221-2; by No. 9 of 2003 s. 44.]

## Provision of "approved starter packs" by registered nurses

- (1) In this regulation —
  - "approved health service" means a health service (as defined in section 3(1) of the Health Services (Conciliation and Review) Act 1995, other than a health service provided by way of medical or epidemiological research) that
    - operates outside the metropolitan region (as defined in section 6 of the Metropolitan Region Town Planning Scheme Act 1959); and
    - has been approved by the Commissioner of Health (b) for the purposes of this regulation;
  - "approved name" has the same meaning as in regulation 35C:
  - "approved starter pack" means a starter pack approved by the Commissioner of Health for the purposes of this regulation;
  - "brand name" has the same meaning as in regulation 35C;
  - "starter pack" means a quantity of a poison included in Schedule 4, prepared by a pharmaceutical chemist and consisting of
    - if the poison is supplied in prepacked individual (a) packs, one individual standard pack;
    - (b) if the poison is a liquid, the smallest pack of the poison available from the manufacturer; or
    - otherwise, not more than 3 days medication of the (c) poison;
  - "starter pack instruction" means an instruction of the kind described in subregulation (2).
- A registered nurse at an approved health service may give an (2) approved starter pack to a patient, other than an in-patient, at the health service if orally instructed to do so by a medical practitioner, who need not be present at the health service.
- Before giving an approved starter pack to a patient a registered (3) nurse must —

As at 04 Apr 2006 Version 07-h0-04 page 39 Part 5

Sale, supply and use of poisons

Schedule 4 poisons Division 2

r. 36AA

- ensure that the approved starter pack is labelled in accordance with subregulation (8); and
- (b) record the details of the provision of the approved starter pack in accordance with subregulation (10).
- A medical practitioner must not give a starter pack instruction (4) unless satisfied that —
  - (a) the patient has an acute medical condition;
  - (b) there is no other medical practitioner at the health service who could reasonably attend to the patient in person; and
  - the distance from the health service to the nearest pharmacy registered under the *Pharmacy Act* 1964 that is open is more than 25 km.
- For the purposes of subregulation (4), a medical practitioner (5) may rely on information provided by the registered nurse as to the patient's condition, the availability of other medical practitioners and the location of the nearest open pharmacy.
- Within 72 hours of giving a starter pack instruction a medical (6) practitioner must give to the registered nurse, or another registered nurse at the health service, written confirmation of the instruction including
  - the name of the medical practitioner; (a)
  - the name of the registered nurse to whom the starter (b) pack instruction was given;
  - the name of the patient; (c)
  - the date and time when the instruction was given; (d)
  - details of the approved starter pack; (e)
  - (f) any relevant directions for use that were to be given to the patient; and
  - any other information that the medical practitioner (g) considers relevant.
- The person in charge of an approved health service must (7)

- (a) keep all written confirmations given under subregulation (6) to registered nurses at the health service for at least 2 years; and
- (b) produce them on demand to any person authorised under the Act to demand production of such records.
- (8) An approved starter pack must be labelled in English with —
  - (a) the words "Keep out of reach of children";
  - (b) the name of the patient;
  - the name and address of the health service; (c)
  - (d) in relation to each poison in the approved starter pack
    - the approved name and strength or amount of the poison; or
    - if the brand name uniquely identifies the strength (ii) of the poison, that brand name;
  - the total quantity of medication contained in the (e) approved starter pack;
  - the date on which the approved starter pack was given to (f) the patient;
  - any directions for use given by the medical practitioner; (g)
  - the number referred to in subregulation (10)(f) (h) identifying the relevant entry in the health service's Starter Pack Supply Book; and
  - any relevant cautionary or advisory statements set out in Appendix K to the SUSDP.
- (9) The person in charge of an approved health service must
  - maintain a Starter Pack Supply Book for the health (a) service consisting of
    - handwritten records in a bound book with sequentially numbered pages; or
    - records kept in another manner which has been (ii) specifically and individually approved in writing

Division 2 Schedule 4 poisons

r. 36A

by the Commissioner of Health for the purposes of this paragraph;

- (b) keep the Starter Pack Supply Book for at least 2 years after the last entry is made in it; and
- (c) produce the Starter Pack Supply Book on demand to any person authorised under the Act to demand production of such records.
- (10) Before giving an approved starter pack to a patient a registered nurse must record the following information in the health service's Starter Pack Supply Book
  - (a) the name and address of the patient;
  - (b) in relation to each poison in the approved starter pack
    - (i) the approved name and strength or amount of the poison; or
    - (ii) if the brand name uniquely identifies the strength of the poison, that brand name;
  - (c) the date and time at which the approved starter pack is to be given to the patient;
  - (d) the name of the medical practitioner;
  - (e) any directions for use given by the medical practitioner;
  - (f) a unique number identifying the entry in the Book; and
  - (g) the registered nurse's name and signature.

[Regulation 36AA inserted in Gazette 29 Jun 2001 p. 3115-18.]

### 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 —

page 42 Version 07-h0-04 As at 04 Apr 2006

- at the medical practitioner's, dentist's or veterinary (a) surgeon's usual place of practice;
- (b) that is kept locked; and
- access to which is available only to the medical (c) practitioner, dentist or veterinary surgeon and persons under his or her personal supervision.
- A medical practitioner, dentist or veterinary surgeon may store (3) substances included in Schedule 4 other than in accordance with subregulation (2) if
  - they are emergency supplies; and
  - the medical practitioner, dentist or veterinary surgeon (b) 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.
- In subregulation (3) (4)

### "emergency supplies" means —

- 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
- in the case of a dentist or veterinary surgeon the (b) substances that are ordinarily carried by dentists or veterinary surgeons who are attending patients at places other than at their usual place of practice.

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

Version 07-h0-04 page 43 As at 04 Apr 2006

Division 2 Schedule 4 poisons

r. 36B

# 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 Feb 1999 p. 556.]

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

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

(1) A prescription for a poison included in Schedule 4 shall comply with the following conditions —

- it shall show in a clearly legible and indelible manner (a)
  - the name and address of prescriber; (i)
  - (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 —
  - $\int (i)$ deleted]
  - (ii) the name and quantity of the substance;
  - (iii) direction for use, if necessary;
  - the date on which it is written; (iv)
  - (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
  - complies with the criteria specified in Appendix L; or
  - is recommended by the Poisons Advisory (ii) Committee and approved in writing by the Executive Director, Public Health,

the prescription shall contain —

- the information required under paragraph (b)(ii) (iii) to (v), in a form generated by the computer;
- the endorsement "Issued under the Poisons (iv) Regulations 1965 (Regulation 37(1)(ba))"; and
- the signature of the prescriber in his or her own (v) 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";

Division 2 Schedule 4 poisons

r. 38

- (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, nurse 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, nurse 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 Feb 1971 p. 519; amended in Gazette 21 Nov 1986 p. 4269; 5 Dec 1986 p. 4467; 17 Aug 1990 p. 4081; 26 Jul 1991 p. 3854; 7 Aug 1992 p. 3869; 26 May 1994 p. 2201; 19 Mar 1996 p. 1222; by No. 9 of 2003 s. 45.]

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

### 38. Dispensing poisons included in Schedule 4 in emergency cases

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

[Regulation 38 amended in Gazette 19 Mar 1996 p. 1222; by No. 9 of 2003 s. 46.7

/38A.Repealed in Gazette 17 Mar 1998 p. 1417.]

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

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

- Subject to subregulation (2) a person, other than a medical (1) practitioner, nurse practitioner or a dentist, shall not administer a poison included in Schedule 4 to a patient in a hospital unless the administration of the poison is authorised in writing on the medication chart of the patient by a medical practitioner, nurse practitioner or a dentist.
- A medical practitioner, nurse practitioner or dentist may (2) verbally authorise the administration of a poison included in Schedule 4 and shall within 24 hours of so doing note such authorisation in writing on the medication chart of the patient.

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

/38B. Repealed in Gazette 24 Jun 1994 p. 2867.]

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

#### 38C. Clomiphene and cyclofenil

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

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

Version 07-h0-04 page 47 As at 04 Apr 2006

Division 2 Schedule 4 poisons

r. 38D

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

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

### 38D. Etretinate or acitretin

- (1) Etretinate or acitretin or a substance containing etretinate or acitretin shall not be prescribed except by a physician or dermatologist.
- (1a) Where etretinate or acitretin or a substance containing etretinate or acitretin is supplied in accordance with a prescription under subregulation (1) the supplier shall ensure that the container in which the etretinate or acitretin or the substance containing etretinate or acitretin is supplied, is labelled with a warning in the following words, or other words having the same effect
  - "WARNING CAUSES BIRTH DEFECTS".
- (2) A physician or dermatologist who prescribes etretinate or acitretin or a substance containing etretinate or acitretin shall ensure that the possibility of pregnancy has been excluded prior to the commencement of the treatment and that the patient is informed that she must not become pregnant for a period of 24 months after completion of the treatment.

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

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

#### 38E. **Prostaglandins**

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

- 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
  - 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 Jun 1989 p. 1604; amended in Gazette 16 Apr 1992 p. 1635; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 11 Apr 1997 p. 1830.]

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

#### 38F. **Isotretinoin**

- (1) Isotretinoin or a substance containing isotretinoin shall not be prescribed except by a physician or dermatologist.
- Where isotretinoin or a substance containing isotretinoin is (1a) supplied in accordance with a prescription under subregulation (1) the supplier shall ensure that the container in which the isotretinoin or the substance containing isotretinoin is supplied, is labelled with a warning in the following words, or other words having the same effect —
  - "WARNING CAUSES BIRTH DEFECTS".
- A physician or dermatologist who prescribes isotretinoin or a (2) 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.

As at 04 Apr 2006 Version 07-h0-04 page 49 Poisons Regulations 1965

Part 5 Sale, supply and use of poisons

**Division 2** Schedule 4 poisons

r. 38G

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

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

### 38G. Thalidomide for human use

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

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

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

### 38H. Chloramphenicol

Chloramphenicol or substances containing chloramphenicol shall not be prescribed except —

page 50 Version 07-h0-04 As at 04 Apr 2006

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

[Regulation 38H inserted in Gazette 2 Jun 1989 p. 1604; amended in Gazette 24 Jun 1994 p. 2868; 11 Apr 1997 p. 1830-1.7

#### **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 —

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

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

/38J. Repealed in Gazette 19 Mar 1996 p. 1223.]

#### 38K. Carnidazole

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

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

#### 38L. Oxolinic acid

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

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

### Poisons Regulations 1965

Part 5 Sale, supply and use of poisons

Division 2 Schedule 4 poisons

r. 38M

### 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 Jun 1994 p. 2868; amended in Gazette 19 Mar 1996 p. 1223; 11 Apr 1997 p. 1831; 27 Nov 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 Jun 1994 p. 2868; amended in Gazette 19 Mar 1996 p. 1223; 11 Apr 1997 p. 1831-2.]

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

#### 380. Bosentan for human use

- (1) Bosentan or a substance containing bosentan shall not be prescribed except
  - by a physician; or
  - by any other medical practitioner authorised in writing (b) by the Commissioner of Health.
- Where bosentan or a substance containing bosentan is supplied (2) in accordance with a prescription under subregulation (1) the supplier shall ensure that the container in which the bosentan or the substance containing bosentan is supplied is labelled with a warning in the following words, or other words having the same effect -
  - "WARNING CAUSES BIRTH DEFECTS".
- A physician, or other medical practitioner, who prescribes bosentan or a substance containing bosentan shall ensure that the possibility of pregnancy has been excluded prior to the commencement of treatment and that the patient is informed that she must not become pregnant during or for a period of 3 months after completion of treatment.

[Regulation 380 inserted in Gazette 5 Oct 2004 p. 4310.]

#### 38P. Teriparatide for human use

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

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

[Regulation 38P inserted in Gazette 5 Oct 2004 p. 4310.]

Division 2 Schedule 4 poisons

r. 39

## 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 Aug 1977 p. 2966; amended in Gazette 2 Oct 1987 p. 3776; 19 Mar 1996 p. 1223-4.]

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

(1) Notwithstanding any other provision of these regulations a stockfeed manufacturer holding an appropriate permit under subregulation (3) may sell by retail to any person producing a written order therefor signed by a veterinary surgeon, a mixture of stockfeed with any poison included in Schedule 4 being an

- antibiotic or sulphonamide, in such quantity and of such composition as is specified in the order.
- The signed order shall be cancelled by the stockfeed (2) 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.
- The provisions of section 23 of the Act do not apply to a sale by (4) a stockfeed manufacturer pursuant to and in accordance with this regulation or to the preparation of a mixture of stockfeed for the purposes of such sale.

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

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

- The master of a ship is authorised to procure and be in (1) 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
  - if the ship is registered in Australia
    - section 125 of the Navigation Act 1912 of the Commonwealth; or
    - the navigation authority of any State of Australia; (ii)

or

**Division 2** Schedule 4 poisons

r. 39C

- if the ship is not registered in Australia
  - 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.
- The holder of an appropriate licence, or any other authorised (2) 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).
- The person in charge of an aircraft is authorised to be in (3) 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.
- The holder of an appropriate licence, or any other authorised (4) person, may supply a poison included in Schedule 4 on receipt of a written order, signed by the manager, or a person authorised in writing by the manager, of the airline company or firm responsible for the operation of the aircraft in the State, certifying that the poison is necessary for the purposes of medical treatment on aircraft.

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

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

The master of a ship that is to carry livestock is authorised to (1) procure and be in possession of any poison included in Schedule 4 that is necessary for compliance —

Version 07-h0-04 page 56 As at 04 Apr 2006

- by the exporter with the Australian Livestock Export Standards — March 2001 (as amended from time to time); or
- by the master with order 18 of the Marine Orders (b) Part 43: Cargo and Cargo Handling — Livestock (as amended from time to time) made under the Navigation Act 1912 of the Commonwealth.
- (2) The holder of an appropriate licence or any other authorised person may supply a poison included in Schedule 4 to the master of a ship on receipt of a written order certifying that the master is authorised under subregulation (1) to procure and be in possession of the poison.
- (3) The written order must be signed by the master of the ship himself or herself and by the exporter of the livestock.
- (4) The master of a ship must store a poison supplied under subregulation (2) in a secure place on board the ship.
- (5) In this regulation —
  - "livestock" means livestock in relation to which an exporter has given a notice of intention to export under order 6 of the Export Control (Animals) Orders as amended, made under the Export Control (Orders) Regulations 1982 in force under the Export Control Act 1982 of the Commonwealth;
  - "exporter" means a person who holds a live-stock export licence under the Australian Meat and Live-stock Industry Act 1997 of the Commonwealth, or a person authorised in writing by the licensee as the licensee's agent;
  - "master of a ship" includes, except in subregulation (3), a person authorised in writing by the master as the master's agent.

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

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

Division 2 Schedule 4 poisons

r. 40

# 40. Special authority to purchase poisons included in Schedule 4

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

	Table
	1

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

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

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

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

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

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

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

[Regulation 40A 4 (formerly regulation 41) inserted in Gazette 8 Jun 1990 p. 2627; amended in Gazette 19 Mar 1996 p. 1225.]

As at 04 Apr 2006 Version 07-h0-04 page 59 **Division 3** General

r. 41

### Division 3 — General

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

#### 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 —

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

[Regulation 41 inserted in Gazette 19 Mar 1996 p. 1225-6.]

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

#### 41A. Sale of poisons included in Schedule 7

- 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.
- A person recording a sale for the purposes of subregulation (1) (2) shall, before delivering the poison to the purchaser, record in a register kept for that purpose particulars of
  - the date of sale; (a)
  - (b) the name and address of the purchaser;
  - the nature and quantity of the poison sold; (c)
  - (d) the address to which the poison is to be delivered, if that address differs from the address recorded under paragraph (b); and
  - the place of intended use, (e)

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 book with each recording written in ink;
  - in a form of electronic means; or (b)
  - such other form as the Commissioner of Health approves (c) in writing.
- A person keeping a register for the purposes of this regulation (4) shall
  - keep that register for a period of at least 2 years at the (a) licensed premises; and
  - produce the register for inspection on demand by an (b) authorised officer.

[Regulation 41A inserted in Gazette 19 Mar 1996 p. 1226 4; amended in Gazette 14 Sep 2001 p. 5076.]

### 41AA. Standard for intramammary antibiotic preparations

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

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

### 41AB. Camphor and naphthalene

A person shall not sell or supply camphor or naphthalene in block, ball, disc or pellet form for domestic use unless the blocks, balls, discs or pellets are enclosed in a device which prevents removal or ingestion of the contents during use.

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

**Division 3** General

r. 41B

### 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 Dec 1986 p. 4874-5; amended in Gazette 27 May 1988 p. 1770; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1226.]

### 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

page 62 Version 07-h0-04 As at 04 Apr 2006

Sale, supply and use of poisons

poisons Part 5
General Division 3

r. 41C

(c) a person authorised to purchase substances included in Schedule 7 by notice given under section 24 of the Act.

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

As at 04 Apr 2006 Version 07-h0-04 page 63

**Division 1** General

r. 42A

# Part 6 — Drugs of addiction

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

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

### **Division 1 — General**

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

# 42A. Interpretation

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

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

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

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

page 64 Version 07-h0-04 As at 04 Apr 2006

**Division 1** 

- 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.

**Division 1** General

r. 43

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

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

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

- (1) Until in any particular case such authority is withdrawn, every pharmaceutical chemist holding a Pharmaceutical Chemist's licence to sell poisons under these regulations is hereby authorised, subject to the conditions, limitations and restrictions imposed by the 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 Jun 1984 p. 1784; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1227.]

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

### 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 Mar 1996 p. 1227-8.]

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

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

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

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

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

#### 43C. Advertising of substances included in Schedule 8

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

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

page 67 As at 04 Apr 2006 Version 07-h0-04

**Division 1** General

r. 44

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

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

### 44. Register of drugs of addiction

(1) In this regulation —

> "authorised person" means a person authorised to manufacture, distribute, sell or possess any drug of addiction, other than a person having possession of a drug of addiction by the authority of a prescription from a medical practitioner, dentist or veterinary surgeon to the extent shown in the prescription.

- 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.
- An authorised person is to record, or cause to be recorded, in the (3) register, in relation to each transaction involving a drug of addiction
  - the name, quantity and form of the drug; (a)
  - the date of the transaction; (b)
  - the name and address of each other person or firm (c) involved in the transaction;
  - the name of the person who wrote the prescription or (d) order:
  - the amount of the drug remaining on hand after the (e) transaction;
  - if the authorised person is a pharmaceutical chemist, the (f) 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.

page 68 Version 07-h0-04 As at 04 Apr 2006

**Division 1** 

- An authorised person is to record, or cause to be recorded, in the (3a) Register the result of each inventory made by the authorised person under regulation 45 on the day on which the inventory is made.
- The register must be maintained in such a way that at any time (4) 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
  - maintain a separate register for each location at which the person manufactures, procures, uses, supplies or keeps drugs of addiction; and
  - keep the register at that location.

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

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

- Subject to subregulations (2) and (3) a person authorised to (1) 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.
- Subject to regulation 31 a drug of addiction may be destroyed (2) by
  - or under the personal supervision of a person declared to (a) be an authorised officer for the purposes of this regulation by the Minister under section 52A of the Act;
  - a police officer acting under the Misuse of Drugs (b) Act 1981.

As at 04 Apr 2006 Version 07-h0-04 page 69 **Division 1** General

r. 44A

- (3) Subject to regulation 31 a person referred to in subregulation (1), other than a person to whom subregulation (2) applies, who seeks to destroy a poison included in Schedule 8 shall carry out that destruction under the supervision of a witness selected, in accordance with subregulation (7), from any of the following categories
  - (a) pharmaceutical chemists authorised to possess and supply poisons included in Schedule 8;
  - (b) medical practitioners authorised to supply poisons included in Schedule 8; and
  - (c) directors of nursing.
- (4) A person who destroys poisons included in Schedule 8 must maintain a register of the poisons destroyed and record in it, at the time of each destruction
  - (a) the date of destruction;
  - (b) the name, strength and quantity of the poison destroyed;
  - (c) the reason for the destruction; and
  - (d) the name of the witness to the destruction,

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

- (5) A pharmaceutical chemist required to provide a monthly return under regulation 52C shall, as part of the return, provide details of the entries recorded in the register, maintained in accordance with subregulation (4), for the relevant period.
- (6) Where the monthly return referred to in subregulation (5) is made
  - (a) on the original of the approved duplicate form, the details shall be entered by the person who destroyed the poison included in Schedule 8 and that person and the person who supervised the destruction shall each sign the entry;

- (b) on the original of the completed printout of the approved computerised recording system, the details shall be accompanied by the name of the person who destroyed the poison included in Schedule 8 and that of the witness who supervised the destruction of the poison.
- (7) For the purposes of subregulation (3), a pharmaceutical chemist, authorised to possess and supply poisons included in Schedule 8 or Schedule 9, who wishes to destroy poisons included in Schedule 8 or Schedule 9 may have another pharmaceutical chemist authorised to possess and supply poisons included in Schedule 8 or Schedule 9 as a witness to that destruction, but otherwise a witness shall not be a member of the same category as that of the person who seeks to destroy the poisons included in Schedule 8.

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

### 44B. Form of registers

- A register kept for the purposes of regulation 44(2) or 44A(4) (1) may be maintained on paper, electronically or in another approved manner.
- (1a) If a register is maintained on paper, all entries required to be made in the register are to be made in ink.
- If a register is maintained other than on paper the information in (2) the register must be recorded or stored in such a way that it
  - will remain in the form in which it was originally recorded or stored; and
  - 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.
- An authorised person must make all the person's registers (4) available for inspection on request by persons authorised under the Act to inspect registers.

r. 44C

- (5) Subject to subregulation (6) a person must not alter, obliterate or delete an entry in a register.
- An authorised person may correct an error in a register (6)
  - if the register is maintained on paper, by making a marginal or foot note and initialling and dating the note;
  - otherwise, in a manner approved by the Commissioner (b) for Health.

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

### 44C. Control of access to electronic registers

- In this regulation (1)
  - "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).
- An authorised person must maintain the register in such a way (2) that entries in the register cannot be deleted.
- An authorised person must maintain the register in such a way (3) that
  - 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.

Version 07-h0-04 page 72 As at 04 Apr 2006

- (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 Feb 2000 p. 994-5.]

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

### 45. Inventory of drugs of addiction

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

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

If such inventory of drugs of addiction in stock does not agree (2) 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 Jun 1984 p. 1784; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 14 Sep 2001 p. 5076.]

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

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

**Division 1** General

r. 47

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

- All records, registers, prescription books, invoices and other (1) 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.
- The records, registers, prescription books, invoices or other (2) 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.
- In the event of a register being lost or destroyed the person to (3) 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.
- A person authorised or licensed to procure and be in possession (4) 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.
- 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.
- The duplicate copy of the form or printout of the computerised (6) 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 Sep 1983 p. 3804; 29 Jun 1984 p. 1784; 31 Jan 1986 p. 332; 7 Aug 1987 p. 3083; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1229.1

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

#### 48. Returns from manufacturers and wholesalers

- 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.
- The form referred to in subregulation (1) may be required by the (2) 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 Sep 1983 p. 3804: amended in Gazette 29 Jun 1984 p. 1784; 25 Jun 1993 p. 3080 and 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1229.]

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

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

- 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
  - if the ship is registered in Australia —

General

r. 49

- (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

**Division 2** 

details to the Commissioner of Health or the officer in charge of the nearest police station.

[Regulation 49 inserted in Gazette 31 Dec 1993 p. 6884-5; amended in Gazette 26 May 1994 p. 2201; 19 Mar 1996 p. 1229.7

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

### **50.** Used poisons included in Schedule 8 at hospitals

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

[Regulation 50 amended in Gazette 29 Jun 1984 p. 1784; 28 May 1993 p. 2597; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1230.7

As at 04 Apr 2006 Version 07-h0-04 page 77

# Division 2 — Supply and prescription

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

## Subdivision 1 — Prescriptions generally

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

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

### 51. **Prescriptions**

- (1) A prescription for the supply of a drug of addiction shall comply with the following conditions
  - the prescription shall bear on its face, legibly printed or (a) written in ink the name and address of the prescriber;
  - it shall not prescribe more than one drug of addiction, (aa) nor any other substance, but may prescribe the same drug in more than one form;
  - subject to paragraph (ba) the prescription shall bear on (b) its face, legibly written in ink in the handwriting of the prescriber —
    - (i) the date when it is written;
    - the signature of the prescriber; (ii)
    - the name, full address and date of birth of the (iii) 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;
    - the description and quantity of the drug of (iv) addiction to be dispensed;
    - precise directions for the use of the drug of (v) addiction, including the dose to be taken or administered and the frequency with which the dose is to be taken or administered;
    - where the drug of addiction is to be dispensed (vi) more than once under the prescription, 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;
- the words 'for dental treatment only' if it is (viii) written by a dentist;
- where it prescribes an unusual dose, an indication (ix) 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
  - 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 —

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

and

- the prescription shall not bear the impression of a rubber (c) 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.
- With the written approval of the Commissioner of Health a person (2) 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

As at 04 Apr 2006 Version 07-h0-04 page 79 r. 51A

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

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

# Subdivision 2 — Supply and prescription to drug addicts

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

# 51A. Definition of "drug addict"

In this Subdivision —

"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 Aug 1980 p. 3028; amended in Gazette 12 Oct 1984 p. 3267; 12 Apr 1991 p. 1608; 12 Aug 2003 p. 3659.]

## 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 Oct 1984 p. 3267; amended in Gazette 11 Apr 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 Apr 1997 p. 1832.]

# 51C. Authorisation of Commissioner of Health required for medical practitioner to prescribe methadone or buprenorphine 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 buprenorphine, or supply methadone or buprenorphine, for the treatment of a person who is —

(a) a drug addict; or

As at 04 Apr 2006 Version 07-h0-04 page 81

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

unless the medical practitioner has —

- 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
- received written authorisation to do so from the Commissioner of Health.

[Regulation 51C inserted in Gazette 29 Aug 1980 p. 3029; amended in Gazette 29 Jun 1984 p. 1784; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 11 Apr 1997 p. 1832; 14 Aug 2001 p. 4253.7

### 51D. Assessment of drug addict for treatment purposes

- Before an authorisation is issued by the Commissioner of Health for the treatment of a drug addict with methadone or buprenorphine the drug addict in relation to whom the treatment is to be authorised, prescribed or used shall be assessed for such treatment by
  - a medical practitioner approved by the Commissioner of (a) Health:
- f(b) and f(c)deleted]
  - 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
  - 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
  - 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 Aug 1980 p. 3029; amended in Gazette 29 Jun 1984 p. 1784; 27 May 1988 p. 1771; 12 Apr 1991 p. 1609; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1230; 29 Feb 2000 p. 995; 14 Aug 2001 p. 4253.]

### 51E. Conditions on treatment of drug addict

- In an authorisation given with respect to the treatment of a particular drug addict with methadone or buprenorphine the Commissioner of Health may specify that any one or more of the conditions and restrictions set out below apply, namely
  - that the prescription be issued by, or treatment administered by, a specified medical practitioner;
  - that the type of methadone or buprenorphine prescribed (b) or administered be of the type specified;
  - that the amount to be prescribed or used for treatment shall not exceed the amount specified;
  - that the amount to be prescribed or used on any one day (d) shall not exceed the amount specified;
  - that the concentration to be prescribed or used shall not (e) exceed the concentration specified;
  - that the intervals between the issue of prescriptions or (f) the administration of the treatment shall be such as are specified;
  - that the prescription be supplied at the pharmacy or (g) 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 buprenorphine or supply methadone or buprenorphine contrary to such conditions and restrictions as are specified.
- (5) A pharmaceutical chemist shall not sell or supply methadone or buprenorphine 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 Aug 1980 p. 3029; amended in Gazette 29 Jun 1984 p. 1784; 12 Apr 1991 p. 1609; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1230; 14 Aug 2001 p. 4253.]

# 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.

- Where a medical practitioner has written, issued or authorised a (2) 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
  - the medical practitioner has first obtained written (a) authorisation under this regulation to do so from the Commissioner of Health; or
  - the Commissioner of Health has issued an authorisation (b) under this regulation to do so in relation to that person and the authorisation is current.
- (3) Notwithstanding any authorisation referred to in subregulation (1) or (2) a medical practitioner shall not write, issue or authorise a prescription or document prescribing the use, sale or supply of methadone or buprenorphine for the treatment of a person or supply methadone or buprenorphine for the treatment of a person except for a person suffering from intractable pain arising from a condition of health other than addiction to drugs.
- (4) In any authorisation issued for the purposes of subregulation (1) or (2) given with respect to a particular person the Commissioner of Health may specify that any one or more of the conditions and restrictions set out below apply, namely —

**Division 2** 

- (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.

Supply and prescription

An authorisation issued prior to 1 October 1980 is valid until (8) revoked by the Commissioner of Health or until it expires whichever first occurs.

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

# Subdivision 3 — Supply and prescription of certain substances

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

### 51G. Interpretation

In this Subdivision —

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

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

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

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

Despite regulations 51B and 51F, a medical practitioner must not supply a stimulant or provide a prescription for a stimulant unless the medical practitioner —

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

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

### Poisons Regulations 1965

Part 6 Drugs of addiction

Division 2 Supply and prescription

r. 51GAB

## 51GAB. Authorisation to supply or prescribe a stimulant

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

[Regulation 51GAB inserted in Gazette 12 Aug 2003 p. 3659-60.]

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

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

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

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

page 88 Version 07-h0-04 As at 04 Apr 2006

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

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

As at 04 Apr 2006 Version 07-h0-04 page 89 Extract from www.slp.wa.gov.au, see that website for further information

r. 51GAE

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

[Regulation 51GAD inserted in Gazette 12 Aug 2003 p. 3660-1.]

# 51GAE. Dose for supply or prescription of a stimulant

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

[Regulation 51GAE inserted in Gazette 12 Aug 2003 p. 3661.]

# 51GAF. Notification to Commissioner of Health of supply or prescription of a stimulant

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

page 90 Version 07-h0-04 As at 04 Apr 2006

Part 6

- the dose of a stimulant supplied to or prescribed for a patient by the authorised practitioner;
- (ii) the type of stimulant supplied to or prescribed for a patient by the authorised practitioner;
- the form of stimulant supplied to or prescribed (iii) for a patient by the authorised practitioner;
- (iv) the name or residential address of a patient who is being treated with a stimulant by the authorised practitioner; or
- (v) the co-prescribers (if any) of the authorised practitioner under regulation 51GAG;

and

- the supply or provision of prescriptions for a stimulant (c) to a patient by the authorised practitioner has ceased.
- The notification is to be in a form approved by the (2) Commissioner of Health.
- (3) Upon receiving notification under subregulation (1)(a) or (b), the Commissioner of Health may by notice to the authorised practitioner order that the treatment be cancelled or varied.
- An authorised practitioner receiving an order under (4) subregulation (3) must comply with the order.

[Regulation 51GAF inserted in Gazette 12 Aug 2003] p. 3661-2.7

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

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

[Regulation 51GAG inserted in Gazette 12 Aug 2003 p. 3662.]

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

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

[Regulation 51GAH inserted in Gazette 12 Aug 2003 p. 3662.]

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

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

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

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

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

### 51GA. Supply of dronabinol

A medical practitioner shall not supply, issue, write or authorise a prescription for delta-9-tetrahydrocannabinol (dronabinol)

page 92 Version 07-h0-04 As at 04 Apr 2006

Supply and prescription

unless that practitioner has been authorised to do so by the Secretary of the Commonwealth Department of Human Services and Health under section 19 of the Therapeutic Goods Act 1989 of the Commonwealth.

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

## 51GB. Supply of flunitrazepam

- Notwithstanding regulations 51B to 51F, a medical practitioner (1) 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
  - that the prescription be issued by or the treatment be administered by the medical practitioner specified in the authorisation;
  - that the amount of flunitrazepam to be prescribed or (b) used for treatment shall not exceed the amount specified;
  - 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;
  - that the intervals between the issue of prescriptions for (e) flunitrazepam or the administration of flunitrazepam shall be such as are specified;
  - that the prescription be supplied at the pharmacy (f) specified;

As at 04 Apr 2006 Version 07-h0-04 page 93

- (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

page 94 Version 07-h0-04 As at 04 Apr 2006

- 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 Apr 1997 p. 1833.]

/51J. Repealed in Gazette 12 Apr 1991 p. 1609.]

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

## Division 3 — Dispensing and delivery

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

### 52. Dispensing drugs of addiction

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

- (3) The following conditions shall be observed by a person who dispenses a drug of addiction under a prescription
  - (a) the dispenser shall satisfy himself or herself
    - (i) that the prescription is in accordance with the requirements of the Act;
    - (ii) that the person who signed the prescription is a medical practitioner, a dentist or a veterinary surgeon; and
    - (iii) in accordance with subregulation (3a), that the prescription was signed by the prescriber whose name appears on the prescription;
  - (b) the drug of addiction shall not be dispensed under the prescription more than the maximum number of times indicated on the prescription, or at intervals less than those indicated on the prescription;
  - (ba) on each occasion on which the drug of addiction is dispensed under the prescription the dispenser shall
    - (i) sign the prescription clearly in ink using his or her usual signature; and
    - (ii) stamp or otherwise mark the prescription clearly in ink with the date on which the drug is dispensed;
  - (bb) on the first occasion on which the drug of addiction is dispensed under the prescription, the dispenser shall stamp or otherwise mark the prescription clearly in ink with the name and address of the dispensary;
  - (c) where the drug of addiction is prescribed by a veterinary surgeon, the dispenser shall not dispense the drug of addiction on more than one occasion under that prescription;
  - (d) where the dispenser dispenses less than the prescribed amount of the drug of addiction on presentation of the prescription and dispenses or intends to dispense the remainder on another occasion or occasions, the

page 96 Version 07-h0-04 As at 04 Apr 2006

**Division 3** 

- dispenser shall on each occasion on which part of the prescribed amount is dispensed, note on the prescription clearly in ink the amount dispensed and the date on which it was dispensed;
- after dispensing the drug of addiction as directed by the prescription the dispenser shall
  - mark the prescription with the number of occasions remaining (if any) on which the drug of addiction is to be dispensed under the prescription; and
  - subject to subregulation (7), retain the (ii) prescription in safe custody at the dispensary;
- (f) the dispenser shall write in ink, or stamp, the word "cancelled" across the prescription in legible letters if
  - the prescription does not clearly indicate the maximum number of occasions on which the drug of addiction is to be dispensed under the prescription;
  - the prescription does not clearly indicate the (ii) intervals at which the drug of addiction is to be dispensed under the prescription; or
  - the drug of addiction has already been dispensed (iii) on the maximum number of occasions on which it can lawfully be dispensed under the prescription;
- the dispenser shall enter, or cause to be entered, in the (g) register maintained under regulation 44, a proper record of the transaction which record shall be made in such a way as to be easily understood;
- (h) before the drug of addiction is handed to the purchaser, the following particulars shall be recorded in accordance with regulation 52B
  - the prescription number;

Dispensing and delivery

r. 52

- (ii) the name, full address and date of birth 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 the drug of addiction is prescribed;
- (iii) a description of the drug of addiction;
- (iv) the quantity of the drug of addiction dispensed;
- (v) directions for the use of the drug of addiction;
- (vi) the date of the prescription;
- (vii) the name and address of the prescriber;
- (viii) a note of the basis on which the dispenser is satisfied for the purposes of subregulation (3)(a)(iii) that the signature on the prescription is the signature of the prescriber whose name appears on the prescription;
- [(j)] deleted
- (k) the label on the bottle or package containing the drug of addiction shall be marked with the prescription number referred to in paragraph (h); and
- [(l) deleted]
- (m) subject to regulation 64, the drug of addiction so dispensed shall conform in quantity, description, composition, strength, form and every other material particular to the directions of the prescriber,

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

(3a) For the purposes of subregulation (3)(a)(iii), the dispenser shall orally ask the prescriber whose name appears on the prescription to verify that the prescriber issued the prescription, unless the dispenser is satisfied that the signature on the

page 98 Version 07-h0-04 As at 04 Apr 2006

**Division 3** 

- prescription is the signature of the prescriber on the basis that the dispenser is familiar with the signature of the prescriber and recognises the signature on the prescription as the prescriber's signature.
- A person shall not dispense a drug of addiction under a prescription marked "cancelled" or that is more than 6 months
- A person shall not dispense a drug of addiction under a (5) 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.
- A pharmaceutical chemist shall retain possession of any (6) 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 a drug of addiction 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 drug of addiction under the prescription.
- The dispenser of a drug of addiction may transfer a prescription (7) into the safe custody of another person if the transfer is approved by the Commissioner of Health under subregulation (7a).

As at 04 Apr 2006 Version 07-h0-04 page 99 Extract from www.slp.wa.gov.au, see that website for further information

#### Poisons Regulations 1965

Part 6 Drugs of addiction

Division 3 Dispensing and delivery

r. 52A

- (7a) The Commissioner of Health may, on the oral application of the dispenser, give approval for the dispenser to transfer the prescription to another person by whom the drug can be dispensed in accordance with these regulations.
- (8) A pharmaceutical chemist shall deliver up any document, prescription, authorisation or record relating to the sale or supply of a poison included in Schedule 8 upon request made by an authorised officer (other than an environmental health officer).

[Regulation 52 amended in Gazette 29 Aug 1980 p. 3031; 23 Sep 1983 p. 3805-6; 29 Jun 1984 p. 1784; 31 Jan 1986 p. 332-3; 7 Aug 1987 p. 3038; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 17 Mar 1995 p. 1026; 19 Mar 1996 p. 1231; 29 Feb 2000 p. 995; 15 Nov 2005 p. 5604-8.]

#### 52A. Movement of drugs of addiction in other circumstances

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

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

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

#### 52B. Manner of recording details

- (1) The details required to be recorded under regulations 52(3)(h) and 52A shall be
  - (a) entered on a duplicate form approved by the 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 —

Division 3

- on an approved duplicate form, the details shall be entered and signed and dated by the person who actually dispensed the poison;
- in an approved computerised recording system, the (b) details shall be accompanied by the name of the person who actually dispensed the poison and the date of the transaction.

[Regulation 52B inserted in Gazette 7 Aug 1987 p. 3083; amended in Gazette 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1231.7

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

#### 52C. Returns to department

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

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

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

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

Where a medical practitioner, dentist or veterinary surgeon in a (1) 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

Version 07-h0-04 As at 04 Apr 2006 page 101 Part 6 Drugs of addiction
Division 3 Dispensing and delivery

r. 53A

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 Sep 1983 p. 3806; 27 May 1988 p. 1771; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 1996 p. 1232.]

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

### 53A. Dispensing certain poisons included in Schedule 8

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

Amphetamine

Buprenorphine

Dexamphetamine

Dextromoramide

Flunitrazepam

Hydromorphone

Methadone

Methylamphetamine

Methylphenidate

Morphine

Oxycodone

Pethidine

Phenmetrazine

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

**Division 3** 

- he is familiar with the prescriber's handwriting; or
- he has verified with the purported prescriber that the (b) prescription was written by him.
- Where a person cannot comply with subregulation (1), for good (2) 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 Sep 1983 p. 3806; amended in Gazette 19 Mar 1996 p. 1232; 26 May 1998 p. 2967; 16 Nov 2001 p. 5985; 13 Aug 2002 p. 4181; 12 Aug 2003 p. 3663.]

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

#### 54. Delivery of poisons included in Schedule 8 on order

- (1) Subject to regulation 53 and to subregulation (3) a poison included in Schedule 8 shall not be delivered to a person except —
  - (a) on the authority of a written order
    - legibly written in ink; (i)
    - bearing on the face thereof (ii)
      - the date when it is written; (I)
      - (II)the name and address of the person requiring it to be supplied;
      - the quantity and description of the (III) poison included in Schedule 8 to be supplied;

and

signed by a person licensed or otherwise (iii) authorised to procure or be in possession of the poison included in Schedule 8;

or

Version 07-h0-04 As at 04 Apr 2006 page 103 r. 54A

- (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 Sep 1983 p. 3807; 2 Jun 1989 p. 1605; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201; 19 Mar 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 Sep 1983 p. 3807; amended in Gazette 19 Mar 1996 p. 1232.]

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

#### 55. Common carrier protected

A common carrier or his 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.

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

#### Division 4 — Safe custody

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

#### **56.** Storing and securing drugs of addiction

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

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
  - 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
  - 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

Version 07-h0-04 As at 04 Apr 2006 page 105 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* <sup>1</sup>;
- (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* <sup>1</sup>, 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

page 106 Version 07-h0-04 As at 04 Apr 2006

otherwise in the possession of a medical practitioner, dentist or veterinary surgeon,

if that medical practitioner, dentist or veterinary surgeon, takes reasonable precautions to protect the poison against theft or loss.

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

> [Regulation 56 inserted in Gazette 25 Jun 1993 p. 3081; amended in Gazette 26 May 1994 p. 2201; 24 Jun 1994 p. 2869; 19 Mar 1996 p. 1232-3.]

#### Prescribed amount of poisons included in Schedule 8 56A.

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

of any poison included in Schedule 8.

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

[Regulation 56A inserted in Gazette 25 Jun 1993 p. 3082; amended in Gazette 19 Mar 1996 p. 1233; 13 Aug 2002 p. 4181.7

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

#### 56B. Location of safe in premises

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

Version 07-h0-04 As at 04 Apr 2006 page 107 [Regulation 56B inserted in Gazette 25 Jun 1993 p. 3082.]

#### 56C. Authorised persons to keep keys to safes

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

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

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

#### 56E. Pharmacist present on premises

A pharmaceutical chemist who is —

**Division 4** 

Part 6

- authorised to be, and is, in possession of a poison included in Schedule 8; and
- (b) present on the pharmacy premises,

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

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

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

A pharmaceutical chemist referred to in regulation 56E shall —

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

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

#### 56G. Poisons included in Schedule 8 in hospital ward

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

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

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

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

Version 07-h0-04 As at 04 Apr 2006 page 109 r. 56H

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

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

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

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

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

## Division 5 — Restrictions on supply

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

#### 57. Labelling

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

page 110 Version 07-h0-04 As at 04 Apr 2006

Division 5

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

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

#### **58.** Improper prescribing or use of drugs of addiction

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

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

As at 04 Apr 2006 Version 07-h0-04 page 111

# Part 7 — Miscellaneous provisions

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

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

# 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 Aug 1980 p. 3031; amended in Gazette 29 Jun 1984 p. 1784; 25 Jun 1993 p. 3085; 26 May 1994 p. 2201.]

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

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

## 64. Substitution of one brand of a drug for another

- (1) In this regulation
  - "approved name", in relation to a poison, means the name for the poison that is listed in the Australian Register of Therapeutic Goods, other than a brand of the poison;
  - "Australian Register of Therapeutic Goods" means the register of that name maintained under section 17 of the *Therapeutic Goods Act 1989* of the Commonwealth;
  - **"brand"**, in relation to a poison, means a name given to the poison by a manufacturer of it and listed in the Australian Register of Therapeutic Goods, other than its approved name.
- (2) If a prescription issued by a medical practitioner, nurse practitioner or a dentist prescribes a poison and describes the

**Division 5** 

- poison by its approved name, a person dispensing the prescription may dispense or supply any brand of the poison.
- Except as provided by this regulation, if a prescription issued by (3) a medical practitioner, nurse practitioner or a dentist prescribes a poison and describes the poison by reference to a brand of it, a person dispensing the prescription must not dispense or supply the poison other than in accordance with the description in the prescription.
- **(4)** If a prescription issued by a medical practitioner, nurse practitioner or a dentist prescribes a poison and describes the poison by reference to a brand of it, a person dispensing the prescription may dispense or supply any brand of the poison, unless the prescription shows a contrary intention.
- If a prescription issued by a medical practitioner or nurse (5) practitioner in respect of a patient in a public hospital prescribes a poison and describes the poison by reference to a brand of it, a person dispensing the prescription may dispense or supply any brand of the poison, whether or not the prescription indicates a contrary intention.
- (6) For the purposes of this regulation, a contrary intention is shown on a prescription if it bears the words "No substitution" or words with a similar effect.

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

#### **65.** Form of warrant (section 55A)

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

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

As at 04 Apr 2006 Version 07-h0-04 page 113

# Appendix A

Poisons Act 1964
Poisons Regulations 1965, regulation 3

# WHOLESALER'S LICENCE

Form 1

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

Licensee	Name	
	Address	
Poisons	The poisons included in —	
	☐ Schedule 1 ☐ Schedule 3 ☐ Schedule 7	
	☐ Schedule 2 ☐ Schedule 4 ☐ Schedule 8	
	to the Poisons Act 1964	
	Manufacturing of poisons (regulation 3(3))	
Premises		
Qualified	Name	
person	Qualifications	
	Supply of poisons (regulation 3(4))	
Premises		
0 110 1	N.	
Qualified person	Name	
person	Qualifications	

# Appendix A

Experienced	Name
person	Qualifications

Other conditions	

<b>Duration of</b>	Date of issue
licence	Date of expiry

[Form 1 inserted in Gazette 14 Sep 2001 p. 5077.] [Forms 1A, 2 and 2A deleted]

Poisons Act 1964

#### PHARMACEUTICAL CHEMIST'S LICENCE TO SELL POISONS

This licence is granted to	
F F	
(name of pharmacy)	
situated at	
Dated at Perth20	
Valid until 30 June 20	

[Forms 3A, 4 and 4A deleted]

Poisons Act 1964

# LICENCE TO SELL BY RETAIL POISONS INCLUDED IN SCHEDULE 2

that person to procure, and to s the poisons included in Schedu	and authorises ell by retail, on behalf of
Dated at Perth	
Valid until 30 June 20	
•	

[Form 5A deleted]

As at 04 Apr 2006 Version 07-h0-04 page 117

Poisons Act 1964

# LICENCE TO SELL BY RETAIL POISONS INCLUDED IN SCHEDULE 7

This licence is granted to that person to procure, and sel	l by retail, on behalf	of
at premises situated atthe following poisons included	d in Schedule 7 —	,
Subject to the following condi	tions —	
Dated at Perth	20	
Valid until 30 June 20		

[Form 6A deleted]

#### Form 6B

# Poisons Act 1964

#### POISONS PERMIT (DISTRIBUTION OF SAMPLES)

This permit is granted to	
, representative of , license , license , license	
nanufacturers of, or wholesale suppliers in, drugs containing poisons included in Schedule 2, 3 or 4 to the <i>Poisons Act 1964</i> ; 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	
of the purposes of that Act, from	
(Name of manufacturers or wholesale suppliers)	•••
and supply them to persons authorised by regulation 8A of the <i>Poisons</i>	
Regulations 1965 (as amended) to receive them.	
Dated at Perth20	
Valid until 30 June 20	

[Form 6C deleted]

## Poisons Act 1964

### POISONS PERMIT (INDUSTRIAL)

	,
	t is granted to
(a)	the poisons included in Schedules to the <i>Poisons Act 1964</i> ;
(b)	the following poisons —
This permi	t 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 Pe	erth
Valid until	30 June 20

[Form 7A deleted]

#### Poisons Act 1964

		1 0150115 1101 1701	
POISON	NS PERMIT (ED	UCATIONAL, ADVISORY	OR RESEARCH)
This permi	t is granted to		and
authorises	that person to purc	hase on behalf of	
(a)		ided in Schedules	to
	the Poisons Act	· ·	
(b)	the following po		
This permi	t is issued subject	to the following conditions —	-
(1)	-	be stored only at premises sit	
(2)	the poisons will		
(3)	the poisons will	be used only for the following	g purposes —
(4)			
( )			
		20	
Valid until	30 June 20		
		Co	ommissioner of Health
1	Form 8 amended i	in Gazette 4 Apr 2006 p. 1406	5.]
		Form 8AA	
		rorm 8AA	
		Poisons Act 1964	
	POISONS	PERMIT (HEALTH SERV	VICES)
authorises	that person to purc	hase on behalf of	
As at 04 Au	nr 2006	Version 07-h0-04	nage 121

page 121 As at 04 Apr 2006 Version 07-h0-04
Extract from www.slp.wa.gov.au, see that website for further information

# Appendix A

(a)	the poisons included in Schedules to the <i>Poisons Act 1964</i> ;
(b)	the following poisons —
(-)	Or and or an arrangement of the second of th
This pe	rmit 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 a	t Perth
Valid u	ntil 30 June 20
	Commissioner of Health
	{Form 8AA inserted in Gazette 4 Apr 2006 p. 1407.]
	[Forms 8A, 9, 9A, 10, 11, 11A deleted]

#### Form 11AA

## Poisons Act 1964

#### STOCKFEED MANUFACTURER'S PERMIT

authorises 1	t is granted to
order of a vincluded in	reterinary surgeon such mixture containing the following poisons Schedule 4 as may be specified in the order, and within the limits as and composition set out in the order.
	luded in Schedule 4 to which this permit applies —
This permi	t is issued subject to the following conditions —
(1)	the mixture will be stored at and sold from premises situated at
(2)	
Dated at Pe	erth
Valid until	30 June 20
[	Form 11AB deleted]
[	Form 12 deleted]

As at 04 Apr 2006 Version 07-h0-04 page 123

## Poisons Act 1964

### POISONS PERMIT (DEPARTMENTAL AND HOSPITAL)

is granted to
the poisons included in Schedules to the <i>Poisons Act 1964</i> ;
the following poisons —
is issued subject to the following conditions —
the poisons will be stored only at premises situated at
the poisons will not be resold unless the poisons referred to above have been purchased on behalf of a public hospital;
the poisons will be used only for the following purposes —
th20
0 June 20
Commissioner of Health

#### Form 13A

[Reg. 10B]

#### Poisons Act 1964

(Section 41A)

## LICENCE TO CULTIVATE ETC A PROHIBITED PLANT

This licence is granted to
t premises situated at
ubject to the following conditions —
Oated:
Valid until 30 June 20
Commissioner of Healt
* delete if not applicable]

As at 04 Apr 2006 Version 07-h0-04 page 125

#### Poisons Act 1964

# APPLICATION FOR APPROVAL OF NEEDLE AND SYRINGE PROGRAMME

I	of
	by apply on behalf ofhe 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	e

[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	y time)	
This warrar	nt ceases to have	ve effect:	
	Date:		
-	Γime:		
of	re reasonable g	grounds for sus	Justice of the Peace am satisfied by complaint made on oath pecting that — ons Act 1964 has been, is being or is
(a)	•	ommitted; and	
(b)	those premis	es (being prem	es set out in this warrant, or in a part of ises used as a residence) something a of that offence,
exercise the Poisons Acassistance,	e entry, search <i>t 1964</i> in relati	and seizure po on to the prem orce, as is reaso	wers set out in section 55(2) of the ises named in this warrant with such mably necessary during the time
			Signature of Justice of the Peace
			Date

As at 04 Apr 2006 Version 07-h0-04 page 127 (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 Jun 1967 p. 1582-3; 22 Sep 1969 p. 2876; 3 May 1974 p. 1435; 5 Oct 1979 p. 3085-6; 7 Jun 1985 p. 1941; 23 May 1986 p. 1716; 15 May 1987 p. 2121; 2 Oct 1987 p. 3776; 27 May 1988 p. 1771; 2 Jun 1989 p. 1605; 17 Aug 1990 p. 4081; 12 Apr 1991 p. 1609; 14 Jun 1991 p. 2879; 16 Apr 1992 p. 1635; 25 Jun 1993 p. 3085; 26 May 1994 p. 2200 and 2201; 24 Jun 1994 p. 2869; 16 Sep 1994 p. 4748-9; 27 Jun 1995 p. 2550; 19 Mar 1996 p. 1234-8; 23 Aug 1996 p. 4089; 14 Sep 2001 p. 5077; 30 Dec 2004 p. 6943; 4 Apr 2006 p. 1406-7.]
```

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

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

[Appendix F repealed in Gazette 1 Aug 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.	Wholesaler's Licence	600	850	175	425
[2.	deleted]				
3.	Pharmaceutical chemist's licence to sell poisons	100	200	75	175
5.	Licence to sell by retail, poisons included in Schedule 2 to the <i>Poisons Act 1964</i>	100	150	50	100
6.	Licence to sell by retail, poisons included in Schedule 7 to the <i>Poisons Act 1964</i>	200	300	75	175
6B.	Poisons permit (Distribution of samples)	100	150	50	100
7.	Poisons permit (Industrial) —				
	(a) for poisons other than those set out in this item	200	300	75	175
	(b) for any one or more of the poisons set out in this item	575	1275	425	1125
	• benzene;				
	• 4,4-diaminodiphenylme	thane (Methy	lene dianiline	);	
	• 4,4'-methylenebis(2-ch	loroaniline);			
8.	Poisons permit (Educational, advisory or research)	100	150	50	100
8AA.	Poisons permit (Health services)	200	300	75	175
11AA	A. Stockfeed manufacturer's permit	200	300	75	175
13.	Poisons permit (Departmental and hospitals) —				
	(a) Departmental	100	150	50	100
	(b) Hospitals	No fee	No fee	No fee	No fee

[Appendix G inserted in Gazette 19 Mar 1996 p. 1238-9; amended in Gazette 11 Apr 1997 p. 1833-4; 14 Sep 2001 p. 5077; 4 Apr 2006 p. 1407.]

As at 04 Apr 2006 Version 07-h0-04 page 129

## 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 Feb 1985 p. 520 (erratum in Gazette 19 Apr 1985 p. 1409); amended in Gazette 19 Mar 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.

[Appendix J inserted in Gazette 20 Sep 1985 p. 3743; amended in Gazette 23 May 1986 p. 1721; 23 Jan 1987 p. 187; 7 Aug 1987 p. 3084; 27 May 1988 p. 1771; 9 Dec 1988 p. 4825; 30 Nov 1990 p. 5908; 26 Jul 1991 p. 3855; 13 Dec 1991 p. 6191; 28 May 1993 p. 2597; 16 Sep 1994 p. 4749; 3 Feb 1995 p. 343; 19 Mar 1996 p. 1239.]

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

NICOTINE, when included in Schedule 3.

As at 04 Apr 2006 Version 07-h0-04 page 131

## Appendix L

(Regulations 37 and 51)

#### Specified criteria for the generation of prescriptions by computer

1.

The computer system shall be designed so that —

- the prescription can be generated by the prescriber only; (a)
- (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;
- 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;
- the directions for use must be determined and included on (d) 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;
- a number which uniquely identifies each prescription form is (f) printed on the form which is related to the clinical or prescription record of the person or animal for whom that prescription was generated;
- the clinical or prescription record of the person or animal for (g) 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

page 132 Version 07-h0-04 As at 04 Apr 2006 computer-printed details, and the system shall allow space on the prescription for these handwritten details.

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

## Appendix M

[Regulations 56(1) and (2)]

### Safes and additional security for storing drugs of addiction

#### 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* <sup>4</sup> 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* <sup>5</sup> 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.

page 134 Version 07-h0-04 As at 04 Apr 2006

#### 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* <sup>1</sup>.
- (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* <sup>4</sup> as a security agent or guard to install that kind of device and alarm control panel.

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

As at 04 Apr 2006 Version 07-h0-04 page 135

#### **Notes**

This is a compilation of the *Poisons Regulations 1965* and includes the amendments made by the other written laws referred to in the following table <sup>1a</sup>. The table also contains information about any reprint.

## **Compilation table**

	-	
Citation	Gazettal	Commencement
Poisons Act Regulations 1965 <sup>6</sup>	29 Jun 1965 p. 1883-914	1 Jul 1965
	10 Feb 1966 p. 410	10 Feb 1966
	16 Nov 1966 p. 2935	16 Nov 1966
	14 Jun 1967 p. 1582-3	14 Jun 1967
	25 Oct 1967 p. 2962	25 Oct 1967
	4 Jun 1968 p. 1694-5	4 Jun 1968
	28 Nov 1968 p. 3457-8	28 Nov 1968
	22 Sep 1969 p. 2874-6	22 Sep 1969
	22 Sep 1969 p. 2877	22 Sep 1969
	9 Feb 1970 p. 370	9 Feb 1970
	12 Aug 1970 p. 2542-3	12 Aug 1970
	11 Dec 1970 p. 3752	11 Dec 1970
	12 Feb 1971 p. 425	12 Feb 1971
	19 Feb 1971 p. 518-21	19 Feb 1971

Extract from www.slp.wa.gov.au, see that website for further information

Citation	Gazettal	Commencement
	26 May 1971 p. 1771-3	26 May 1971
	7 Sep 1971 p. 3277-9	7 Sep 1971
	23 Dec 1971 p. 5318	23 Dec 1971

Reprint of the *Poisons Act Regulations 1965* authorised 12 Jul 1972 published in *Gazette* 25 Jul 1972 p. 2755-801 (includes amendments listed above except those in *Gazette* 23 Dec 1971)

	22 Feb 1974 p. 553	22 Feb 1974
	3 May 1974 p. 1434-5	3 May 1974
	15 Apr 1976 p. 1183	15 Apr 1976
	26 Aug 1977 p. 2966-73	26 Aug 1977
	4 Nov 1977 p. 4087	4 Nov 1977
	20 Oct 1978 p. 3760	20 Oct 1978
	1 Jun 1979 p. 1437	1 Jul 1979
	5 Oct 1979 p. 3085-6	5 Oct 1979
	7 Dec 1979 p. 3799-805	7 Dec 1979
	29 Aug 1980 p. 3027-31	1 Oct 1980 (see <i>Gazette</i> 29 Aug 1980 p. 3015)
Poisons Act Amendment Regulations 1980	7 Nov 1980 p. 3746	7 Nov 1980

Reprint of the *Poisons Act Regulations 1965* authorised 7 Sep 1981 published in *Gazette* 15 Sep 1981 p. 3975-4029 (includes amendments listed above)

Poisons Act Amendment 6 Nov 1981 6 Nov 1981 Regulations 1981 p. 4527

As at 04 Apr 2006 Version 07-h0-04 page 137

Citation	Gazettal	Commencement
Poisons Amendment Regulations 1982	16 Jul 1982 p. 2727-8	16 Jul 1982
Poisons Amendment Regulations (No. 2) 1982	24 Dec 1982 p. 4904	24 Dec 1982
Poisons Amendment Regulations 1983	28 Jan 1983 p. 341	28 Jan 1983
Poisons Amendment Regulations (No. 2) 1983	23 Sep 1983 p. 3803-7	23 Sep 1983
Poisons Amendment Regulations 1984	6 Apr 1984 p. 928 (erratum 13 Apr 1984 p. 1020)	6 Apr 1984
Health Legislation Amendment Regulations 1984	29 Jun 1984 p. 1780-4	1 Jul 1984 (see r. 2)
Poisons Amendment Regulations (No. 2) 1984	12 Oct 1984 p. 3267	12 Oct 1984
Poisons Amendment Regulations 1985	8 Feb 1985 p. 519-20 (erratum 19 Apr 1985 p. 1409)	8 Feb 1985
Poisons Amendment Regulations (No. 2) 1985	8 Feb 1985 p. 520-1	8 Feb 1985
Poisons Amendment Regulations (No. 3) 1985	15 Mar 1985 p. 941-54 (erratum 29 Mar 1985 p. 1110)	15 Mar 1985
Poisons Amendment Regulations (No. 5) 1985	12 Apr 1985 p. 1285-6	1 Jul 1985 (see r. 2)
Poisons Amendment Regulations (No. 6) 1985	31 May 1985 p. 1882	31 May 1985
Poisons Amendment Regulations (No. 4) 1985	7 Jun 1985 p. 1941	7 Jun 1985
Poisons Amendment Regulations (No. 6) 1985	5 Jul 1985 p. 2392	5 Jul 1985

Version 07-h0-04
Extract from www.slp.wa.gov.au, see that website for further information As at 04 Apr 2006 page 138

Citation	Gazettal	Commencement
Poisons Amendment Regulations (No. 8) 1985	20 Sep 1985 p. 3743	20 Sep 1985
Poisons Amendment Regulations 1986	31 Jan 1986 p. 332-3	31 Jan 1986
Poisons Amendment Regulations (No. 2) 1986	28 Feb 1986 p. 616-17	28 Feb 1986
Poisons Amendment Regulations (No. 3) 1986	28 Feb 1986 p. 618	28 Feb 1986
Poisons Amendment Regulations (No. 4) 1986	23 May 1986 p. 1716-20 (erratum 20 Jun 1986 p. 2049-54)	23 May 1986
Poisons Amendment Regulations (No. 5) 1986	23 May 1986 p. 1721 (erratum 30 May 1986 p. 1769)	23 May 1986
Poisons Amendment Regulations (No. 7) 1986	11 Jul 1986 p. 2339-40	15 Jul 1986
Poisons Amendment Regulations (No. 6) 1986	1 Aug 1986 p. 2739	1 Aug 1986
Poisons Amendment Regulations (No. 8) 1986	21 Nov 1986 p. 4269	21 Nov 1986
Poisons Amendment Regulations (No. 9) 1986	21 Nov 1986 p. 4270	21 Nov 1986
Poisons Amendment Regulations (No. 10) 1986	5 Dec 1986 p. 4466-7	5 Dec 1986
Poisons Amendment Regulations (No. 12) 1986	19 Dec 1986 p. 4874-5	19 Dec 1986
Poisons Amendment Regulations 1987	23 Jan 1987 p. 187	23 Jan 1987
Poisons Amendment Regulations (No. 2) 1987	20 Mar 1987 p. 954	20 Mar 1987
Poisons Amendment Regulations (No. 3) 1987	15 May 1987 p. 2121	15 May 1987

As at 04 Apr 2006 Version 07-h0-04 Extract from www.slp.wa.gov.au, see that website for further information page 139

Citation	Gazettal	Commencement		
Reprint of the <i>Poisons Regulations 1965</i> as at 22 Jul 1987 published in <i>Gazette</i> 5 Aug 1987 p. 2987-3078 (includes amendments listed above)				
Poisons Amendment Regulations (No. 4) 1987	7 Aug 1987 p. 3083-4	7 Aug 1987		
Poisons Amendment Regulations (No. 5) 1987	18 Sep 1987 p. 3596	18 Sep 1987		
Poisons Amendment Regulations (No. 6) 1987	2 Oct 1987 p. 3776	2 Nov 1987 (see r. 2)		
Poisons Amendment Regulations 1988	18 Mar 1988 p. 838-52	18 Mar 1988		
Poisons Amendment Regulations (No. 2) 1988	18 Mar 1988 p. 837	18 Mar 1988		
Poisons Amendment Regulations (No. 3) 1988	27 May 1988 p. 1769-71	27 May 1988		
Poisons Amendment Regulations (No. 4) 1988	11 Nov 1988 p. 4443-4	11 Nov 1988		
Poisons Amendment Regulations (No. 5) 1988	9 Dec 1988 p. 4825	9 Dec 1988		
Poisons Amendment Regulations 1989	2 Jun 1989 p. 1603-5	2 Jun 1989		
Poisons Amendment Regulations (No. 2) 1989	16 Jun 1989 p. 1742	1 Jul 1989 (see r. 3)		
Poisons Amendment Regulations (No. 3) 1989	25 Aug 1989 p. 2842	25 Aug 1989		
Poisons Amendment Regulations (No. 4) 1989	25 Aug 1989 p. 2842	25 Aug 1989		
Poisons Amendment Regulations (No. 3) Amendment Regulations 1989	6 Oct 1989 p. 3738	6 Oct 1989		
Poisons Amendment Regulations 1990	8 Jun 1990 p. 2626-7	8 Jun 1990		
Poisons Amendment Regulations (No. 2) 1990	22 Jun 1990 p. 3035	22 Jun 1990		
Poisons Amendment Regulations (No. 3) 1990	17 Aug 1990 p. 4080-1	17 Aug 1990		

As at 04 Apr 2006 page 140

Citation	Gazettal	Commencement
Poisons Amendment Regulations (No. 4) 1990	23 Nov 1990 p. 5790-2	1 Jan 1991 (see r. 2)
Poisons Amendment Regulations (No. 5) 1990	30 Nov 1990 p. 5908	30 Nov 1990
Poisons Amendment Regulations 1991	12 Apr 1991 p. 1608-9	12 Apr 1991
Poisons Amendment Regulations (No. 2) 1991	14 Jun 1991 p. 2879	14 Jun 1991
Poisons Amendment Regulations (No. 4) 1991	28 Jun 1991 p. 3149	1 Jul 1991 (see r. 2)
Poisons Amendment Regulations (No. 3) 1991	26 Jul 1991 p. 3854-5	26 Jul 1991
Poisons Amendment Regulations (No. 5) 1991	13 Dec 1991 p. 6090-1	13 Dec 1991
Poisons Amendment Regulations 1992	16 Apr 1992 p. 1634-5	16 Apr 1992
Poisons Amendment Regulations (No. 2) 1992	26 Jun 1992 p. 2700	1 Aug 1992 (see r. 2)
Poisons Amendment Regulations (No. 3) 1992	7 Aug 1992 p. 3868-9	7 Aug 1992
Poisons Amendment Regulations (No. 4) 1992	7 Aug 1992 p. 3864-6	7 Aug 1992
Reprint of the <i>Poisons Regulations</i> above)	1965 as at 7 Jan 1	993 (includes amendments listed
Poisons Amendment Regulations 1993	28 May 1993 p. 2595-7	28 May 1993
Poisons Amendment Regulations (No. 2) 1993	25 Jun 1993 p. 3078-85	25 Jun 1993
Poisons Amendment Regulations (No. 3) 1993	9 Jul 1993 p. 3329	1 Aug 1993 (see r. 2)
Poisons Amendment Regulations (No. 4) 1993	1 Oct 1993 p. 5360-1	1 Nov 1993 (see r. 2)
Poisons Amendment Regulations (No. 5) 1993	12 Nov 1993 p. 6146-7	12 Nov 1993

As at 04 Apr 2006 Version 07-h0-04 Extract from www.slp.wa.gov.au, see that website for further information page 141

Citation	Gazettal	Commencement
Poisons Amendment Regulations (No. 7) 1993	31 Dec 1993 p. 6883-5	31 Dec 1993
Poisons Amendment Regulations 1994	26 May 1994 p. 2195-201	26 May 1994
Poisons Amendment Regulations (No. 2) 1994	24 Jun 1994 p. 2864-70	24 Jun 1994
Poisons Amendment Regulations (No. 3) 1994	24 Jun 1994 p. 2854-5	1 Aug 1994 (see r. 2)
Poisons Amendment Regulations (No. 5) 1994	2 Sep 1994 p. 4532-3	2 Sep 1994
Poisons Amendment Regulations (No. 6) 1994	16 Sep 1994 p. 4748-9	16 Sep 1994
Poisons Amendment Regulations (No. 7) 1994	23 Dec 1994 p. 7076	23 Dec 1994
Poisons Amendment Regulations (No. 9) 1994	3 Feb 1995 p. 341-3	3 Feb 1995
Poisons Amendment Regulations 1995	17 Mar 1995 p. 1026-7	17 Mar 1995
Poisons Amendment Regulations (No. 2) 1995	28 Apr 1995 p. 1466	28 Apr 1995
Poisons Amendment Regulations (No. 3) 1995	28 Apr 1995 p. 1466-7	1 Jun 1995 (see r. 2)
Poisons Amendment Regulations (No. 4) 1995	27 Jun 1995 p. 2550-1	1 Jul 1995 (see r. 2)
Poisons Amendment Regulations (No. 6) 1996	5 Sep 1995 p. 4162	5 Sep 1995
Poisons Amendment Regulations (No. 5) 1995	19 Sep 1995 p. 4382-4	19 Sep 1995
Poisons Amendment Regulations 1996	17 Jan 1996 p. 267	17 Jan 1996
Poisons Amendment Regulations (No. 2) 1996	19 Mar 1996 p. 1216-39	20 Mar 1996 (see r. 2 and <i>Gazette</i> 19 Mar 1996 p. 1203)
Poisons Amendment Regulations (No. 4) 1996	23 Aug 1996 p. 4088-9	23 Aug 1996

page 142 Version 07-h0-04
Extract from www.slp.wa.gov.au, see that website for further information As at 04 Apr 2006

Citation	Gazettal	Commencement
Poisons Amendment Regulations (No. 5) 1996	1 Oct 1996 p. 5088	1 Oct 1996
<b>Reprint of the </b> <i>Poisons Regulations</i> above) (correction in <i>Gazette</i> 29 Nov		1996 (includes amendments listed
Poisons Amendment Regulations 1997	11 Apr 1997 p. 1828-34	11 Apr 1997
Poisons Amendment Regulations 1998	17 Mar 1998 p. 1417	17 Mar 1998
Poisons Amendment Regulations (No. 2) 1998	26 May 1998 p. 2966-7	19 Jun 1998 (see r. 2)
Poisons Amendment Regulations (No. 3) 1998	27 Nov 1998 p. 6343-4	27 Nov 1998
Poisons Amendment Regulations 1999	19 Feb 1999 p. 554-6	19 Feb 1999
Poisons Amendment Regulations 2000	29 Feb 2000 p. 992-5	29 Feb 2000
Reprint of the <i>Poisons Regulations</i> above)	<i>1965</i> as at 12 May	y 2000 (includes amendments listed
Poisons Amendment Regulations 2001	29 Jun 2001 p. 3115-18	29 Jun 2001
Poisons Amendment Regulations (No. 2) 2001	14 Aug 2001 p. 4253	14 Aug 2001
Poisons Amendment Regulations (No. 3) 2001	14 Sep 2001 p. 5073-7	14 Sep 2001
Poisons Amendment Regulations (No. 4) 2001	16 Nov 2001 p. 5985	16 Nov 2001
Poisons Amendment Regulations 2002	13 Aug 2002 p. 4181	13 Aug 2002
Reprint 7: The <i>Poisons Regulations</i> above)	1965 as at 10 Jan	a 2003 (includes amendments listed
Nurses Amendment Act 2003 Pt. 3 Div. 5 assented to 9 Apr 2003 <sup>7</sup>		9 Apr 2003 (see s. 2)
Poisons Amendment Regulations 2003	12 Aug 2003 p. 3658-65	12 Aug 2003

As at 04 Apr 2006 Version 07-h0-04 Extract from www.slp.wa.gov.au, see that website for further information page 143

Citation	Gazettal	Commencement
Poisons Amendment Regulations 2004	5 Oct 2004 p. 4309-11	5 Oct 2004
Poisons Amendment Regulations (No. 3) 2004	30 Dec 2004 p. 6943	1 Jan 2005 (see r. 2 and <i>Gazette</i> 31 Dec 2004 p. 7130)
Poisons Amendment Regulations (No. 2) 2004	4 Jan 2005 p. 3-4	4 Jan 2005
Poisons Amendment Regulations 2005	15 Nov 2005 p. 5602-8	1 Jan 2006 (see r. 2)
Poisons Amendment Regulations 2006	4 Apr 2006 p. 1406-7	4 Apr 2006

Repealed by the *Mental Health Act 1981* which was repealed by the *Mental Health Act 1996*.

"

(2) A licence issued under regulation 4 of the *Poisons*\*Regulations 1965 and in force immediately before the day on which this regulation commences, continues in force on and after that day, as if it were a licence issued under regulation 3 of those regulations as amended by this regulation.

<sup>4</sup> Renumbering of regulation 41 to regulation 40A effected by amendment in *Gazette* 19 March 1996 p. 1225.

Repealed by the Security and Related Activities (Control) Act 1996.

Now known as the *Poisons Regulations 1965*; citation amended (see note to r. 1).

The *Nurses Amendment Act 2003* s. 50 reads as follows:

"

#### 50. Existing power to amend regulations unaffected

Nothing in this Division prevents any of the *Poisons Regulations 1965* from being amended in accordance with the *Poisons Act 1964*.

,,

page 144 Version 07-h0-04 As at 04 Apr 2006

The *Poisons Amendment Regulations (No. 3) 2001* r. 4(2) reads as follows: