South Australia

Controlled Substances (Poisons) Regulations 2011

under the *Controlled Substances Act 1984*

Contents

Part 1—Preliminary

1—Short title

These regulations may be cited as the *Controlled Substances (Poisons) Regulations 2011*.

3—Interpretation

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

Act means the *Controlled Substances Act 1984*;

address means street address;

approved electronic communication means an electronic communication of a kind approved from time to time by the Minister;

approved electronic form, in relation to a prescription for a drug, means—

(a) a form approved from time to time by the Secretary under the Commonwealth Regulations; or

(b) a form approved from time to time by the Minister,

for the giving of prescriptions for drugs in electronic form;

approved information technology requirements means information technology requirements approved from time to time by the Minister;

APVMA means the Australian Pesticides and Veterinary Medicines Authority of the Commonwealth;

Australian jurisdiction means the Commonwealth or a State or Territory of the Commonwealth;

Chief Executive has the same meaning as in the *Health Care Act 2008*;

Commonwealth Regulations means the *National Health (Pharmaceutical Benefits) Regulations 2017* of the Commonwealth;

correctional institution has the same meaning as in the *Correctional Services Act 1982*;

council has the same meaning as in the *Local Government Act 1999*;

council subsidiary means a subsidiary of a council established under the *Local Government Act 1999*;

data source entity means any of the following:

(a) eRx Script Exchange Pty Ltd;

(b) MediSecure Pty Ltd;

(c) Medication Knowledge Pty Ltd;

(d) a prescription exchange service operating in an Australian jurisdiction;

dental hygienist means a person registered under the *Health Practitioner Regulation National Law*—

(a) to practise in the dental profession (other than as a student); and

(b) in the dental hygienists division of that profession;

dental therapist means a person registered under the *Health Practitioner Regulation National Law*—

(a) to practise in the dental profession (other than as a student); and

(b) in the dental therapists division of that profession;

diesel fuel means a petroleum or shale product used or capable of being used in propelling a diesel engined motor vehicle;

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

domestic partner means a person who is a domestic partner within the meaning of the *Family Relationships Act 1975*, whether declared as such under that Act or not;

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

electronic communication has the same meaning as in the *Electronic Communications Act 2000*;

electronic prescription means a prescription given in an approved electronic form;

enrolled nurse means a person registered under the *Health Practitioner Regulation National Law*—

(a) to practise in the nursing and midwifery profession as a nurse (other than as a student); and

(b) in the enrolled nurses division of that profession;

health service facility means a hospital, nursing home or other facility at which a health service is provided for the public or any section of the public for the purpose of curing, alleviating, diagnosing or preventing the spread of any mental or physical illness, disease, injury, abnormality or disability;

information technology requirements has the same meaning as in the *Electronic Communications Act 2000*;

liquefied petroleum gas means a hydrocarbon fluid composed predominantly of any of the following hydrocarbons or mixtures of all or any of them:

(a) propane (C_3H_8);

(b) propylene (C_3H_6);

(c) butane (C_4H_{10});

(d) butylene (C_4H_8);

medication chart prescription has the same meaning as in the Commonwealth Regulations;

Metropolitan Adelaide means Metropolitan Adelaide as defined by the *Development Act 1993* immediately before 1 July 2019;

monitored drug means any of the following:

(a) any S8 poison;

(b) any S4 poison that is a benzodiazepine;

(c) any S4 poison that contains Codeine;

(d) any of the following S4 poisons:

(i) Gabapentin;

(ii) Pregabalin;

(iii) Quetiapine;

(iv) Tramadol;

(v) Zolpidem;

(vi) Zopiclone;

monitored drugs database means an electronic database kept by the Department that contains information relating to the sale, supply, prescription, administration and use of monitored drugs;

motor spirit means petrol or another petroleum or shale product used or capable of being used in propelling a motor vehicle (other than diesel fuel or liquefied petroleum gas);

National Health Act means the *National Health Act 1953* of the Commonwealth;

National Health (Continued Dispensing) Determination means the determination of that name, as in force from time to time, made under section 89A(3) of the National Health Act;

optometrist means a person registered under the *Health Practitioner Regulation National Law* to practise in the optometry profession (other than as a student);

oral health therapist means a person registered under the *Health Practitioner Regulation National Law*—

(a) to practise in the dental profession (other than as a student); and

(b) in the oral health therapists division of that profession;

petroleum product means a volatile solvent comprised of—

(a) motor spirit; or

(b) diesel fuel; or

(c) liquefied petroleum gas;

pharmaceutical benefit has the same meaning as in Part VII of the National Health Act;

podiatrist means a person registered under the *Health Practitioner Regulation National Law* to practise in the podiatry profession (other than as a student);

poison—see regulation 5;

prescribed (continued dispensing) pharmaceutical benefit means a pharmaceutical benefit listed in the National Health (Continued Dispensing) Determination as a pharmaceutical benefit that may be supplied under section 89A of the National Health Act by approved pharmacists without a prescription;

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

record means—

(a) a documentary record; or

(b) a record made by an electronic, electromagnetic, photographic or optical process; or

(c) any other kind of record;

registered nurse means a person registered under the *Health Practitioner Regulation National Law*—

(a) to practise in the nursing and midwifery profession as a nurse (other than as a student); and

(b) in the registered nurses division of that profession;

scheduled medicine means a medicine that contains a substance included in a schedule of the Uniform Poisons Standard;

S4 drug means—

(a) an S4 poison; or

(b) a substance designed for human or animal therapeutic use that has been approved by—

(i) the TGA for inclusion in the Australian Register of Therapeutic Goods; or

(ii) APVMA for inclusion in the Public Chemical Registration Information System (PUBCRIS),

but has not yet been—

(c) listed in some other schedule of the Uniform Poisons Standard; or

(d) exempted from listing in the Uniform Poisons Standard;

section 22 poison means a poison to which section 22 of the Act applies by virtue of regulation 25;

spouse—a person is the spouse of another if they are legally married;

TGA means the Therapeutic Goods Administration of the Commonwealth;

Uniform Poisons Standard means the current Poisons Standard as defined in the Commonwealth Act and as modified by deleting Sections 54(1) and (2), 57, 58, 59, 60 and 64 and Appendices B, D and J;

Vaccine Administration Code means the document of that name published by the Department as in force from time to time.

(2) In these regulations, a reference to an ***S1 poison*** is a reference to a poison listed in Schedule 1 of the Uniform Poisons Standard, a reference to an ***S2 poison*** is a reference to a poison listed in Schedule 2 of the Uniform Poisons Standard, and so on.

(3) In these regulations, ***incorporated hospital*** and ***SAAS*** have the same respective meanings as in the *Health Care Act 2008*.

(4) For the purposes of these regulations—

(a) an electronic prescription for a drug is ***presented*** when it is accessed electronically for the purpose of dispensing the drug; and

(b) a prescription for a drug given to a pharmacist by fax is ***presented*** when a faxed copy of the prescription is transmitted to the pharmacy at which the drug is to be dispensed.

4—Application of regulations

These regulations do not apply in relation to—

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

(b) a poison listed in Appendix G of the Uniform Poisons Standard when contained in a preparation in a concentration not exceeding the concentration specified in Appendix G for that poison; or

(c) a poison that is listed in any of the Schedules 1 to 6 (but is not listed in Schedule 7 or 8) of the Uniform Poisons Standard when contained in a preparation in a concentration not exceeding 10 milligrams per litre or 10 milligrams per kilogram.

Part 2—Controlled substances

5—Declaration of poisons (section 12(1) of Act)

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

(a) the primary substances listed in Schedules 1 to 8 and Schedule 10 of the Uniform Poisons Standard;

(b) section 17A, 17B and 17C precursors;

(c) the following related substances, but subject to any express exclusion contained in the Uniform Poisons Standard:

(i) the artificial form of a primary substance;

(ii) if a primary substance is a plant (other than a plant included in Schedule 8 of the Uniform Poisons Standard)—that plant, or any part of that plant, when packed or prepared for therapeutic use;

(iii) every salt, active principle or derivative (including an ester or ether) of a primary substance and every salt of such an active principle or derivative;

(iv) every alkaloid of a primary substance and every salt of such an alkaloid;

(v) every stereoisomer of a primary substance and every salt of such a stereoisomer.

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

(3) A reference in these regulations to a poison will be taken to include a reference to the primary substance and its related substances (in each case whether in a pure form, or contained in a preparation or admixture).

6—Declaration of prescription drugs (section 12(2) of Act)

Pursuant to section 12(2) of the Act, S4 poisons and S8 poisons are declared to be prescription drugs.

7—Declaration of drugs of dependence (section 12(3) of Act)

Pursuant to section 12(3) of the Act, S8 poisons are declared to be drugs of dependence.

8—Declaration of volatile solvents (section 12(7) of Act)

Pursuant to section 12(7) of the Act, the following are declared to be volatile solvents:

(a) the following substances (whether in their natural or artificial form):

Acetone (dimethyl ketone, propanone)

Amyl nitrite (isopentyl nitrite)

Bromochlorodifluoromethane (BCF)

Butane

Butanone (methyl ethyl ketone)

Butyl nitrite

Carbon tetrachloride

Chlorofluorocarbons and fluorocarbons except where separately specified

Chloroform

Dichloromethane (methylene chloride)

Diethyl ether (ethoxyethane)

Dimethyl ether (methoxymethane)

Enflurane

Ethyl acetate

Ethyl chloride (chloroethane)

Halothane

Heptane

Hexane

Isoamyl nitrite

Isobutane (2-methylpropane)

Isobutyl nitrite (2-methylpropyl nitrite)

Isoflurane

Methoxyflurane

Methyl acetate

Methyl isobutyl ketone (4-methylpentan-2-one)

Methyl tert-butyl ether

Nitrous oxide

Octane

Octyl nitrite

Pentane

Petrol

Propane

Sevoflurane

Tetrachloroethylene (perchloroethylene, tetrachloroethene)

Toluene (methylbenzene)

1,1,1-trichloroethane (methylchloroform)

Trichloroethylene (trichloroethene)

Xylene (xylol);

(b) structural isomers of a substance specified in paragraph (a);

(c) preparations or admixtures containing any proportion of a substance specified in paragraph (a);

(d) preparations or admixtures containing any proportion of structural isomers of a substance specified in paragraph (a).

Part 3—Application of Part 4 of Act (general offences)

9—Manufacture, production and packing (section 13 of Act)

Section 13 of the Act applies to all S1 poisons, S2 poisons, S3 poisons and S7 poisons.

10—Exemption from section 13 of Act

The holder of a licence under the Commonwealth Act to manufacture goods is exempt from the requirement to hold a licence under section 13 of the Act in respect of the manufacture of those goods.

11—Sale by wholesale (section 14 of Act)

Section 14 of the Act applies to all S1 poisons, S2 poisons, S3 poisons and S7 poisons.

12—Sale or supply to end user (section 15 of Act)

(1) Section 15 of the Act applies to all S1 poisons, S2 poisons, S3 poisons and S7 poisons.

(2) A council, council subsidiary or health service facility is exempt from section 15 of the Act in respect of the supply by the council, council subsidiary or health service facility of adrenaline for administration to a person as part of an immunisation program delivered by the council, council subsidiary or health service facility.

13—Directions to be given for safe and proper use of S3 poisons sold by retail etc

(1) Subject to subregulation (2), a person who sells by retail or supplies an S3 poison must personally (not through an assistant) give oral directions, supplemented wherever practicable with written directions, for the safe and proper use of the poison to the person purchasing or being supplied with the poison.

Maximum penalty: $3 000.

(2) An interpreter may be used to assist in the giving of oral directions if the person purchasing or being supplied with the poison is not sufficiently familiar with the English language.

14—Special provisions relating to sale or supply of pseudoephedrine

(1) A person must not sell or supply pseudoephedrine unless a prescribed identification document or a birth certificate is produced by the person to whom the pseudoephedrine is to be sold or supplied.

Maximum penalty: $3 000.

(2) A person who sells or supplies pseudoephedrine must make and keep a record of the following information:

(a) the name and address of the person to whom the pseudoephedrine is being sold or supplied;

(b) the form of prescribed identification document produced by the person to whom the pseudoephedrine is being sold or supplied;

(c) the unique identification number (if any) on the prescribed identification document produced;

(d) the date of the sale or supply;

(e) the directions given for the safe and proper use of the pseudoephedrine;

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

(g) a unique identifier enabling those records to be linked with the pseudoephedrine sold or supplied.

Maximum penalty: $3 000.

(3) Subregulations (1) and (2) do not apply in relation to—

(a) the sale of pseudoephedrine by wholesale; or

(b) the sale or supply of pseudoephedrine in the course of professional practice by—

(i) a pharmacist in a hospital; or

(ii) a registered health practitioner other than a pharmacist; or

(iii) a veterinary surgeon.

(4) A person who makes a record under subregulation (2) must keep it in an electronic form that is accessible via the internet by the Chief Executive and the Commissioner of Police.

Maximum penalty: $3 000.

(5) In this regulation—

Australian student identification card means a card issued by an Australian educational institution to identify a person studying at the institution;

birth certificate of a person means a certified copy of, or extract from, a register of births kept under an Australian law, or under the law of the country in which the person was born;

driver's licence means—

(a) a driver's licence issued under the *Motor Vehicles Act 1959*; or

(b) an interstate licence, interstate learner's permit or foreign licence within the meaning of that Act;

prescribed identification document means a current—

(a) driver's licence; or

(b) firearms licence; or

(c) passport (other than an Australian passport); or

(d) proof of age card; or

(e) Australian student identification card,

that bears a photograph of the holder;

proof of age card means a proof of age card issued by the Registrar of Motor Vehicles or by a corresponding public authority of another State or a Territory of the Commonwealth.

15—Sale of certain poisons (section 16 of Act)

(1) Section 16 of the Act applies to all S7 poisons.

(2) For the purposes of section 16(4) of the Act, a person who sells S7 poisons must keep records of such matters as are specified in Part 2 Section 56(1) of the Uniform Poisons Standard.

16—Declaration of precursors (sections 17A, 17B and 17C of Act)

(1) Section 17A of the Act applies to the following poisons:

1-Chlorophenyl-2-aminopropane

3,4-Methylenedioxyphenylpropan-2-one (PMK)

1-Phenyl-2-bromopropane

1-Phenyl-1-chloro-2-methylaminopropane

1-Phenyl-2-chloropropane

1-Phenyl-2-iodopropane

1-Phenyl-2-nitropropene.

(2) Section 17B of the Act applies to the following poisons:

Chemical name	Alternative name	CAS number
Acetic anhydride		108-24-7
4-Allylpyrocatechol	2-Hydroxychavicol	1126-61-0
alpha Phenylacetonitrile	alpha Acetyl Phenylacetonitrile	4468-48-8
4-Amino-butanoic acid	Piperidinic acid	56-12-2
Anethole	trans-Anethole	4180-23-8
		104-46-1
Bromobenzene	Phenylbromide	108-86-1
Bromosafrole		38589-39-8
Boron tribromide		10294-33-4
1,4-Butanediol	Tetramethylene Glycol	110-63-4
1-Chlorophenyl-2-aminopropane		
Ephedrine (including salts)	L-Ephedrine	50-98-6
Ethyl phenylacetate	Benzene acetic acid, ethyl ester	101-97-3
Gamma butyrolactone		96-48-0
Gamma hydroxybutanoic acid (including salts)	Gamma hydroxybutyric acid	
Hydriodic acid	Hydrogen iodide	10034-85-2
4-Hydroxybutanal	4-Hydroxybutyraldehyde	5371-52-8
2-Hydroxytetrahydrofuran	Tetrahydro-2-furanol	1346-46-9
4-Hydroxybutanoic acid lactone	Gamma-valerolactone	9648-0
4-Hydroxybutanoic acid nitrile	4-Hydroxybutyronitrile	628-22-8
4-Hydroxypentanoic acid	Gamma Valerolactone	108-29-2
Hypophosphite salts		
Hypophosphorous acid	Phosphinic acid	6303-21-5
Lithium aluminium hydride	LAH	16853-85-3
Methcathinone	Ephedrone	
3,4-Methylenedioxy-phenylacetic acid	1,3-Benzodioxolo-5-acetic acid	2861-28-1
3,4-Methylenedioxyphenylpropan-2-one		4676-39-5
N-Methylephedrine		552-79-4
Methyl phenylacetate	Benzeneacetic acid, methyl ester	101-41-7
N-Methylpseudoephedrine		51018-28-1
Norpseudoephedrine		53643-20-2
2-Pyrrolidone	Gamma-butyrolactam	616-45-5
Phenylacetamide		103-81-1

Chemical name	Alternative name	CAS number
Phenylacetic acid (including salts)		103-82-2
Phenylacetonitrile	Benzyl cyanide/Benzeneacetonitrile/ Benzyl nitrile	140-29-4
Phenylacetyl chloride		103-80-0
1-Phenyl-2-bromopropane	(+-)-2-Bromo-1-phenylpropane	2114-39-8
1-Phenyl-2-chloropropane		
1-Phenyl-2-iodopropane	(2-Iodopropyl)benzene	29527-87-5
1-Phenyl-2-nitropropene		
Phenylpropanolamine	Norephedrine	37577-28-9
1-Phenyl-2-propanone	Benzyl methyl ketone, Phenylacetone	103-79-7
1-Phenyl-2-propanone oxime		
1-Phenyl-2-propanol		14898-87-4
2-Phenyl-propanal	Hydratropic aldehyde	93-53-8
Phosphorus		7723-14-0
Phosphorous acid	Phosphonic Acid	10294-56-1
1-Phenyl-1-propanone	Phenylethylketone, Propiophenone	99-55-0
Piperonal	3,4-Methylenedioxy-benzaldehyde, Heliotropine	120-57-0
Pseudoephedrine (including salts)		
Pyridine		110-86-1
Safrole	5-(2-Propenyl)-1,3-Benzodioxide	94-59-7
Sassafras oil		8006-80-2
Sodium bis(2-methoxyethoxy) aluminium hydride	Sodium dihydrido-bis(2-methoxyethoxy) aluminate	22722-98-1
Sodium cyanoborohydride	Sodium borocyanohydride	25895-60-7

(3) Section 17C of the Act applies to the following poisons:

Acetaldehyde

N-Acetylanthranilic acid

Allylbenzene

Ammonium formate

Anthranilic acid

Benzaldehyde

1,3-benzodioxole

Benzyl bromide

Benzyl chloride

5-bromo-1,3-benzodioxole

Chromic acid (including salts)

Ergometrine

Ergotamine

Ethanamine

N-Ethylephedrine

N-Ethylpseudoephedrine

Eugenol

Formaldehyde

Formamide

Hydrobromic acid

Iodine (including iodide salts)

Isosafrole

Lithium

Lysergic acid

Magnesium

Mandelic acid

Mercuric chloride

Mercury

Methylamine

Methylammonium salts

N-methylformamide

Nitroethane

Nitromethane

Palladium (including salts)

Phenylalanine

Piperidine

Platinum

Potassium

Propionic anhydride

Raney nickel

Sodium

Sodium borohydride

Thionyl chloride

Thorium (including salts)

Trans-beta-methylstyrene.

17—End user statement for precursors (sections 17B and 17C of Act)

For the purposes of sections 17B(1)(c) and 17C(1)(a) of the Act, the form of end user statement in Schedule 1 is prescribed.

18—Regulation of prescription drugs—administration of certain S4 drugs (section 18(1d)(a)(iii) of Act)

(1) For the purposes of section 18(1d)(a)(iii) of the Act, a dental hygienist, dental therapist, oral health therapist or podiatrist is authorised to administer any of the following S4 drugs:

Articaine

Benzocaine

Bupivacaine

Levobupivacaine

Lignocaine

Mepivacaine

Prilocaine

Ropivacaine.

(2) For the purposes of section 18(1d)(a)(iii) of the Act, an optometrist is authorised to administer any of the following S4 drugs:

Eye drops containing 0.5% or less of amethocaine

Eye drops containing 1.0% or less of atropine sulphate

Eye drops containing 1.0% or less of cyclopentolate hydrochloride

Eye drops containing 2.0% or less of homatropine hydrobromide

Eye drops containing 0.5% or less of lignocaine

Eye drops containing 0.5% or less of oxybuprocaine

Eye drops containing 2.0% or less of pilocarpine nitrate

Eye drops containing 0.5% or less of proxymetacaine

Eye drops containing 1.0% or less of tropicamide.

(3) For the purposes of section 18(1d)(a)(iii) of the Act, a registered health practitioner of a class determined by the Minister may administer a prescription drug (not being a drug of dependence) to a person if—

(a) the registered health practitioner has successfully completed a training program approved by the Minister from time to time for the purposes of this subregulation; and

(b) the drug is listed in the Vaccine Administration Code or is a drug approved by the Minister from time to time for the purposes of this subregulation; and

(c) the drug is administered as part of—

(i) an immunisation program delivered by—

(A) an incorporated hospital; or

(B) SAAS; or

(C) a council or council subsidiary; or

(ii) an immunisation program delivered by an organisation approved by the Minister for the purposes of this subregulation; and

(d) the drug is administered in accordance with—

(i) the Vaccine Administration Code; and

(ii) —

(A) in the case of a drug administered as part of the *National Immunisation Program—the National Immunisation Program Schedule* and the *Australian Immunisation Handbook*; or

(B) in any other case—requirements specified by the Minister.

(4) In this regulation—

Australian Immunisation Handbook means *The Australian Immunisation Handbook* published by the Commonwealth Department of Health and Ageing, as in force from time to time;

National Immunisation Program Schedule means the *National Immunisation Program Schedule* published by the Commonwealth Department of Health and Ageing, as in force from time to time.

19—Regulation of prescription drugs—prescription of certain S4 drugs by medical practitioners (section 18(2) of Act)

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

(a) each of the S4 drugs listed in column 1 of the table below, when used for the purpose set out in column 2, is a prescribed prescription drug; and

(b) the qualifications and requirements specified in that table alongside a drug or list of drugs in column 3 are prescribed qualifications and requirements.

	Prescription drug	Use	Qualifications and requirements
1	Clomiphene Cyclofenil Follitropin alpha (recombinant human follicle stimulating hormone) Follitropin beta (recombinant human follicle stimulating hormone) Luteinising hormone Urofollitrophin (follicle stimulating hormone)	Human use	Medical practitioner who— (a) is registered in the specialty of endocrinology or obstetrics and gynaecology; or (b) provides services to a fertility unit, an endocrinology unit or obstetrics and gynaecology unit of a teaching hospital in South Australia.
2	Acitretin Bexarotene Etretinate	Human use	Medical practitioner who— (a) is registered in the specialty of dermatology, oncology or haematology; or (b) is a medical registrar working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is registered in some other specialty and is authorised by the Minister to prescribe such drugs.
3	Isotretinoin	Human internal use	Medical practitioner who— (a) is registered in the specialty of dermatology, oncology or haematology; or (b) is a medical registrar working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is registered in some other speciality and is authorised by the Minister to prescribe such drugs.

	Prescription drug	Use	Qualifications and requirements
4	Tretinoin	Human internal use	Medical practitioner who— (a) is registered in the specialty of oncology or haematology; or (b) is a medical registrar working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is registered in some other speciality and is authorised by the Minister to prescribe such drugs.
5	Lenalidomide Pomalidomide Thalidomide	Human use	A medical practitioner who— (a) is registered in the specialty of oncology or haematology; or (b) is a medical registrar working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is authorised by the Minister to prescribe such drugs.
6	Ambrisentan Bosentan Macitentan Sitaxentan	Human use	A medical practitioner who— (a) is registered as a specialist; or (b) is a medical registrar who is working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is authorised by the Minister to prescribe such drugs.
7	Enzalutamide	Human use	A medical practitioner who— (a) is registered as a specialist; or (b) is a medical registrar who is working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is authorised by the Minister to prescribe such drugs.

	Prescription drug	Use	Qualifications and requirements
8	Riociguat	Human use	A medical practitioner who— (a) is registered as a specialist; or (b) is a medical registrar who is working under the supervision of a medical practitioner referred to in paragraph (a); or (c) is authorised by the Minister to prescribe such drugs.

(2) A medical practitioner who prescribes an S4 drug listed in the table in subregulation (1) (other than in item 1) must—

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

(b) provide the patient with written information about the drug and its potential side effects; and

(c) inform the patient of the dangers should the patient unlawfully supply the drug to another person; and

(d) if the patient is a female of child-bearing age—

(i) ensure that the possibility of pregnancy has been excluded prior to commencement of treatment; and

(ii) inform her that she must not become pregnant during treatment or within the prescribed period after completion of treatment; and

(e) obtain written consent for the treatment from the patient.

Maximum penalty: $5 000.

(3) In this regulation—

prescribed period means—

(a) in the case of treatment with a drug listed in item 2 of the table in subregulation (1) (other than bexarotene)—24 months;

(b) in the case of treatment with bexarotene or a drug listed in item 3, 4, 5 or 8 of that table—1 month;

(c) in the case of treatment with a drug listed in item 6 or 7 of that table—3 months.

20—Regulation of prescription drugs—prescription of certain S8 poisons by medical practitioners (section 18(2) of Act)

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

(a) each of the S8 poisons listed in column 1 of the table below, when used for the purpose set out in column 2, is a prescribed prescription drug; and

(b) the qualifications and requirements specified in that table alongside a drug in column 3 are prescribed qualifications and requirements.

	Prescription drug	Use	Qualifications and requirements
1	N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA)	Human use, for the treatment of post-traumatic stress disorder	A medical practitioner— (a) who is registered in the specialty of psychiatry; and (b) for whom an authority under section 19(5) of the Commonwealth Act that covers MDMA is in force.
2	Psilocybine (Psilocybin)	Human use, for the treatment of treatment-resistant depression	A medical practitioner— (a) who is registered in the specialty of psychiatry; and (b) for whom an authority under section 19(5) of the Commonwealth Act that covers psilocybine is in force.

(2) A medical practitioner who prescribes an S8 poison listed in the table in subregulation (1) must, within 1 business day of prescribing the poison and for the purposes of the Chief Psychiatrist performing the Chief Psychiatrist's functions under the *Mental Health Act 2009*, give notice to the Chief Psychiatrist—

(a) in a form determined by the Chief Psychiatrist; and

(b) containing such information as the Chief Psychiatrist may determine.

21—Exemptions from section 18 of Act

(1) A council, council subsidiary or health service facility is exempt from section 18(1c)(d) of the Act in respect of the supply of an S4 drug under an immunisation program run by the council, council subsidiary or health service facility.

(2) A pharmacist who sells or supplies an S4 drug without dispensing a prescription is exempt from section 18(1b)(a) and (1c)(a) of the Act in relation to that sale or supply if—

(a) the drug is sold or supplied to a council, council subsidiary or health service facility for use in an immunisation program delivered by the council, council subsidiary or health service facility and the pharmacist has received a written order for the drug from the council, council subsidiary or health service facility; or

(b) the drug is for use by a person who holds a licence to sell, supply or administer an S4 drug and the pharmacist has received a written order for the drug from the licensee; or

(c) the drug is sold or supplied for the mass treatment of certain animals to the owner of the animals and—

(i) the pharmacist has received a written order for the drug from a veterinary surgeon; or

(ii) —

(A) the drug is an antibiotic; and

(B) the pharmacist has received a written order for the drug from an inspector appointed under the *Livestock Act 1997*; and

(C) the written order is on a form approved by the Chief Inspector of Stock under that Act and has been countersigned by the Chief Inspector; or

(d) the drug is sold or supplied to a registered health practitioner or veterinary surgeon authorised to sell, supply or administer S4 drugs and the pharmacist has received a written order for the drug from that practitioner or veterinary surgeon; or

(e) the drug is authorised or required by the law of any place to be carried on board a ship and the pharmacist has received a written order for the drug from the master or medical officer of the ship; or

(f) the drug is not one listed in the table in regulation 19(1) for the purposes of section 18(2) of the Act and the pharmacist—

(i) is satisfied that—

(A) the person for whom it is to be sold or supplied is being medically treated with the drug; and

(B) the continued sale or supply of that drug is essential to the health of that person; and

(C) there is good reason for the person's inability to produce a prescription for the drug; and

(ii) sells or supplies—

(A) where the pharmacist is satisfied that the person for whom it is to be sold or supplied is affected by an emergency specified by the Minister by notice under subregulation (2a) and the sale or supply occurs during the period specified in relation to that emergency in the same notice—

- for drugs that are on the Pharmaceutical Benefits Scheme—no more than the standard Pharmaceutical Benefits maximum quantity; or
- for drugs that are not on the Pharmaceutical Benefits Scheme—the quantity that is contained in the smallest standard pack in which the drug is generally available; or

(B) in any other case—

- if the drug is a cream, ointment or liquid or one that is packaged in such a manner as to promote the safe and proper use of the drug—the smallest standard package or container made by the manufacturer; or
- if the drug is not a cream, ointment or liquid or other drug described above—no more than 3 days dosage of the drug; and

(iii) on the day on which the drug is sold or supplied, records—

(A) his or her name as the seller or supplier of the drug; and

(B) the date; and

(C) the trade name or the approved name of the drug, or, if it does not have either a trade name or approved name, its ingredients; and

(D) the name and address of the person for whom the drug is sold or supplied; and

(E) the form, strength and quantity of the drug; and

(F) the directions given for the safe and proper use of the drug, including (where appropriate) the route of administration of the drug; or

(g) the drug is a prescribed (continued dispensing) pharmaceutical benefit and the sale or supply is made in accordance with the conditions specified in the National Health (Continued Dispensing) Determination.

(2a) If the Minister is satisfied that an emergency (within the meaning of the *Emergency Management Act 2004*) is occurring in an area of the State, the Minister may, by notice in the Gazette, specify the emergency and a period of time in relation to that emergency for the purposes of subregulation (2)(f)(ii)(A).

(2b) A notice under subregulation (2a)—

(a) may specify the emergency by reference to any factor the Minister thinks fit (including, without limitation, by a description of the circumstances of the emergency, the area within which the emergency is occurring or by any description by which the emergency is commonly known); and

(b) may, from time to time as the Minister thinks fit, be varied or substituted by a new notice or be revoked.

(3) The holder of a licence under the Commonwealth Act to manufacture goods is exempt from section 18(1e) of the Act in respect of the manufacture of those goods.

(4) In this regulation—

Pharmaceutical Benefits Scheme means the Pharmaceutical Benefits Scheme under the National Health Act.

22—Exemptions from section 18A of Act

(1) A registered health practitioner authorised to prescribe or supply a drug of dependence is exempt from section 18A(1) of the Act in respect of the prescription or supply of such a drug for use by a person in respect of whom a section 18A authority exists if—

(a) in the case of a person who is receiving treatment in a hospital or correctional institution—

(i) the registered health practitioner notifies the holder of the section 18A authority that the practitioner has prescribed or supplied the drug or is intending to prescribe or supply the drug in respect of that person; and

(ii) the drug is only administered to the person while in the hospital or correctional institution; and

(iii) if the drug is solely for the treatment of drug dependence—the dose administered does not exceed the dose authorised; or

(b) in the case of a person who is being discharged from a hospital following treatment in the hospital—

(i) the registered health practitioner notifies the holder of the section 18A authority that the practitioner has prescribed or supplied the drug or is intending to prescribe or supply the drug in respect of that person; and

(ii) if the drug is solely for the treatment of drug dependence—the dose prescribed does not exceed the dose authorised; or

(c) in the case of a person not referred to in paragraph (a) or (b)—

(i) the registered health practitioner prescribing or supplying the drug—

(A) notifies the holder of the section 18A authority that the practitioner has prescribed or supplied the drug or is intending to prescribe or supply the drug in respect of that person; or

(B) is a medical practitioner (including a locum for the time being substituting for such a practitioner) in the same practice as the holder of the section 18A authority; and

(ii) the registered health practitioner prescribing or supplying the drug does so with the approval of the holder of the section 18A authority; and

(iii) the registered health practitioner prescribing or supplying the drug complies with the section 18A authority relating to the person for whom the drug is prescribed or to whom the drug is supplied.

(2) A registered health practitioner authorised to prescribe or supply a drug of dependence is exempt from section 18A(1) of the Act in relation to the prescription or supply of such a drug for a person in respect of whom a section 18A authority does not exist if—

(a) the drug (not being dextromoramide or pethidine) is for use by a person aged 70 years or more; or

(b) the drug (not being dextromoramide or pethidine) is for use by a person whose life expectancy is reasonably believed by the registered health practitioner principally responsible for treatment of the person, to be less than 12 months and—

(i) the registered health practitioner has informed the Minister of the person's name and address, date of birth and the nature of the condition for which the drug is prescribed; and

(ii) the prescription for the drug is endorsed either "Notified Palliative Care Patient" or "NPCP"; or

(c) the drug is for use by a person who is receiving treatment in a hospital or correctional institution and the duration of treatment of the person with the drug while the person is in the hospital or correctional institution does not exceed 14 days; or

(d) the drug is for use by a person who is being discharged from a hospital following treatment in the hospital and the duration of treatment of the person with the drug after discharge does not exceed 14 days; or

(e) —

(i) the drug is prescribed or supplied by a registered health practitioner solely for the treatment of drug dependence and as part of a drug treatment service program administered by an incorporated hospital; and

(ii) an application for a section 18A authority is made in respect of the person by a registered health practitioner practising at the drug treatment service program within 5 business days of the drug being prescribed or supplied to the person.

(3) In this regulation—

section 18A authority means an authority granted by the Minister to a registered health practitioner under section 18A of the Act to prescribe or supply a drug of dependence.

23—Sale or supply of volatile solvents (section 19 of Act)

(1) Section 19(3) of the Act applies to—

(a) nitrous oxide; and

(b) volatile solvents that are petroleum products.

(1a) For the purposes of section 19(3) of the Act, the age prescribed is—

(a) in the case of nitrous oxide—18 years; or

(b) in the case of a volatile solvent that is a petroleum product—16 years.

(1b) A person is exempt from section 19(3) of the Act in respect of the supply of nitrous oxide to a person who is under the age of 18 years if—

(a) the first person lawfully carries on a business of selling nitrous oxide; and

(b) the second person is an employee of the first person; and

(c) the supply is in the ordinary course of business.

(1c) The Minister may, by notice in the Gazette, exempt any person from section 19(3) of the Act in respect of the sale or supply of nitrous oxide subject to such conditions (if any) as the Minister thinks fit.

(2) A person who sells or supplies a volatile solvent for use as an inhalant in medical or dental treatment is exempt from section 19 of the Act in respect of that sale or supply.

23A—Special provisions relating to retail sale of nitrous oxide

(1) A person must not sell a substance that is, or purports to be, nitrous oxide by retail between the hours of 10 pm and 5 am on the following day.

Maximum penalty: $5 000.

(2) A person who sells a substance that is, or purports to be, nitrous oxide from premises by retail must ensure that the substance is—

(a) stored in a part of the premises to which members of the public are not permitted access; and

(b) stored in such a way that it is not visible to members of the public at the premises.

Maximum penalty: $5 000.

(3) A person who sells a substance that is, or purports to be, nitrous oxide from premises by retail must display a notice that complies with the requirements in subregulation (4) in a manner and position that is likely to attract the attention of customers.

Maximum penalty: $2 500.

Expiation fee: $315.

(4) A notice displayed under subregulation (3) must comply with the following requirements:

(a) the notice must display the following words:

IT IS UNLAWFUL TO SELL OR SUPPLY NITROUS OXIDE TO PERSONS UNDER THE AGE OF 18 YEARS. PERSONS MAY BE REQUIRED TO PRODUCE EVIDENCE OF AGE WHEN MAKING A PURCHASE;

(b) the words required to be displayed must appear on the notice in legible letters or numerals not less than 15 millimetres in height and be of a colour that contrasts with the background colour of the notice.

24—Automatic vending machines (section 20 of Act)

(1) Section 20(1) of the Act does not apply to—

(a) an S5 poison that is sold or supplied by means of an automatic vending machine located at a car washing facility provided that the first aid instructions, warning statements and safety directions for the poison specified in the Uniform Poisons Standard are displayed at the facility; or

(b) the following products sold or supplied by means of an automatic vending machine:

(i) condoms with or without spermicides or viricides;

(ii) lubricants with or without spermicides or viricides; or

(c) injecting equipment sold or supplied by way of an automatic vending machine at a location and site approved by the Minister; or

(d) an unscheduled medicine sold or supplied by way of an automatic vending machine provided that—

(i) the medicine is sold or supplied in the original unopened pack supplied by the manufacturer; and

(ii) the medicine is sold or supplied in a pack that contains not more than 2 adult doses of the medicine; and

(iii) the automatic vending machine is presented and located in such a way that makes unsupervised access by children unlikely.

(2) In this regulation—

injecting equipment means—

(a) alcohol swabs, needles, syringe filters, syringes, tourniquets, water for injection or winged infusion sets; or

(b) a kit containing 1 or more of the items specified in paragraph (a);

unscheduled medicine means a medicine that is included in the Australian Register of Therapeutic Goods and is not a scheduled medicine.

25—Possession of poisons (section 22 of Act)

(1) Section 22 of the Act applies to the following poisons:

4-aminopropiophenone

Acrolein

Arsenic as an S7 poison

Chloropicrin

Cyanides as S7 poisons

Cyanogen

DDT

Fluoroacetamide

Fluoroacetic acid

Hydrocyanic acid as an S7 poison

Methyl bromide

Mirex

Sodium fluoroacetate

Strychnine as an S7 poison

Thallium.

(2) A person is exempt from section 22 of the Act in respect of the possession of 4-aminopropiophenone if—

(a) the 4-aminopropiophenone is a constituent of baits designed for destroying vertebrate animals; and

(b) the concentration of 4-aminopropiophenone in each bait does not exceed 2%; and

(c) the total amount of 4-aminopropiophenone in the particular quantity of baits for destroying vertebrate animals does not exceed 5 kilograms; and

(d) the person—

(i) has the written approval of the Minister to acquire and possess those baits; and

(ii) acquires the baits from a supplier approved by the Minister.

(3) A person is exempt from section 22 of the Act in respect of the possession of sodium fluoroacetate if—

(a) —

(i) in the case of sodium fluoroacetate that is contained in a capsule for use with a Pest Canid Ejector designed for destroying foxes or wild dogs—the concentration of sodium fluoroacetate in each capsule does not exceed 0.8%; or

(ii) in the case of sodium fluoroacetate that is a constituent of baits designed for destroying vertebrate animals—the concentration of sodium fluoroacetate in each bait does not exceed 0.04%; and

(b) the total amount of sodium fluoroacetate present in the particular quantity of capsules or baits does not exceed 50 grams; and

(c) the person—

(i) has the written approval of the Minister to acquire and possess those capsules or baits; and

(ii) acquires the capsules or baits from a supplier approved by the Minister.

(4) A person is exempt from section 22 of the Act in respect of the possession of strychnine if—

(a) the person is the owner or occupier, or an agent or employee of an owner or occupier, of land that is situated outside a township and outside Metropolitan Adelaide; and

(b) the strychnine is a constituent of baits designed for destroying mice; and

(c) the quantity of baits in the person's possession does not exceed 5 kilograms; and

(d) the amount of strychnine present in any quantity of the baits does not exceed 0.5%.

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

Maximum penalty: $3 000.

(6) The Minister may exempt a person who is licensed under the *Controlled Substances (Pesticides) Regulations 2017* from the requirement to hold a licence under section 22 of the Act in respect of the use of a pesticide that is a section 22 poison.

26—Packaging and labelling of poisons (section 24 of Act)

(1) For the purposes of section 24(b) of the Act, the package or container—

(a) must comply with the requirements set out in the Uniform Poisons Standard; and

(b) in the case of a package or container for an S2 poison, S3 poison, S4 poison or S8 poison, must—

(i) be impervious to, and incapable of chemical reaction with, the poison when the package or container is under conditions of temperature and pressure that are likely to be encountered in normal use; and

(ii) have sufficient strength and impermeability to prevent leakage of the poison during handling, transport and storage of the package or container under normal handling conditions; and

(iii) in the case of a package or container intended to be opened more than once—be able to be securely and readily closed and reclosed; and

(iv) in the case of a prescribed medicine—comply with the packaging requirements of Therapeutic Goods Order No 95.

(2) For the purposes of section 24(c) of the Act, a package or container in which a poison for human or animal therapeutic use is sold by retail on prescription, or is supplied on prescription—

(a) must have affixed to it a label that complies with Appendix L Clause 1 of the Uniform Poisons Standard; and

(b) must, in the case of a poison that is listed in column 1 of Appendix L Clause 2 of the Uniform Poisons Standard have affixed to it a label that contains the warning statements prescribed for that poison by Appendix F Clause 1 of that Standard; and

(c) must, in the case of a preparation for internal use by humans that contains a poison listed in Appendix K of the Uniform Poisons Standard, have affixed to it a label that contains the sedation warning statement 39, 40 or 90 as specified in Appendix F Clause 1 of that Standard.

(3) For the purposes of section 24(c) of the Act, a package or container in which a prescribed S3 poison is sold by retail, or is supplied—

(a) must have affixed to it a label that—

(i) complies with Appendix L Clause 1 of the Uniform Poisons Standard; and

(ii) in the case of pseudoephedrine—contains a unique identifier enabling that poison to be linked with the records required to be kept under regulation 14; and

(b) must, in the case of a preparation for internal use by humans that contains a poison listed in Appendix K of the Uniform Poisons Standard, have affixed to it a label that contains the sedation warning statement 39, 40 or 90 as specified in Appendix F Clause 1 of that Standard.

(4) For the purposes of section 24(c) of the Act, a package or container in which a poison designed for human or animal therapeutic use (other than a prescribed S3 poison) is sold by retail or is supplied—

(a) must have affixed to it the label appearing on the package or container for the poison as supplied by the manufacturer (being a label that complies with the Uniform Poisons Standard); or

(b) must have affixed to it—

(i) a label that complies with Appendix L Clause 1 of the Uniform Poisons Standard; and

(ii) in the case of a preparation for internal use by humans that contains a poison listed in Appendix K of that Standard—a label that contains the sedation warning statement 39, 40 or 90 as specified in Appendix F Clause 1 of that Standard.

(5) For the purposes of section 24(c) of the Act, a package or container in which a poison (other than a poison designed for human or animal therapeutic use or a prescribed S3 poison) is sold by retail or is supplied (other than on prescription) must have affixed to it a label that complies with the Uniform Poisons Standard.

(6) A registered health practitioner or veterinary surgeon who is authorised to prescribe, sell or supply a prescribed medicine is exempt from the requirement to comply with the packaging requirements of Therapeutic Goods Order No 95 in relation to the sale or supply of that prescribed medicine to a particular person if the registered health practitioner or veterinary surgeon believes that the person would suffer undue hardship through difficulty in opening a container that complies with the requirements of that Order.

(7) The Minister may grant an exemption from specified requirements of section 24(b) or (c) of the Act to a seller or supplier in respect of a particular product if the Minister is satisfied that the product is otherwise adequately packaged or labelled.

(8) The Minister may grant a seller or supplier, or a class of sellers or suppliers, an exemption from subregulation (1)(b)(iv) in relation to specified packaging requirements of Therapeutic Goods Order No 95 for a specified prescribed medicine.

(9) In this regulation—

prescribed medicine means—

(a) a medicine that contains a substance listed in Schedule 1 to Therapeutic Goods Order No 95 or a salt, ester or other derivative of such a substance; or

(b) a product that—

(i) contains a substance listed in Schedule 1 to Therapeutic Goods Order No 95 or a salt, ester or other derivative of such a substance; and

(ii) is intended solely for use in animals;

prescribed S3 poison means any of the following S3 poisons:

(a) dihydrocodeine in cough preparations;

(d) pseudoephedrine;

Therapeutic Goods Order No 95 means *Therapeutic Goods Order No. 95 - Child-resistant packaging requirements for medicines 2017* made under the Commonwealth Act on 29 November 2017, as in force from time to time.

27—Storage of poisons (section 25 of Act)

For the purposes of section 25 of the Act, the following requirements apply:

(a) a person must not store a poison in a container that—

(i) is normally used for containing food or beverages; or

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

(b) a person must not store an S2 poison in premises where such a poison is sold by retail unless—

(i) it is stored in a part of the premises to which the public is not permitted access; or

(ii) if it is stored in a part of the premises to which the public is permitted access, it—

(A) is stored not less than 1.2 metres above floor level; or

(B) is enclosed in—

- a child-resistant package; or
- a blister pack; or
- a container approved by the Minister; or

(C) is stored in a container that has a capacity of not less than 5 litres; or

(D) is stored in a container that has a gross weight of not less than 5 kilograms;

(c) a person must not store an S3 poison or S4 poison in premises where such a poison is sold by retail unless it is stored in a part of the premises to which the public is not permitted access;

(d) a person must not store an S6 poison or S7 poison in premises where such a poison is sold by retail except in accordance with the requirements of Part 2 Section 54(3) and (4) of the Uniform Poisons Standard;

(e) a person must not store a drug of dependence except in accordance with the requirements of the *Code of Practice for the Storage and Transport of Drugs of Dependence*, published by the Department, as in force from time to time;

(f) a person must not store pentobarbital in injectable preparations except in a locked container.

28—Consignment of poisons for transport

A person must not—

(a) consign a poison for transport unless it is packed in such a way as to avoid leakage arising from the ordinary risks of handling and transport; or

(b) consign for transport a drug of dependence except in accordance with the requirements of the *Code of Practice for the Storage and Transport of Drugs of Dependence*, published by the Department, as in force from time to time.

Maximum penalty: $5 000.

29—Transport of poisons (section 26 of Act)

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

(a) transport an S2 poison, S3 poison, S4 poison or S8 poison in a vehicle in which any food, or component of food, for human or animal consumption is being transported unless that poison is carried in a part of the vehicle effectively separated from that part of the vehicle containing the food; or

(b) transport a drug of dependence except in accordance with the requirements of the *Code of Practice for the Storage and Transport of Drugs of Dependence*, published by the Department, as in force from time to time.

30—Prohibition on use of certain poisons for certain purposes (section 27 of Act)

(1) For the purposes of section 27 of the Act, a person must not sell, supply, purchase or use an S7 poison for a domestic purpose or domestic gardening purpose.

(2) For the purposes of section 27 of the Act, a person must not sell, supply, prescribe or use a poison listed in Schedule 10 of the Uniform Poisons Standard for the purpose or purposes indicated in relation to that poison in that Schedule (other than amygdalin for human therapeutic use).

31—Prohibition on use of certain poisons

(1) A person must not sell, supply, prescribe or use amygdalin for human therapeutic use unless—

(a) special access to amygdalin has been authorised in accordance with the requirements of sections 18 and 31A of the Commonwealth Act and regulation 12A of the *Therapeutic Goods Regulations 1990* made under that Act; and

(b) permission for the importation of amygdalin (subject to special access authorisation) has been granted under regulation 5H and Schedule 8 item 12AA of the *Customs (Prohibited Imports) Regulations 1956* of the Commonwealth.

Maximum penalty: $5 000.

(2) A person must not—

(a) prescribe, sell, supply or purchase a poison produced for the treatment of animals if the person knows, or if there are reasonable grounds for suspecting, that the poison is intended for human use; or

(b) administer to any person (including himself or herself) a poison produced for the treatment of animals; or

(c) use choramphenicol for the treatment of stock bred, raised or used for the purpose of providing a product for human consumption.

Maximum penalty: $5 000.

(3) In this regulation—

stock means—

(a) a bird or other animal; or

(b) a bee of the genus *Apis* or *Megachile*.

32—Restrictions on advertising (section 28 of Act)

(1) Section 28 of the Act applies to—

(a) all poisons listed in Schedule 10 of the Uniform Poisons Standard; and

(b) all S3 poisons other than those listed in Appendix H of the Uniform Poisons Standard; and

(c) all S4 poisons and S8 poisons; and

(d) all controlled drugs other than drugs of dependence.

(2) A person is exempt from section 28 of the Act if—

(a) the person only publishes an advertisement of a poison in a journal that is circulated predominantly among registered health practitioners, medical administrators, scientists working in medical laboratories or persons who are licensed to sell the poison by wholesale; or

(b) the person only publishes an advertisement of a poison that consists of a price list that complies with the *Price Information Code of Practice* published by the TGA as in force from time to time.

(3) In this regulation—

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

Part 4—Prescriptions and dispensing

33—How prescriptions are to be given

(1) Subject to this regulation, a prescriber must give a prescription for a drug—

(a) in writing; or

(b) in an approved electronic form.

Maximum penalty: $5 000.

(2) A prescriber may, if of the opinion that good reason exists for doing so, give a prescription for a drug to a pharmacist by—

(a) telephone; or

(b) fax; or

(c) an approved electronic communication.

(3) If a prescriber gives a prescription in writing, the prescriber must give the prescription to—

(a) in the case of a prescription for a drug for human use—

(i) the person for whom the drug is to be supplied; or

(ii) a person acting on behalf of the person for whom the drug is to be supplied; or

(b) in the case of a prescription for a drug for animal use—

(i) the owner of the animal; or

(ii) a person acting on behalf of the owner of the animal.

Maximum penalty: $5 000.

(4) If a prescription is given in an approved electronic form, the prescriber must—

(a) in the case of a prescription in a form approved by the Secretary under the Commonwealth Regulations—prepare and submit the prescription in accordance with any approved information technology requirements (as defined in the Commonwealth Regulations) by means of an eligible electronic communication (as defined in the Commonwealth Regulations); or

(b) in the case of a prescription in a form approved by the Minister—prepare and submit the prescription in accordance with approved information technology requirements (if any) by means of an approved electronic communication.

Maximum penalty: $3 000.

(5) If a prescription is prepared in an approved electronic form, the prescriber must include in the prescription—

(a) the date on which the prescription is given; and

(b) the prescriber's professional name, address and telephone number; and

(c) the full name and address of the person for whom the prescription is intended; and

(d) the name, dose form and (if relevant) the route of administration of the drug being prescribed; and

(e) if applicable—the strength of the drug being prescribed; and

(f) the dose of the drug to be administered to the person for whom the drug is being prescribed; and

(g) the frequency at which the drug is to be administered; and

(h) the total amount of the drug to be supplied each time the prescription is dispensed; and

(i) the total number of times the drug may be dispensed; and

(j) if the prescription is for a drug of dependence for human use—the date of birth of the person for whom the prescription is intended; and

(k) the words—

(i) "For dental treatment only" if the prescriber is a dentist; or

(ii) "For podiatric treatment only" if the prescriber is a podiatrist; or

(iii) "For animal treatment only" if the prescriber is a veterinary surgeon.

Maximum penalty: $3 000.

(6) If a prescription for a monitored drug for human use is prepared in an approved electronic form, the prescriber must—

(a) keep a record of—

(i) the details required by subregulation (5) to be included in the prescription; and

(ii) the date of birth of the person for whom the prescription has been prepared; and

(b) transmit that record electronically to a data source entity at, or immediately following, the time the record is created (unless subregulation (6a) applies).

Maximum penalty: $5 000.

Expiation fee: $1 250.

(6a) If a prescriber is unable to transmit a record relating to a prescription in accordance with subregulation (6)(b) because the electronic system used to keep the record is not compatible with the electronic system of a data source entity, the prescriber must transmit the record electronically to the Chief Executive so that it is received no later than—

(a) if the prescription is prepared on a day falling within the first 14 days of a month—the 21st day of that month; or

(b) if the prescription is prepared on any other day—the 7th day of the month following the month in which the prescription was prepared; or

(c) in any case, such later day as the Chief Executive may, on application, authorise.

Maximum penalty: $5 000.

Expiation fee: $1 250.

(6b) The Minister may exempt a prescriber or class of prescribers from the operation of subregulation (6)(b) or (6a) (or both) if satisfied that proper cause exists for the exemption.

(7) If a prescription is given to a pharmacist by telephone, the prescriber must give the pharmacist—

(a) the prescriber's professional name, address and telephone number; and

(b) the full name and address of the person for whom the prescription is intended (or, if the prescription is intended for an animal, the species of animal for which it is intended, the name and address of the owner of the animal and the name (if any) of the animal); and

(c) the name, dose form and (if relevant) the route of administration of the drug being prescribed; and

(d) if applicable—the strength of the drug being prescribed; and

(e) the dose of the drug to be administered to—

(i) the person for whom the drug is being prescribed; or

(ii) the animal in relation to which the drug is being prescribed,

(as the case may be);

(f) the total amount of the drug to be supplied; and

(g) the frequency at which the drug is to be administered; and

(h) if the prescription is for a drug of dependence for human use—the date of birth of the person for whom the prescription is intended.

Maximum penalty: $3 000.

(8) If a prescription is given to a pharmacist by telephone—

(a) the prescriber must, immediately after so giving the prescription, complete a prescription in writing that—

(i) clearly states that it is given in confirmation of the prescription given by telephone on the particular date on which it is so given; and

(ii) otherwise complies with these regulations; and

(b) the prescriber must forward the written prescription to the pharmacist—

(i) if the prescription is for a drug of dependence—within 24 hours of giving the prescription by telephone; or

(ii) in any other case—as soon as practicable after giving the prescription by telephone.

Maximum penalty: $3 000.

(9) If a prescription is given to a pharmacist by fax, the prescriber must forward the original prescription to the pharmacist—

(a) in the case of a prescription for a drug of dependence—within 24 hours of giving the prescription by fax; or

(b) in any other case—as soon as practicable after giving the prescription by fax,

unless the prescriber has endorsed the prescription given by fax with the name and address of a single pharmacy at which the prescription may be dispensed.

Maximum penalty: $3 000.

(10) If a prescription is given to a pharmacist by an approved electronic communication, the prescriber must comply with any requirements imposed by the Minister.

Maximum penalty: $3 000.

(11) This regulation does not apply to a prescriber who gives a prescription for a drug if—

(a) the prescription is a medication chart prescription; and

(b) the provisions of the Commonwealth Regulations applying to the giving of a medication chart prescription for a pharmaceutical benefit are complied with in relation to the giving of the prescription of the drug (whether or not the drug is a pharmaceutical benefit).

34—Written prescriptions

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

(a) date the prescription with the date on which the prescription is written and sign the prescription; and

(b) include on the prescription—

(i) his or her professional name, address and telephone number; and

(ii) the full name and address of the person for whom the prescription is intended or, if the prescription is intended for an animal, the species of animal for which it is intended, the name and address of the owner of the animal and the name (if any) of the animal; and

(iii) the words—

(A) "For dental treatment only" if the prescriber is a dentist; or

(B) "For podiatric treatment only" if the prescriber is a podiatrist; or

(C) "For animal treatment only" if the prescriber is a veterinary surgeon; and

(c) specify on the prescription—

(i) the name, dose form and (if relevant) the route of administration of the drug being prescribed; and

(ii) if applicable—the strength of the drug; and

(iii) the dose of the drug to be administered to the person for whom, or the animal for which, it is prescribed; and

(iv) the frequency at which the drug is to be administered; and

(v) the total amount of the drug to be supplied each time the prescription is dispensed; and

(vi) the total number of times the drug may be dispensed; and

(d) if the prescription is for a drug of dependence for human use, comply with the following additional requirements:

(i) include on the prescription the date of birth of the person for whom the prescription is intended;

(ii) express the total amount of the drug to be specified under subparagraph (c)(v) in both words and numerals.

Maximum penalty: $3 000.

(1a) A prescriber who writes a prescription for the supply of a monitored drug for human use—

(a) must keep a record of—

(i) the details required to be included and specified under subregulation (1); and

(ii) the date of birth of the person for whom the prescription has been written; and

(b) if the record is kept in electronic form—must transmit that record electronically to a data source entity at, or immediately following, the time the record is created (unless subregulation (1b) applies).

Maximum penalty: $5 000.

Expiation fee: $1 250.

(1b) If a prescriber is unable to transmit a record relating to a prescription in accordance with subregulation (1a)(b) because the electronic system used to keep the record is not compatible with the electronic system of a data source entity, the prescriber must transmit the record electronically to the Chief Executive so that it is received no later than—

(a) if the prescription is written on a day falling within the first 14 days of a month—the 21st day of that month; or

(b) if the prescription is written on any other day—the 7th day of the month following the month in which the prescription was prepared; or

(c) in any case, such later day as the Chief Executive may, on application, authorise.

Maximum penalty: $5 000.

Expiation fee: $1 250.

(1c) The Minister may exempt a prescriber or class of prescribers from the operation of subregulation (1a)(b) or (1b) (or both) if satisfied that proper cause exists for the exemption.

(2) If a prescriber writes a prescription for an above average strength or potentially dangerous dose of a drug, he or she must—

(a) underline the statement of the dose of the drug on the prescription; and

(b) sign his or her initials alongside the underlined portion of the prescription referred to in paragraph (a).

Maximum penalty: $3 000.

(4) This regulation does not apply to a person who writes a prescription for a drug if—

(a) the prescription is a medication chart prescription; and

(b) the provisions of the Commonwealth Regulations applying to the giving of a medication chart prescription for a pharmaceutical benefit are complied with in relation to the giving of the prescription for the drug (whether or not the drug is a pharmaceutical benefit).

34A—Giving prescriptions for monitored drugs—special provisions

(1) Before a prescriber gives a prescription for the supply of a monitored drug for human use (whether the prescription is given in writing, in an approved electronic form, by telephone, by fax or by an approved electronic communication), the prescriber must take all reasonable steps to check relevant information held in the monitored drugs database relating to the person for whom the drug is to be prescribed.

Maximum penalty: $5 000.

(2) Subregulation (1) does not apply if—

(a) the drug (not being dextromoramide or pethidine) is for use by a person aged 70 years or more; or

(b) the drug (not being dextromoramide or pethidine) is for use by a person whose life expectancy is reasonably believed by the registered health practitioner principally responsible for treatment of the person, to be less than 12 months and—

(i) the prescriber has informed the Minister of the person's name and address, date of birth and the nature of the condition for which the drug is prescribed; and

(ii) the prescription for the drug is endorsed either "Notified Palliative Care Patient" or "NPCP"; or

(c) the drug is for use by a person who is receiving treatment in a hospital or a correctional institution and the duration of treatment of the person with the drug while the person is in the hospital or correctional institution does not exceed 14 days; or

(d) the drug is for use by a person who is being discharged from a hospital following treatment in the hospital and the duration of treatment of the person with the drug after discharge does not exceed 14 days.

35—Dispensing prescriptions

(1) If a pharmacist or medical practitioner dispenses a drug pursuant to a prescription, the pharmacist or medical practitioner must—

(a) in the case of a written prescription or electronic prescription—record in or on the prescription—

(i) the pharmacist's or medical practitioner's name, business name (if any) and business address; and

(ii) the date on which the drug is dispensed; and

(iii) the unique identifier applicable to the drug; or

(b) in the case of a prescription given by fax that is endorsed with the name and address of a single pharmacy at which the prescription is to be dispensed—endorse on the faxed copy—

(i) the pharmacist's or medical practitioner's name, business name (if any) and business address; and

(ii) the date on which the drug is dispensed; and

(iii) the unique identifier applicable to the drug.

Maximum penalty: $5 000.

(2) A pharmacist or medical practitioner who dispenses a drug pursuant to a prescription must, on the day on which the drug is dispensed, record the following information:

(a) the unique identifier applicable to the drug dispensed on the prescription;

(b) the name of the pharmacist or medical practitioner as the dispenser;

(c) the date on which the drug is dispensed;

(d) the trade name or the approved name of the drug, or, if it does not have either a trade or approved name, the ingredients of the drug;

(e) if the drug is dispensed for a person—

(i) the full name and address of the person; and

(ii) in the case of a monitored drug—the person's date of birth;

(f) if the drug is intended for an animal—the species of animal for which it is intended, the name and address of the owner of the animal and the name (if any) of the animal;

(g) the form, strength and quantity of the dispensed drug;

(h) the directions given for the safe and proper use of the dispensed drug;

(i) the name, address and business telephone number of the person who prescribed the drug;

(j) the number of times the prescription may be dispensed and (if the prescription so specifies) the intervals at which the drug may be dispensed;

(k) any instructions the prescriber has included in or on the prescription in relation to a specialised supply of the drug;

(l) if the prescription is endorsed for dispensing at a single pharmacy—the name and address of that pharmacy.

Maximum penalty: $5 000.

(3) A pharmacist or medical practitioner must not do the following:

(a) in the case of a prescription for an S4 poison that does not specify the number of times the drug is to be dispensed—dispense the drug more than once pursuant to the prescription;

(b) in the case of a prescription that specifies the number of times and the intervals at which the drug may be dispensed—dispense the drug more times than the number specified or at intervals less than those specified;

(c) in the case of a prescription that specifies the number of times, but not the intervals at which, the drug may be dispensed—dispense the drug more frequently than the pharmacist or medical practitioner considers appropriate.

Maximum penalty: $5 000.

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

(a) has lost a previously dispensed supply of a drug; or

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

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

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

Maximum penalty: $5 000.

(6) If a prescription given by fax is endorsed with the name and address of a single pharmacy at which the drug may be dispensed, a pharmacist must not dispense the drug unless the pharmacist is on duty at that pharmacy.

Maximum penalty: $5 000.

(7) A pharmacist or medical practitioner must not dispense a drug if—

(a) the prescription for the drug—

(i) is presented or otherwise sought to be dispensed—

(A) in the case of a drug of dependence—more than 6 months after the date on which it was written; or

(B) in any other case—more than 12 months after the date on which it was written; or

(ii) has been cancelled; or

(iii) is partly or wholly illegible; or

(iv) does not comply with the Act or these regulations; or

(b) there are reasonable grounds for suspecting that the prescription has been altered, forged or obtained by false pretences.

Maximum penalty: $5 000.

(8) If a prescription for a drug that is to be dispensed for the first or only time is given in writing, a pharmacist or medical practitioner must not dispense the drug unless the original written prescription for the drug is presented to the pharmacist or medical practitioner.

Maximum penalty: $5 000.

(9) If a prescription for a drug that is to be dispensed for the first or only time is given by fax, a pharmacist or medical practitioner must not dispense the drug unless the faxed prescription is endorsed with the name and address of a single pharmacy at which the drug may be dispensed.

Maximum penalty: $5 000.

(10) If a prescription for a drug that is to be dispensed for the second or subsequent time is given in writing, a pharmacist or medical practitioner must not dispense the drug unless—

(a) the original written prescription for the drug and a written record (whether made on the prescription or on a separately attached repeat authorisation) of the number of times the drug has been dispensed are presented to the pharmacist or medical practitioner; or

(b) a duplicate or copy of the written prescription for the drug and a written record (made both on the duplicate or copy (as the case may be) and on a separately attached repeat authorisation) of the number of times the drug has been dispensed are presented to the pharmacist or medical practitioner.

Maximum penalty: $5 000.

(11) If a pharmacist or medical practitioner—

(a) dispenses a drug pursuant to a written prescription; and

(b) the drug is fully dispensed,

the pharmacist or medical practitioner must endorse the prescription with the word "CANCELLED" on the day on which the drug is dispensed.

Maximum penalty: $5 000.

(12) If a pharmacist—

(a) dispenses a drug pursuant to a prescription given by fax that is endorsed with the name of a single pharmacy at which the prescription may be dispensed; and

(b) the drug is fully dispensed,

the pharmacist must endorse the faxed copy of the prescription with the word "CANCELLED" on the day on which the drug is dispensed.

Maximum penalty: $5 000.

(13) If a pharmacist or medical practitioner—

(a) dispenses a drug pursuant to an electronic prescription; and

(b) the drug is fully dispensed,

the pharmacist or medical practitioner must record in or on the prescription, on the day that the prescription is dispensed, that the prescription is cancelled.

(14) A pharmacist or medical practitioner who dispenses a prescription for an S4 poison must, unless the prescription is for any reason forwarded to the Department or the Minister—

(a) in the case of a written prescription—

(i) retain the original or duplicate prescription for at least 1 year; and

(ii) keep the original or duplicate prescription readily available for inspection by an authorised officer during that period; or

(b) in the case of a prescription given by fax—

(i) retain the faxed copy of the prescription for at least 1 year; and

(ii) keep the faxed copy of the prescription readily available for inspection by an authorised officer during that period; or

(c) in the case of an electronic prescription—

(i) retain the electronic prescription or a computer-generated printed copy of it for at least 1 year; and

(ii) keep the electronic prescription or a computer-generated printed copy of it readily available for inspection by an authorised officer during that period.

Maximum penalty: $5 000.

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

(16) For the purposes of this regulation, a prescription for a drug is ***fully dispensed*** if—

(a) in the case of a prescription authorising dispensing of the drug once only—the drug has been dispensed on 1 occasion; or

(b) in the case of a prescription authorising dispensing of the drug more than once—the drug has been dispensed for the last time.

(17) This regulation (other than subregulations (2), (7)(a) and (7)(b)) does not apply to a pharmacist or medical practitioner who dispenses a drug on a prescription if—

(a) the prescription is a medication chart prescription; and

(b) the provisions of the Commonwealth Regulations applying to the sale or supply of a pharmaceutical benefit have been complied with in relation to the sale or supply of the drug (whether or not the drug is a pharmaceutical benefit).

35A—Dispensing prescriptions for drugs of dependence and other monitored drugs—special provisions

(1) A pharmacist who dispenses a monitored drug on prescription must—

(a) each time that the drug is dispensed—make a record in electronic form that complies with regulation 35(2); and

(b) transmit that record electronically to a data source entity at, or immediately following, the time the record is created (unless subregulation (2) applies).

Maximum penalty: $5 000.

Expiation fee: $1 250.

(2) If a pharmacist is unable to transmit a record relating to a prescription in accordance with subregulation (1)(b) because the electronic system used to make the record is not compatible with the electronic system of a data source entity, the pharmacist must transmit the record electronically to the Chief Executive so that it is received no later than—

(a) if the drug is dispensed on a day falling within the first 14 days of a month—the 21st day of that month; or

(b) if the drug is dispensed on any other day—the 7th day of the month following the month in which the drug was dispensed; or

(c) in any case, such later day as the Chief Executive may, on application, authorise.

Maximum penalty: $5 000.

Expiation fee: $1 250.

(3) A pharmacist or medical practitioner who dispenses a drug of dependence on prescription must—

(a) in the case of a written prescription—

(i) retain the original prescription or a copy of the prescription for at least 2 years; and

(ii) keep it readily available for inspection by an authorised officer during that period; and

(iii) on request by an authorised officer—send a copy of the prescription to the authorised officer; or

(b) in the case of a prescription given by fax—

(i) retain the faxed copy of the prescription for at least 2 years; and

(ii) keep the faxed copy of the prescription readily available for inspection by an authorised officer during that period; and

(iii) on request by an authorised officer—send a copy of the faxed copy of the prescription to the authorised officer; or

(c) in the case of an electronic prescription—

(i) retain the electronic prescription or a computer-generated printed copy of it for at least 2 years; and

(ii) keep the electronic prescription or a computer-generated printed copy of it readily available for inspection by an authorised officer during that period; and

(iii) on request by an authorised officer—send a computer-generated printed copy of the electronic prescription to the authorised officer.

Maximum penalty: $5 000.

Expiation fee: $1 250.

(4) A pharmacist or medical practitioner must not—

(aa) dispense a monitored drug unless the pharmacist or practitioner has taken all reasonable steps to check relevant information held in the monitored drugs database relating to the person for whom the drug is to be dispensed; or

(a) dispense more than 2 days supply of a drug of dependence unless at least 1 of the following applies:

(i) the person for whose use the drug is prescribed is known to the pharmacist or practitioner;

(ii) the pharmacist or practitioner recognises the signature on the prescription as that of the prescriber who purportedly gave the prescription;

(iii) the pharmacist or practitioner has verified with the prescriber who purportedly gave the prescription that the prescription was in fact given by that prescriber; or

(b) hand over a drug of dependence dispensed by the pharmacist or medical practitioner until—

(i) the person for whose use the drug is dispensed—

(A) has signed and dated the prescription or, if the prescription was given by fax, the faxed copy of the prescription; and

(B) has, unless the person is known to the pharmacist or practitioner, produced satisfactory evidence of his or her identity; or

(ii) the person for whose use the drug is dispensed—

(A) has signed a computer-generated printed copy of the prescription that includes all the information required to be provided on a written prescription; and

(B) has, unless known to the pharmacist or practitioner, produced satisfactory evidence of his or her identity; or

(iii) an agent acting on behalf of the person for whose use the drug is intended—

(A) has signed and dated the prescription or, if the prescription was given by fax, the faxed copy of the prescription; and

(B) has, unless the agent is known to the pharmacist or practitioner, produced satisfactory evidence of his or her identity; or

(iv) an agent acting on behalf of the person for whose use the drug is intended—

(A) has signed a computer-generated printed copy of the prescription that includes all the information required to be provided on a written prescription; and

(B) has, unless known to the pharmacist or practitioner, produced satisfactory evidence of his or her identity.

Maximum penalty: $5 000.

(5) This regulation (other than subregulation (3)) does not apply to a pharmacist or medical practitioner who dispenses a monitored drug on prescription if—

(a) the prescription is a medication chart prescription; and

(b) the provisions of the Commonwealth Regulations applying to the sale or supply of a pharmaceutical benefit have been complied with in relation to the sale or supply of the drug (whether or not the drug is a pharmaceutical benefit).

(6) Subregulation (4)(aa) does not apply if—

(a) the drug (not being dextromoramide or pethidine) is for use by a person aged 70 years or more; or

(b) the prescription for the drug (not being dextromoramide or pethidine) is endorsed either "Notified Palliative Care Patient" or "NPCP"; or

(c) the drug is for use by a person who is receiving treatment in a hospital or a correctional institution and the duration of treatment of the person with the drug while the person is in the hospital or correctional institution does not exceed 14 days; or

(d) the drug is for use by a person who is being discharged from a hospital following treatment in the hospital and the duration of treatment of the person with the drug after discharge does not exceed 14 days.

35B—Dispensing prescriptions—S4 drugs in serious shortage

(1) If—

(a) a prescription for an S4 drug is presented to a pharmacist for dispensing; and

(b) the drug to which the prescription relates is a medicine in respect of which a Serious Shortage Medicine Substitution Notice issued by the TGA under the Commonwealth Act is in force; and

(c) the pharmacist is unable to dispense the prescription because the pharmacist does not have, and cannot obtain, the drug to which the prescription relates in the strength, release form or dose form specified in the prescription; and

(d) the person for whom the prescription has been given consents to receiving the drug in a strength, release form or dose form specified in the Notice instead; and

(e) the pharmacist is of the opinion that it is appropriate to supply the person with the drug in a strength, release form or dose form specified in the Notice,

the pharmacist may supply the person with the drug in a strength, release form or dose form specified in the Notice in accordance with the conditions stated in the Notice.

(2) If a pharmacist supplies a drug as authorised by subregulation (1), the pharmacist must, as soon as practicable, give the prescriber of the drug notice in writing of the strength, release form and dose form in which the drug was supplied.

Maximum penalty: $3 000.

(3) For the purposes of these regulations, if a pharmacist supplies a drug as authorised by subregulation (1), the pharmacist will be taken to have dispensed the prescription for the drug presented to the pharmacist.

Part 5—Special provisions relating to drugs of dependence

36—Interpretation

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

health service pharmacy means a pharmacy that is part of a health service facility;

order means an order other than a prescription;

supplier means—

(a) a pharmacist; or

(b) a person licensed under the Act to manufacture, sell by wholesale or supply drugs of dependence;

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

(2) For the purposes of this Part—

(a) a reference to the administration of a drug is, if the drug is administered continuously over an extended period (for example, by means of an intravenous drip or pump) a reference to the commencement of administration by that means; and

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

37—Special restrictions on prescription or supply of drugs of dependence by registered health practitioners and veterinary surgeons

(1) A person must not prescribe or supply a drug of dependence for use by his or her spouse, domestic partner, parent, grandparent, child, grandchild, brother or sister unless—

(a) the prescription or supply is authorised by the Minister; or

(b) the prescription or supply is in circumstances of a verifiable emergency.

Maximum penalty: $5 000.

Expiation fee: $1 250.

(2) A registered health practitioner must not prescribe or supply a drug of dependence for use by himself or herself unless the prescription or supply is in circumstances of a verifiable emergency.

Maximum penalty: $5 000.

Expiation fee: $1 250.

(3) Subregulation (1) does not apply to the supply of a drug of dependence by a pharmacist if the pharmacist is dispensing a prescription for the drug.

(4) A veterinary surgeon must not prescribe, sell or supply a drug of dependence for an animal without having first examined the animal unless the prescription, sale or supply is in circumstances of a verifiable emergency.

Maximum penalty: $5 000.

38—Restriction on prescribing or supplying S2, S3 or S4 poisons containing S8 poisons

A prescriber must not prescribe or supply for use by a person who the prescriber knows or has reasonable cause to believe is dependent on drugs—

(a) an S2 poison or S3 poison that contains a poison listed in Schedule 8 of the Uniform Poisons Standard; or

(b) an S4 poison that contains a poison listed in Schedule 8 of the Uniform Poisons Standard,

for the purpose of maintaining or treating the person's dependence unless the prescriber prescribes or supplies the drug in accordance with an authority granted by the Minister.

Maximum penalty: $5 000.

39—Records to be kept by manufacturers of drugs of dependence

A person who manufactures a drug of dependence must—

(a) record the following details immediately after the drug is manufactured:

(i) the date of manufacture;

(ii) the trade name or the approved name of the drug or, if it does not have either a trade or approved name, its ingredients;

(iii) the amount and, if applicable, the strength of the drug manufactured;

(iv) the total amount of the drug now on the premises on which the drug was manufactured; and

(b) sign and date the record immediately after the record is made.

Maximum penalty: $5 000.

40—Records to be kept by sellers and suppliers of drugs of dependence

(1) A supplier who sells or supplies a drug of dependence must comply with the following provisions:

(a) the supplier must, immediately after selling or supplying the drug—

(i) make a record in electronic form of—

(A) his or her name and business address; and

(B) the name and address of the person to whom the drug was sold or supplied; and

(C) the date on which the drug was sold or supplied; and

(D) the trade or approved name of the drug or, if the drug does not have either a trade or approved name, the ingredients in the drug; and

(E) the amount and, if applicable, the strength of the drug; and

(F) if the drug was sold or supplied on order—the invoice number (if any) for the sale or supply of the drug;

(ii) make a record of the total amount of the drug now in stock on the premises from which the drug was sold or supplied and sign the record;

(b) if the drug is sold or supplied in accordance with an order, the supplier must, as soon as practicable after selling or supplying the drug, cancel the order by writing "CANCELLED" on the order or, if the order was given by fax endorsed with the name and address of a single pharmacy that may sell or supply the drug, on the faxed copy of the order;

(c) the supplier must transmit the record referred to in paragraph (a)(i) electronically to the Chief Executive so that it is received no later than the 7th day of the month following the month in which the drug was sold or supplied or such later date as the Chief Executive may, on application by the supplier, authorise.

Maximum penalty: $5 000.

(1a) A supplier who sells or supplies a drug of dependence on an order must—

(a) retain the original order or a copy of the order for a period of at least 2 years; and

(b) keep it readily available for inspection by an authorised officer; and

(c) on request by an authorised officer—send a copy of the order to the authorised officer.

(2) Subregulation (1)(c) does not apply to—

(a) persons licensed under the Act to manufacture drugs of dependence or sell drugs of dependence by wholesale; or

(b) pharmacies (including health service pharmacies) in respect of the supply of drugs of dependence to a health service facility.

(3) A person who makes a record under subregulation (1) must ensure that the record is kept at all times on the premises from which the drug was supplied.

Maximum penalty: $5 000.

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

(a) unless the supplier has reasonable cause to believe that the person who ordered the drug is lawfully authorised to do so; and

(b) unless the person receiving the drug—

(i) provides the supplier with a signed and dated receipt for the drug; and

(ii) is known to the supplier or produces satisfactory evidence of his or her identity.

Maximum penalty: $5 000.

(5) If a drug of dependence is authorised or required by the law of any place to be carried aboard a ship, a person must not supply that drug for carriage aboard a ship unless he or she has received a written order for the drug from the master or medical officer of the ship.

Maximum penalty: $5 000.

(6) The Minister may exempt a supplier, or a class of suppliers, from this regulation, or specified provisions of this regulation, if satisfied that the supplier, or class of suppliers, has adequate arrangements for the keeping of records.

41—Records to be kept by suppliers of drugs of dependence who receive such drugs

(1) If a supplier of drugs of dependence receives such a drug, or a person receives a drug of dependence from a supplier on order, the person receiving the drug must—

(a) give to the person who provided the drug a signed and dated receipt for the drug; and

(b) record the following details and sign the record:

(i) the name and address of the person who provided the drug;

(ii) the name and address of the person who took delivery of the drug;

(iii) the date on which the drug was received;

(iv) the trade or approved name of the drug or, if the drug does not have either a trade or approved name, the ingredients in the drug;

(v) the amount and, if applicable, the strength of the drug;

(vi) if the drug was provided on order—the invoice number (if any) for the supply of the drug;

(vii) the total amount of the drug now in stock on the premises at which the drug was received.

Maximum penalty: $5 000.

(2) A person who makes a record under this regulation must ensure that the record is kept at all times on the premises at which the drug was received.

Maximum penalty: $5 000.

(3) The Minister may exempt a person, or class of persons, from this regulation, or specified provisions of this regulation, if satisfied that the person, or class of persons, has adequate arrangements for the keeping of records and the security of drugs of dependence.

42—Supply or administration of drugs of dependence by registered health practitioner

(1) A registered health practitioner who supplies a drug of dependence for use by a person, or who administers a drug of dependence to a person, must, immediately after the drug is so supplied or administered, record the following details and sign the record:

(a) his or her name;

(b) the full name and address (or, in the case of a patient in a ward of a health service facility, the location of the ward) of the person to whom the drug is supplied or administered;

(c) in the case of the supply of the drug to a person acting on behalf of the person for whose use the drug is intended, the full name and address of the person for whose use the drug is intended;

(d) the trade name or approved name of the drug or, if it does not have either a trade or approved name, its ingredients;

(e) the amount and, if applicable, the strength of the drug supplied or administered;

(f) the date;

(g) the time at which the drug was supplied or administered;

(h) the amount of the drug (if any) now remaining—

(i) in stock on the premises at which the drug is supplied or administered; or

(ii) otherwise in the possession of the practitioner.

Maximum penalty: $5 000.

(2) Subregulation (1) does not apply to a pharmacist.

(3) If an error is discovered in a record made for the purposes of subregulation (1), the person authorised to make the record must correct it in the following way:

(a) it must not be deleted, whited out with correction fluid or erased;

(b) it must be ruled out or otherwise marked so as to still be clearly legible after it has been so ruled out or marked;

(c) a footnote or margin note reference must be made alongside the error;

(d) the footnote or margin note must—

(i) be made on the same page as the page on which the error occurs;

(ii) contain the correct information and the date of the correction;

(iii) be endorsed with the name and signature of the person making the correction.

Maximum penalty: $5 000.

(4) The Minister may exempt a registered health practitioner, or class of registered health practitioners, from this regulation, or specified provisions of this regulation, if satisfied that the registered health practitioner, or class of registered health practitioners, has adequate arrangements for the keeping of records.

43—Sale, supply or administration of drugs of dependence by veterinary surgeon

A veterinary surgeon who sells or supplies a drug of dependence for an animal or administers such a drug to an animal must, on the day on which the drug is so sold, supplied or administered, record the following details and sign the record:

(a) his or her name;

(b) the species of animal for which the drug is sold, supplied or administered, the name and address of the owner of the animal and the name (if any) of the animal;

(c) the trade name or approved name of the drug or, if it does not have either a trade or approved name, its ingredients;

(d) the amount and, if applicable, the strength of the drug sold, supplied or administered;

(e) the date;

(f) the time at which the drug was sold, supplied or administered;

(g) the amount of the drug (if any) now remaining—

(i) in stock on the premises at which the drug is sold, supplied or administered; or

(ii) otherwise in the possession of the veterinary surgeon.

Maximum penalty: $5 000.

44—Additional requirements for administration of drugs of dependence in health service facility

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

(a) the registered health practitioner principally responsible for the treatment of the person while in the health service facility, or a registered nurse or a midwife acting in accordance with a standing order prepared or endorsed by the health service facility and approved by the Minister must—

(i) ensure that the prescribed instructions in respect of the drug are entered in the person's medication record; and

(ii) endorse the relevant entries with his or her name and signature and the date of the making of the entries;

(b) the drug must be administered to the person by a registered health practitioner in accordance with all instructions in the person's medication record;

(c) the drug must not be administered to the person unless the administration is witnessed by a registered health practitioner, or, if a registered health practitioner is not reasonably available, by some other responsible person;

(d) the registered health practitioner who administers the drug must, immediately after doing so, ensure that the name and signature of the person who witnessed the administration of the drug is recorded;

(e) if a registered health practitioner gives prescribed instructions by telephone as to the administration of a drug of dependence to a person in a health service facility—

(i) the practitioner must give the instructions to—

(A) a registered health practitioner who is authorised to administer drugs of dependence; and

(B) another responsible person employed at the health service facility; and

(ii) the practitioner to whom the instructions are given must, immediately after receiving the instructions by that method, ensure that the following information is recorded in the person's medication record and sign the record:

(A) his or her full name;

(B) the prescribed instructions in respect of the drug;

(C) the words "by telephone";

(D) the date on which the telephone instructions were given;

(E) the name of the registered health practitioner who gave the telephone instructions;

(F) the name and signature of the other person to whom the instructions were given in accordance with subparagraph (i); and

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

Maximum penalty: $5 000.

(2) The designated nurse or designated midwife for a ward of a health service facility for a particular shift must ensure that the following additional record-keeping requirements are met in respect of drugs of dependence in the ward:

(a) all relevant records required to be kept under these regulations in respect of those drugs must be kept in the ward;

(b) all drugs of dependence must be counted at the end of the shift and—

(i) if the balance in respect of a particular drug is found to be correct, the word "correct", the time and date and the nurse's or midwife's name and signature must be recorded alongside the entry for the drug; and

(ii) if the balance in respect of a particular drug is found to be incorrect—

(A) the word "incorrect", a brief explanation of the discrepancy, if known, the time and date and the nurse's or midwife's name and signature must be recorded alongside the entry for the drug; and

(B) the Director of Nursing or manager of the health service facility, and the health service facility pharmacist, if any, must be notified, as soon as practicable, that an incorrect amount of drugs is stored in the ward;

(c) the drugs count and records made under paragraph (b)—

(i) must be witnessed by the designated nurse or designated midwife for the ward for the next shift and endorsed with his or her name and signature; or

(ii) must, if the next shift does not commence immediately after the previous shift—

(A) be witnessed by a nurse or midwife working on the same shift as the nurse or midwife who made the entry and be endorsed with the name and signature of the witnessing nurse or midwife; and

(B) be checked by the designated nurse or designated midwife for the ward for the next shift at the commencement of that shift and be endorsed with his or her name and signature.

Maximum penalty: $5 000.

(3) The Director of Nursing or, if there is no Director of Nursing, the manager of a health service facility must ensure that for each shift for each ward of the health service facility a nurse or midwife is designated as having responsibility for record keeping under subregulation (2).

Maximum penalty: $5 000.

(4) The nurse or midwife designated under subregulation (3) must be a nurse or midwife present on the ward during the shift and may only be an enrolled nurse if no registered nurse or midwife will be present.

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

(a) all drugs of dependence delivered to the health service facility or a ward of the health service facility are received by a registered health practitioner employed at the health service facility or, if such a practitioner is not reasonably available, by some other responsible person; and

(b) an accurate and up-to-date balance of stocks of all drugs of dependence in each ward of the health service facility is maintained at all times; and

(c) the requirements of this regulation are complied with.

Maximum penalty: $5 000.

(5a) The Minister may exempt a health service facility, or class of health service facilities, from this regulation, or specified provisions of this regulation, if satisfied that the health service facility, or class of health service facilities, has adequate arrangements for the administration of drugs of dependence.

(6) In this regulation—

designated midwife for a ward of a health service facility for a shift means a midwife designated under subregulation (3) as having responsibility for record keeping under subregulation (2) for the ward for the shift;

designated nurse for a ward of a health service facility for a shift means a nurse designated under subregulation (3) as having responsibility for record keeping under subregulation (2) for the ward for the shift;

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

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

44A—Special provisions relating to the supply and administration of certain drugs of dependence

(1) A drug of dependence to which this regulation applies may only be supplied or administered to a person for whom it has been prescribed—

(a) by the medical practitioner who prescribed the drug of dependence for the person; and

(b) at a prescribed health service facility; and

(c) in accordance with an approved treatment protocol.

(2) A person who supplies or administers a drug in contravention of subregulation (1) commits an offence.

Maximum penalty: $5 000.

(3) This regulation applies in relation to the following drugs of dependence:

(a) N,α-dimethyl-3,4-(methylenedioxy)phenylethylamine (MDMA);

(b) Psilocybine (Psilocybin).

(4) In this regulation—

approved treatment protocol means a treatment protocol which has been approved by an ethics committee;

ethics committee has the same meaning as in the Commonwealth Act;

prescribed health service facility means—

(a) an approved treatment centre or authorised community mental health facility (both within the meaning of the *Mental Health Act 2009*); or

(b) any other health service facility, or health service facility of a class, determined by the Minister by notice in the Gazette to be a prescribed health service facility for the purposes of this regulation.

45—Destruction of drugs of dependence

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

(a) the destruction is witnessed by another person, being—

(i) an authorised officer; or

(ii) a police officer; or

(iii) a registered health practitioner; or

(iv) a veterinary surgeon; or

(v) a person who has been authorised in writing by the Chief Executive of the SA Ambulance Service to administer drugs of dependence; and

(b) the person destroying the drug ensures that the following information is recorded in respect of the drug immediately after its destruction:

(i) the full names and the signatures of the person and the witness to the destruction;

(ii) the trade name or approved name of the drug or, if it did not have either a trade or approved name, its ingredients;

(iii) the amount and, if applicable, the strength of the drug;

(iv) the date and time of the destruction;

(v) the amount of the drug (if any) now remaining in stock on the premises at which the destroyed drug was stored.

Maximum penalty: $5 000.

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

(a) a person for whose use the drug was lawfully prescribed or supplied; or

(b) a police officer or an authorised officer.

Part 5A—Special provisions relating to certain paints and tinters

45A—Restrictions on manufacture, sale, supply and use of certain paints and tinters

(1) A person must not manufacture, sell, supply or use—

(a) a First Group Paint for application to—

(i) a roof or any surface to be used for the collection or storage of potable water; or

(ii) furniture; or

(iii) any fence, wall, post, gate or building (interior or exterior) other than a building which is used exclusively for industrial purposes or mining or any oil terminal; or

(iv) any premises used for the manufacture, processing, preparation, packing or serving of products intended for human or animal consumption; or

(b) an anti-fouling or anti-corrosive paint containing more than 0.1% Lead; or

(ba) a paint (other than an anti-fouling or anti-corrosive paint) or tinter containing more than 0.009% Lead; or

(c) a paint for application to toys unless the paint complies with the specification for coating materials contained in AS/NZS ISO 8124.3:2012 *Safety of toys Part 3: Migration of certain elements (ISO 8124-03:2010, MOD)*, as in force from time to time; or

(d) a paint or tinter that contains a pesticide (other than a fungicide, algaecide, bactericide or antifouling agent).

Maximum penalty: $5 000.

(2) Subregulation (1) applies only in relation to a paint or tinter that contains a poison.

(2a) For the purposes of this regulation, the proportion of Lead contained in a paint is calculated as a percentage of the element present in the non-volatile content of the paint.

(3) In this regulation, ***First Group Paint***, ***paint***, ***pesticide***, ***tinter*** and ***toy*** have the same respective meanings as in the Uniform Poisons Standard.

Part 6—Other offences

46—Prohibition on giving samples of S8 poisons

A person must not give another person a sample of an S8 poison.

Maximum penalty: $5 000.

47—Offences relating to sale or supply of poisons

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

(a) an S2 poison, S3 poison, S4 poison, S7 poison or S8 poison; or

(b) an S5 poison or S6 poison that is not a product sample.

Maximum penalty: $5 000.

(2) A person must not, in any residential premises, or from door-to-door, or in a public place, sell or supply an S5 poison or S6 poison that is a product sample except as permitted by Part 2 Section 61 of the Uniform Poisons Standard.

Maximum penalty: $5 000.

(3) For the purposes of subregulations (1) and (2), a poison is a product sample if—

(a) it is supplied directly to the consumer free of charge, or at a nominal charge, as a mechanism to promote the sale of the product; and

(b) it is supplied in a small pack produced specifically for the purposes of promotion, or packaged in a normal commercial pack that in other circumstances a consumer would need to purchase.

(4) A person must not sell or supply an S2 poison, S3 poison, S4 poison or S8 poison in a container that—

(a) is normally used for containing food or beverages; or

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

Maximum penalty: $5 000.

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

Maximum penalty: $5 000.

(6) In this regulation—

public place includes—

(a) a place to which free access is permitted to the public, with the express or tacit consent of the owner or occupier of that place; and

(b) a place to which the public are admitted on payment of money, the test of admittance being the payment of money only; and

(c) a road, street, footway, court, alley or thoroughfare that the public are allowed to use, notwithstanding that the road, street, footway, court, alley or thoroughfare is on private property.

48—Offence to dispose of poison

A person must not—

(a) dispose of or use, or cause to be disposed of or used, an S5 poison, S6 poison or S7 poison except in accordance with the requirements of Part 2 Section 55 of the Uniform Poisons Standard; or

(b) dispose of or use, or cause to be disposed of or used, an S2 poison, S3 poison, S4 poison or S8 poison in any manner that constitutes, or is likely to constitute, a risk to public health or safety.

Maximum penalty: $5 000.

49—Keeping of records etc

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

(a) in respect of any entry in the records, retain the records at the registered address of the business in this State for a period of—

(i) in the case of records relating to S7 poisons—for a period of 5 years; or

(ii) in any other case—for a period of 2 years,

from the day on which the entry was made; and

(b) have the records readily available for inspection at all reasonable times; and

(c) during that period, take all reasonable steps to ensure that the records are protected against deterioration, loss, theft and unauthorised access, modification or use.

Maximum penalty: $3 000.

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

(3) Details that are required to be recorded under these regulations in respect of drugs of dependence must, unless otherwise specified, be recorded in a register of drugs of dependence (and any electronic register of drugs of dependence must be in a form approved by the Minister).

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

50—Vicarious liability

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

Part 7—Miscellaneous

51—Personal identification code equivalent to signature

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

(2) In this regulation—

personal identification code means a code that—

(a) is allotted to a person by his or her employer for use by that person in connection with official duties; and

(b) is known only by that person and such other persons as may be authorised by the employer for management purposes.

52—Permits (section 56(1) of Act)

An application for a permit under section 56(1) of the Act must be made in writing to the Minister and signed by the applicant.

53—Prescribed professional associations (section 58(1a) of Act)

For the purposes of section 58(1a) of the Act, the following professional associations are prescribed:

(a) in the case of publishing information to medical practitioners—

(i) the Australian Medical Association; and

(ii) the Royal Australian College of General Practitioners;

(b) in the case of publishing information to pharmacists—

(i) the Friendly Society Medical Association; and

(ii) the Pharmaceutical Society of Australia; and

(iii) the Pharmacy Guild of Australia; and

(iv) the Society of Hospital Pharmacists of Australia.

53A—Disclosure of confidential information contained in monitored drugs database (section 60A(1)(e) of Act)

(1) Information contained in the monitored drugs database relating to a particular person may be disclosed to a prescriber involved in the medical treatment or care of that person to enable that prescriber to access that information and disclose that information to—

(a) any registered health practitioner involved in the medical treatment or care of that person; and

(b) any pharmacist to whom a prescription for a monitored drug for that person has been presented.

(2) Information contained in the monitored drugs database relating to a particular person may be disclosed to a pharmacist to whom a prescription for a monitored drug for that person has been presented to enable that pharmacist to access that information and disclose that information to—

(a) any other pharmacist to whom a prescription for a monitored drug for that person has been presented; and

(b) any registered health practitioner involved in the medical treatment or care of that person.

(3) Information contained in the monitored drugs database may be disclosed to a health authority of an Australian jurisdiction responsible for the administration or enforcement of a law that regulates the sale, supply, prescription, administration and use of monitored drugs.

(4) Information contained in the monitored drugs database may be disclosed in accordance with an authorisation given by the Minister.

54—Corresponding laws (section 61(4) of Act)

For the purposes of the definition of ***corresponding law*** in section 61(4) of the Act, the following laws are prescribed:

(a) the *Drugs of Dependence Act 1989* of the Australian Capital Territory;

(b) the *Drugs Misuse and Trafficking Act 1985* of New South Wales;

(c) the *Misuse of Drugs Act 1990* of the Northern Territory;

(d) the *Drugs Misuse Act 1986* of Queensland;

(e) the *Poisons Act 1971* of Tasmania;

(f) the *Drugs, Poisons and Controlled Substances Act 1981* of Victoria;

(g) the *Misuse of Drugs Act 1981* of Western Australia.

55—Place at which codes, standards and other documents must be kept for public inspection etc (section 63(5a)(a) of Act)

For the purposes of section 63(5a)(a) of the Act, the office of the Department at 11-13 Hindmarsh Square, Adelaide is prescribed.

56—Approvals, determinations and exemptions

(1) The Minister may, at any time, by notice in writing—

(a) impose such conditions as the Minister thinks fit on an approval or exemption granted by the Minister, or on a determination made by the Minister, under these regulations; or

(b) vary or revoke the conditions of such an approval, determination or exemption as the Minister thinks fit; or

(c) revoke, as the Minister thinks fit, an approval or exemption granted by the Minister, or a determination made by the Minister, under these regulations.

(2) A person must not contravene or fail to comply with a condition of an approval or exemption granted by the Minister, or a determination made by the Minister, under these regulations.

Maximum penalty: $3 000.

Schedule 1—Forms

End user statement

The chemical product I wish to purchase is classified as a possible illicit drug precursor or auxiliary reagent. I understand that to be supplied this product a signed end user declaration must be provided together with an order.

Catalogue No	Product Name	Quantity	Pack Size	Order No

Intended use: ☐Analytical ☐Research and Design ☐Manufacturing ☐Resale ☐Other

Please specify full details of assay, project, product customer etc

Purchaser details and declaration

I, *[insert full name]* being *[insert position]* on behalf of *[insert name of company or institution and ACN]*
Address:
Account No:
declare that the above chemical product will not be used for the manufacture of illicit drugs.

Signature:
Date:

Details of collecting agent's identification

Current Passport No:
Country of Issue:
Current Photograph Licence No:
Expiry date:
Photo Identification Card Type:

End user distributor/supplier details and declaration

I, *[insert full name]* being *[insert position]* on behalf of *[insert name of company or institution and ACN]*
Address:
Account No:
declare that the above chemical product will not be used for the manufacture of illicit drugs.

Signature:
Date:

Note—

1 Please attach a photocopy of current driver's licence bearing a photograph.

2 The form must be completed with all details.

Schedule 2—Transitional provisions

Part 2—Transitional provisions

2—Approvals of child-resistant packaging or containers for S2, S5 or S6 poisons

An approval under regulation 20(c)(ii)(B) of the *Controlled Substances (Poisons) Regulations 1996* in force immediately before the commencement of these regulations will, on that commencement, be taken to be an approval under regulation 27(b)(ii)(B) of these regulations.

3—Authorisations to prescribe certain S4 drugs

An authorisation under Schedule K of the *Controlled Substances (Poisons) Regulations 1996* in force immediately before the commencement of these regulations will, on that commencement, be taken to be an authorisation under regulation 19(1) of these regulations.

4—Exemptions from requirement to hold licence under section 22 of Act

An exemption under regulation 17 of the *Controlled Substances (Poisons) Regulations 1996* in force immediately before the commencement of these regulations will, on that commencement, be taken to be an exemption under regulation 25(6) of these regulations.

5—Exemptions from section 24(b) or 24(c) of Act

(1) An exemption under regulation 18(2) of the *Controlled Substances (Poisons) Regulations 1996* in force immediately before the commencement of these regulations will, on that commencement, be taken to be an exemption under regulation 26(7) of these regulations.

(2) An exemption under regulation 19(3) of the *Controlled Substances (Poisons) Regulations 1996* in force immediately before the commencement of these regulations will, on that commencement, be taken to be an exemption under regulation 26(7) of these regulations.

Legislative history

Notes

- Please note—References in the legislation to other legislation or instruments or to titles of bodies or offices are not automatically updated as part of the program for the revision and publication of legislation and therefore may be obsolete.
- Earlier versions of these regulations (historical versions) are listed at the end of the legislative history.
- For further information relating to the Act and subordinate legislation made under the Act see the Index of South Australian Statutes or www.legislation.sa.gov.au.

Legislation revoked by principal regulations

The *Controlled Substances (Poisons) Regulations 2011* revoked the following:

Controlled Substances (Poisons) Regulations 1996

Controlled Substances (Volatile Solvents) Regulations 1996

Principal regulations and variations

New entries appear in bold.

Year	No	Reference	Commencement
2011	140	*Gazette 9.6.2011 p2334*	1.7.2011: r 2
2013	179	*Gazette 11.7.2013 p3034*	11.7.2013: r 2
2016	17	*Gazette 3.3.2016 p811*	3.3.2016: r 2
2017	14	*Gazette 16.2.2017 p557*	1.4.2017: r 2
2017	317	*Gazette 5.12.2017 p4849*	1.7.2018: r 2
2017	319	*Gazette 5.12.2017 p4857*	5.12.2017: r 2
2019	31	*Gazette 18.4.2019 p1074*	18.4.2019: r 2
2019	246	*Gazette 19.12.2019 p4387*	1.4.2020: r 2
2020	1	*Gazette 13.1.2020 p80*	13.1.2020: r 2
2020	209	*Gazette 18.6.2020 p3397*	18.6.2020: r 2
2020	287	*Gazette 22.10.2020 p4875*	1.11.2020: r 2
2021	3	*Gazette 27.1.2021 p164*	27.1.2021: r 2
2021	9	*Gazette 4.2.2021 p253*	4.6.2021: r 2
2021	186	*Gazette 16.12.2021 p4409*	1.4.2022: r 2
2023	1	*Gazette 18.1.2023 p57*	1.2.2023: r 2
2023	**62**	***Gazette 29.6.2023 p2071***	**1.7.2023: r 2**

Provisions varied

New entries appear in bold.

Entries that relate to provisions that have been deleted appear in italics.

Provision	How varied	Commencement
Pt 1		
r 2	*omitted under Legislation Revision and Publication Act 2002*	*11.7.2013*
r 3		
r 3(1)		
approved electronic communication	inserted by 209/2020 r 4(1)	18.6.2020
approved electronic form	inserted by 209/2020 r 4(1)	18.6.2020
approved information technology requirements	inserted by 209/2020 r 4(1)	18.6.2020
Australian jurisdiction	inserted by 287/2020 r 4(1)	1.11.2020
Chief Executive	CE varied to read Chief Executive by 179/2013 r 4(1)	11.7.2013
Commonwealth Regulations	inserted by 209/2020 r 4(2)	18.6.2020
correctional institution	inserted by 186/2021 r 4	1.4.2022
council subsidiary	inserted by 179/2013 r 4(2)	11.7.2013
data source entity	inserted by 287/2020 r 4(2)	1.11.2020
electronic communication	inserted by 209/2020 r 4(3)	18.6.2020
electronic prescription	inserted by 209/2020 r 4(3)	18.6.2020
information technology requirements	inserted by 209/2020 r 4(4)	18.6.2020
medication chart prescription	inserted by 179/2013 r 4(3)	11.7.2013
	varied by 319/2017 r 4	5.12.2017
	substituted by 209/2020 r 4(5)	18.6.2020
Metropolitan Adelaide	substituted by 287/2020 r 4(3)	1.11.2020
monitored drug	inserted by 287/2020 r 4(3)	1.11.2020
monitored drugs database	inserted by 287/2020 r 4(3)	1.11.2020
National Health Act	inserted by 179/2013 r 4(4)	11.7.2013

National Health (Continued Dispensing) Determination	inserted by 179/2013 r 4(4)	11.7.2013
National Health (Residential Medication Chart) Determination	*inserted by 179/2013 r 4(4)*	*11.7.2013*
	deleted by 17/2016 r 4	*3.3.2016*
pharmaceutical benefit	inserted by 179/2013 r 4(5)	11.7.2013
prescribed (continued dispensing) pharmaceutical benefit	inserted by 179/2013 r 4(6)	11.7.2013
prescribed (residential medication chart) pharmaceutical benefit	*inserted by 179/2013 r 4(6)*	*11.7.2013*
	deleted by 17/2016 r 4	*3.3.2016*
Uniform Poisons Standard	amended by 1/2023 r 3	1.2.2023
Vaccine Administration Code	inserted by 179/2013 r 4(7)	11.7.2013
r 3(3)	inserted by 179/2013 r 4(8)	11.7.2013
r 3(4)	inserted by 287/2020 r 4(4)	1.11.2020
Pt 2		
r 5		
r 5(1)	varied by 17/2016 r 5	3.3.2016
Pt 3		
r 12		
r 12(1)	r 12 redesignated as r 12(1) by 179/2013 r 5	11.7.2013
r 12(2)	inserted by 179/2013 r 5	11.7.2013
r 14		
r 14(3)	varied by 17/2016 r 6	3.3.2016
r 14(4)	varied by 179/2013 r 6	11.7.2013
r 15		
r 15(2)	substituted by 14/2017 r 4	1.4.2017
	amended by 1/2023 r 4	1.2.2023
r 16		
r 16(3)	substituted by 317/2017 r 4	1.7.2018
r 18		
r 18(1)	varied by 179/2013 r 7(1)	11.7.2013
r 18(3)	inserted by 179/2013 r 7(2)	11.7.2013

	varied by 319/2017 r 5	5.12.2017
r 18(4)	inserted by 179/2013 r 7(2)	11.7.2013
r 19		
r 19(1)	varied by 17/2016 r 7(1)	3.3.2016
r 19(3)		
prescribed period	varied by 17/2016 r 7(2), (3)	3.3.2016
r 20	deleted by 179/2013 r 8	11.7.2013
	inserted by 62/2023 r 3	**1.7.2023**
r 21		
r 21(1)	substituted by 179/2013 r 9(1)	11.7.2013
r 21(2)	varied by 179/2013 r 9(2)—(13)	11.7.2013
	varied by 1/2020 r 4(1)	13.1.2020
r 21(2a) and (2b)	inserted by 1/2020 r 4(2)	13.1.2020
r 21(4)	inserted by 1/2020 r 4(3)	13.1.2020
r 22		
r 22(2)	varied by 319/2017 r 6	5.12.2017
r 22(3)		
correctional institution	*deleted by 186/2021 r 5*	*1.4.2022*
r 23		
r 23(1)	substituted by 246/2019 r 4	1.4.2020
r 23(1a)—(1c)	inserted by 246/2019 r 4	1.4.2020
r 23A	inserted by 246/2019 r 5	1.4.2020
r 25		
r 25(1)	varied by 17/2016 r 8(1)	3.3.2016
r 25(2)	substituted by 17/2016 r 8(2)	3.3.2016
r 25(3)	ceased to have effect and omitted under *Legislation Revision and Publication Act 2002*	3.3.2016
	inserted by 17/2016 r 8(2)	3.3.2016
r 25(6)	varied by 319/2017 r 7	5.12.2017
r 25(7) and (8)	*deleted by 17/2016 r 8(3)*	*3.3.2016*
r 26		
r 26(1)	varied by 14/2017 r 5	1.4.2017
	varied by 31/2019 r 4(1)	18.4.2019
r 26(2)—(4)	amended by 1/2023 r 5	1.2.2023
r 26(6)	varied by 179/2013 r 10(1)—(3)	11.7.2013
	varied by 31/2019 r 4(2)	18.4.2019
r 26(7)	varied by 179/2013 r 10(4)	11.7.2013
r 26(8)	substituted by 17/2016 r 9	3.3.2016
	varied by 31/2019 r 4(3)	18.4.2019
r 26(9)	inserted by 17/2016 r 9	3.3.2016
prescribed medicine	varied by 31/2019 r 4(4)	18.4.2019

prescribed S3 poison	(b), (c) deleted by 31/2019 r 4(5)	18.4.2019
Therapeutic Goods Order No 80	*deleted by 31/2019 r 4(6)*	*18.4.2019*
Therapeutic Goods Order No 95	inserted by 31/2019 r 4(6)	18.4.2019
r 27	varied by 179/2013 r 11	11.7.2013
	(b)(ii)(C) deleted by 179/2013 r 11	11.7.2013
	substituted by 14/2017 r 6	1.4.2017
	varied by 9/2021 r 4	4.6.2021
	amended by 1/2023 r 6	1.2.2023
r 29	varied by 14/2017 r 7	1.4.2017
r 30		
r 30(2)	varied by 17/2016 r 10(1), (2)	3.3.2016
r 32		
r 32(1)	varied by 17/2016 r 11	3.3.2016
Pt 4		
r 33 before substitution by 209/2020		
r 33(6)	*substituted by 17/2016 r 12*	*3.3.2016*
	varied by 319/2017 r 8	*5.12.2017*
r 33(7)	*inserted by 179/2013 r 12*	*11.7.2013*
	deleted by 17/2016 r 12	*3.3.2016*
r 33	substituted by 209/2020 r 5	18.6.2020
r 33(6)	substituted by 287/2020 r 5	1.11.2020
	varied by 186/2021 r 6(1)	1.4.2022
r 33(6a)	inserted by 287/2020 r 5	1.11.2020
	substituted by 186/2021 r 6(2)	1.4.2022
r 33(6b)	inserted by 186/2021 r 6(2)	1.4.2022
r 34		
r 34(1)	varied by 287/2020 r 6(1)	1.11.2020
	(d)(iii) deleted by 287/2020 r 6(2)	1.11.2020
r 34(1a)	inserted by 287/2020 r 6(2)	1.11.2020
	varied by 186/2021 r 7(1)	1.4.2022
r 34(1b)	inserted by 287/2020 r 6(2)	1.11.2020
	substituted by 186/2021 r 7(2)	1.4.2022
r 34(1c)	inserted by 287/2020 r 6(2)	1.11.2020
	varied by 186/2021 r 7(3)	1.4.2022
r 34(3)	*deleted by 209/2020 r 6(1)*	*18.6.2020*
r 34(4)	inserted by 179/2013 r 13	11.7.2013
	substituted by 17/2016 r 13	3.3.2016
	varied by 319/2017 r 9	5.12.2017

	varied by 209/2020 r 6(2)	18.6.2020
r 34A	inserted by 186/2021 r 8	1.4.2022
r 35 before substitution by 209/2020		
r 35(1)	*varied by 179/2013 r 14(1)*	*11.7.2013*
	varied by 17/2016 r 14(1)—(3)	*3.3.2016*
r 35(1a) and (1b)	*inserted by 17/2016 r 14(4)*	*3.3.2016*
r 35(2)	*varied by 179/2013 r 14(1)*	*11.7.2013*
r 35(10)	*deleted by 17/2016 r 14(5)*	*3.3.2016*
r 35(12)	*inserted by 179/2013 r 14(2)*	*11.7.2013*
	substituted by 17/2016 r 14(6)	*3.3.2016*
	varied by 319/2017 r 10	*5.12.2017*
r 35	substituted by 209/2020 r 7	18.6.2020
r 35(2)	varied by 287/2020 r 7(1)	1.11.2020
r 35(16)	substituted by 287/2020 r 7(2)	1.11.2020
r 35A	inserted by 209/2020 r 7	18.6.2020
r 35A(1)	varied by 287/2020 r 8(1)	1.11.2020
	varied by 186/2021 r 9(1), (2)	1.4.2022
r 35A(1a)	*inserted by 287/2020 r 8(2)*	*1.11.2020*
	deleted by 186/2021 r 9(3)	*1.4.2022*
r 35A(2)	substituted by 186/2021 r 9(3)	1.4.2022
r 35A(3)	varied by 287/2020 r 8(3)	1.11.2020
r 35A(4)	varied by 186/2021 r 9(4)	1.4.2022
r 35A(5)	varied by 287/2020 r 8(4)	1.11.2020
r 35A(6)	inserted by 186/2021 r 9(5)	1.4.2022
r 35B	inserted by 3/2021 r 4	27.1.2021
Pt 5		
r 37		
r 37(1)	varied by 287/2020 r 9(1)	1.11.2020
r 37(2)	substituted by 179/2013 r 15	11.7.2013
	varied by 287/2020 r 9(2)	1.11.2020
r 37(3)	substituted by 179/2013 r 15	11.7.2013
r 37(4)	substituted by 179/2013 r 15	11.7.2013
r 38	substituted by 179/2013 r 16	11.7.2013
r 39	substituted by 179/2013 r 17	11.7.2013
r 40		
r 40(1)	varied by 179/2013 r 18(1)—(9)	11.7.2013
	substituted by 17/2016 r 15(1)	3.3.2016
r 40(1a)	inserted by 17/2016 r 15(1)	3.3.2016
r 40(2)	varied by 179/2013 r 18(1)	11.7.2013
	varied by 17/2016 r 15(2)	3.3.2016
r 40(6)	inserted by 17/2016 r 15(3)	3.3.2016

r 41		
r 41(3)	inserted by 17/2016 r 16	3.3.2016
r 42		
r 42(1)	varied by 179/2013 r 19(1), (2)	11.7.2013
r 42(4)	inserted by 17/2016 r 17	3.3.2016
r 43	varied by 179/2013 r 20(1)—(6)	11.7.2013
r 44		
r 44(1)	varied by 179/2013 r 21	11.7.2013
r 44(5a)	inserted by 17/2016 r 18	3.3.2016
r 44A	**inserted by 62/2023 r 4**	**1.7.2023**
r 45		
r 45(1)	varied by 179/2013 r 22	11.7.2013
Pt 5A	inserted by 14/2017 r 8	1.4.2017
r 45A		
r 45A(1)	varied by 186/2021 r 10(1)	1.4.2022
r 45A(2a)	inserted by 186/2021 r 10(2)	1.4.2022
Pt 6		
r 47	substituted by 14/2017 r 9	1.4.2017
r 47(2)	amended by 1/2023 r 7	1.2.2023
r 48	substituted by 14/2017 r 10	1.4.2017
	amended by 1/2023 r 8	1.2.2023
r 49		
r 49(1)	varied by 14/2017 r 11	1.4.2017
r 49(3)	substituted by 17/2016 r 19	3.3.2016
Pt 7		
r 53	substituted by 17/2016 r 20	3.3.2016
r 53A	inserted by 287/2020 r 10	1.11.2020
r 53A(4)	inserted by 186/2021 r 11	1.4.2022
r 56	inserted by 179/2013 r 23	11.7.2013
	substituted by 17/2016 r 21	3.3.2016
Sch 2		
Pt 1	*omitted under Legislation Revision and Publication Act 2002*	*11.7.2013*

Historical versions

11.7.2013
3.3.2016
1.4.2017
5.12.2017
1.7.2018
18.4.2019
13.1.2020
1.4.2020

18.6.2020
1.11.2020
27.1.2021
4.6.2021
1.4.2022
1.2.2023