

NORTHERN TERRITORY OF AUSTRALIA

MEDICINES, POISONS AND THERAPEUTIC GOODS REGULATIONS

As in force at 1 May 2016

Table of provisions

Part 1	Preliminary matters	
1	Citation	1
2	Commencement	1
3	Definitions	1
4	Australian/New Zealand Standard	2
5	Corresponding law	2
6	Modification of medicines and poisons standard	2
Part 2	Dealing with regulated substances	
Division 1	Requisitions, prescriptions and administration and supply orders	
7	Written requisition to pharmacist	3
8	Prescription issued by health practitioner	3
9	Prescription issued by veterinarian	4
10	Additional requirements for prescription for Schedule 8 substance	5
11	Prescription may be issued to agent	5
12	Conditions on which prescription may be issued to partner	5
13	Administration order	6
14	Supply order – person discharged from hospital	6
15	Supply order – nurse at residential facility	7
16	Supply order – person in charge of declared place	8
17	Formal requirements for requisitions, prescriptions and administration and supply orders	8
Division 2	Dealings to be witnessed	
18	Record of supply or administration of Schedule 8 substance	9
19	Destruction of Schedule 8 substance	9
20	Administration of Schedule 9 substance must be witnessed	9
21	Destruction of Schedule 9 substance	10
Division 3	Storage and transport	
22	Storage of Schedule 2 substance by retailer	10
23	Storage of Schedule 3 substance by authority holder	10
24	Storage of Schedule 2, 3 or 4 substance at pharmacy	11
25	Storage of Schedule 4 substance by authority holder	12

26	Storage of Schedule 4 substance at residential facility or declared place	12
27	Storage of methylated spirit	12
28	Storage of Schedule 7 substance by manufacturer or wholesaler	13
29	Storage of Schedule 7 substance by retailer	13
30	Storage of Schedule 7 substance by authority holder	14
31	Storage of Schedule 8 substance	15
32	Delivery person must not leave certain regulated substances unattended.....	15

Division 4 Packaging and labelling

33	Packaging requirements	16
34	Labelling requirements	16
35	Container not to be used for human-use substance	17

Division 5 Manufacture, supply and use of paints

36	Paint applied to premises, structures and furniture.....	17
37	Paint for toys.....	17
38	Paint containing pesticide.....	17

Division 6 Advertising

39	Pharmacist pricelist advertising certain Scheduled substances.....	18
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Part 3 Authorities to deal with regulated substances

40	Additional conditions – certificate of registration.....	18
41	Duration of Schedule 8 authorisation for treating child's ADHD.....	18
42	Contents of authority	19
43	Authority holder to give notice of change of particulars	19

Part 4 Regulated substance registers

Division 1 Maintaining regulated substance registers

Subdivision 1 Pseudoephedrine register

44	Keeping of register	20
45	Details to be recorded	20

Subdivision 2 Schedule 4 register

46	Keeping of register	20
47	Details to be recorded	21

Subdivision 3		Schedule 7 register
48	Keeping of register	21
49	Details to be recorded	21
Subdivision 4		Schedule 8 register
50	Maintenance of register – persons in charge of premises	22
51	Keeping of register – medical kit holder.....	23
52	Keeping of register – other persons.....	23
53	Form of Schedule 8 register	24
54	Details to be recorded	24
Subdivision 5		Schedule 9 register
55	Keeping of register	25
56	Form of Schedule 9 register	25
57	Details to be recorded	26
Subdivision 6		Manufacturer/wholesaler register
58	Keeping of register	26
59	Details to be recorded	27
Subdivision 7		General requirements
60	Form of register entries	27
61	Period of retention of registers.....	27
Division 2	Offences relating to regulated substance registers	
62	Offence not to maintain register.....	27
63	Offence not to sign entry.....	28
64	Offence to make false or misleading entry	28
65	Offence to change entry	28
66	Offence not to record details of supply of pseudoephedrine.....	29
67	Offence not to sign register after certain dealings with Schedule 8 or 9 substance	29
68	Offence not to sign register after witnessing certain dealings with Schedule 8 or 9 substance.....	29
69	Offence not to ensure witness signs register after certain dealings with Schedule 8 or 9 substance	30
70	Offence not to maintain register where substance kept.....	30
71	Offence not to report possible loss etc. of regulated substance	31
72	Offence not to report destruction, loss etc. of register	31

Part 5	Other records and notices	
Division 1	General requirements	
73	Retention of documents relating to receipt or supply of regulated substances	32
74	Retention of prescriptions	32
75	Record of supply or administration of Schedule 4 or 8 substance in clinical or other records	32
76	Form and period of retention of records	33
Division 2	Offences relating to records and notices	
77	Offence not to make or keep record	33
78	Offence not to give fraudulent prescription to police	34
79	Offence not to report supply or administration of Schedule 8 substance at declared place	34
80	Offence not to report administration of Schedule 8 substance from medical kit	34
Part 6	Legal proceedings	
81	Declared provisions	35
81A	Declared provisions	35
Part 7	Infringement notice offences	
82	Infringement notice offence and prescribed amount payable	35
83	When infringement notice may be given	35
84	Contents of infringement notice	35
85	Payment by cheque	36
86	Withdrawal of infringement notice	36
87	Application of Part	37
Part 8	Administrative matters	
88	Content of scheduled substance treatment protocol	37
89	Information in register of authorities	37
90	Appointed Committee members	38
91	Fees	39
Schedule 1	Infringement notice offences and prescribed amounts	
Schedule 2	Fees	

ENDNOTES

NORTHERN TERRITORY OF AUSTRALIA

As in force at 1 May 2016

MEDICINES, POISONS AND THERAPEUTIC GOODS REGULATIONS

Regulations under the *Medicines, Poisons and Therapeutic Goods Act*

Part 1 Preliminary matters

1 Citation

These Regulations may be cited as the *Medicines, Poisons and Therapeutic Goods Regulations*.

2 Commencement

These Regulations commence on the commencement of the *Medicines, Poisons and Therapeutic Goods Act*.

3 Definitions

In these Regulations:

infringement notice, see regulation 83.

infringement notice offence, see regulation 82(1).

key includes an electronic swipe card and electronic proximity device.

maintain, in relation to a regulated substance register, means keep the register or ensure the register is kept.

personal custody, of a key by a person, includes keeping the key in a combination-operated key safe, the combination of which the person keeps confidential.

pharmacist-in-charge:

- (a) of a pharmacy – means the person appointed under Schedule 7, clause 7(1) of the *Health Practitioners Act* to be the pharmacist-in-charge of the pharmacy business carried on in the pharmacy; or

- (b) of a pharmacy department – means the person appointed under Schedule 7, clause 7(3) of the *Health Practitioners Act* to be the pharmacist-in-charge of the pharmacy department.

pharmacy department, see Schedule 7, clause 1 of the *Health Practitioners Act*.

prescribed amount, see regulation 82(2).

regulated substance register means a register required to be maintained under Part 4, Division 1.

Schedule 8 register means a register in relation to Schedule 8 substances required to be kept under regulation 50, 51 or 52.

4 Australian/New Zealand Standard

In these Regulations, a reference consisting of the letters "AS/NZS" followed by a number is a reference to the standard so numbered published jointly by or for Standards Australia Limited ABN 85 087 326 690 and Standards New Zealand.

5 Corresponding law

For paragraph (b) of the definition **corresponding law** in section 5 of the Act, each of the following laws is a corresponding law:

- (a) *Controlled Substances Act 1984* (SA);
- (b) *Drugs, Poisons and Controlled Substances Act 1981* (Vic);
- (c) *Health Act 1937* (Qld);
- (d) *Medicines, Poisons and Therapeutic Goods Act 2008* (ACT);
- (e) *Poisons Act 1964* (WA);
- (f) *Poisons Act 1971* (Tas);
- (g) *Poisons and Therapeutic Goods Act 1966* (NSW).

6 Modification of medicines and poisons standard

- (1) This regulation modifies the medicines and poisons standard for section 14(2) of the Act.
- (2) Each substance listed in Appendix D, paragraph 1 of the medicines and poisons standard is taken to be excluded from Appendix D of the medicines and poisons standard.

Part 2 Dealing with regulated substances

Division 1 Requisitions, prescriptions and administration and supply orders

Note for Division 1

A requisition, prescription, administration order or supply order may be issued electronically in accordance with the Electronic Transactions (Northern Territory) Act.

7 Written requisition to pharmacist

For section 57(2) of the Act, a written requisition for the supply of a Schedule 4 or 8 substance must contain the following information:

- (a) the name of the health practitioner issuing it;
- (b) the date of issue;
- (c) the ward or department of the hospital for which the substance is to be supplied;
- (d) the name of the substance and the form, strength and quantity to be supplied;
- (e) the signature of the health practitioner.

8 Prescription issued by health practitioner

For section 87(1)(a) of the Act, a prescription issued by an authorised prescriber who is a health practitioner must:

- (a) state the following particulars of the authorised prescriber:
 - (i) name;
 - (ii) business address and telephone number;
 - (iii) health profession; and
- (b) state the date of issue; and
- (c) state the name and address of the person for whom it is issued; and
- (d) state the name of the substance, and the dose, form and strength, for which it is issued; and

- (e) if it is for an unusual or dangerous dose – include the authorised prescriber's initials beside an underlined reference to the dose; and
- (f) state the quantity of the substance to be supplied; and
- (g) if it is a repeat prescription – state the number of repeats permitted; and
- (h) state the start date for supply, if different from the date the prescription is issued; and
- (i) include directions for the use of the substance that are adequate to allow the substance to be taken or administered safely; and
- (j) be written in terms and symbols used in ordinary professional practice; and
- (k) if it is issued by:
 - (i) a dentist – state it is issued for dental purposes only; or
 - (ii) an optometrist – state it is issued for the treatment of a condition of the eye only; or
 - (iii) a podiatrist – state it is issued for podiatry treatment only; and
- (l) if it is issued for a Schedule 8 substance – meet the requirements specified in regulation 10; and
- (m) be signed by the authorised prescriber.

9 Prescription issued by veterinarian

For section 87(1)(a) of the Act, a prescription issued by an authorised prescriber who is a veterinarian must:

- (a) contain the information mentioned in section 32(2) of the *Agricultural and Veterinary Chemicals (Control of Use) Act*, and
- (b) state the date of issue; and
- (c) state the name and address of the person who owns, or is in charge of, the animal for which it is issued; and
- (d) state it is issued for animal treatment only; and

- (e) if it is issued for a Schedule 8 substance – meet the requirements specified in regulation 10; and
- (f) be signed by the authorised prescriber.

10 Additional requirements for prescription for Schedule 8 substance

- (1) A prescription for a Schedule 8 substance must state:
 - (a) if it is issued for:
 - (i) a person – the date of birth of the person; or
 - (ii) an animal – sufficient information to identify the animal; and
 - (b) the quantity of the substance to be supplied in words and numerals; and
 - (c) if it is issued by an authorised health practitioner under a Schedule 8 authorisation or Schedule 8 exemption – the number or other identifier of the authorisation or exemption; and
 - (d) if it is a repeat prescription – the minimum repeat interval.
- (2) In addition, a prescription for a Schedule 8 substance of a particular form and strength must not authorise the supply of any other substance, including a Schedule 8 substance of a different form or strength.

11 Prescription may be issued to agent

For section 89(1)(b)(iv) of the Act, a person who acts for the patient is prescribed.

12 Conditions on which prescription may be issued to partner

For section 89(2)(c) of the Act, the conditions for the issue of a prescription are:

- (a) the recipient has been diagnosed with chlamydia that has been confirmed microbiologically by nucleic acid amplification test or related technologies; and
- (b) the partner is at significant risk of contracting chlamydia; and
- (c) the prescription is for a single dose of Azithromycin.

13 Administration order

For section 92(2) of the Act, an administration order for a Scheduled substance must:

- (a) state the name of the authorised prescriber issuing it; and
- (b) if the order is written – state the date of issue and be signed by the authorised prescriber; and
- (c) state the name, address and, if applicable, hospital registration number of the person to whom the substance is to be administered; and
- (d) state the name of the substance, and the dose, form and strength, to be administered; and
- (e) state the route, frequency and period of administration; and
- (f) state the start date for administration, if different from the date the order is issued.

14 Supply order – person discharged from hospital

For section 92(2) of the Act, a supply order authorising the supply of a Scheduled substance to a person on the person's discharge as a patient of a hospital must:

- (a) state the following particulars of the authorised prescriber issuing the order:
 - (i) name;
 - (ii) hospital pager number or telephone number;
 - (iii) name of the hospital and ward or department in which the prescriber is working;
 - (iv) health profession; and
- (b) state the date of issue; and
- (c) state the name, address and hospital registration number of the person to whom the substance is to be supplied; and
- (d) state the name of the substance, and the dose, form and strength, to be supplied; and
- (e) state the quantity of the substance to be supplied; and

- (f) include directions for the use of the substance that are adequate to allow the substance to be taken or administered safely; and
- (g) be signed by the authorised prescriber.

15 Supply order – nurse at residential facility

- (1) For section 92(2) of the Act, a supply order authorising the supply of a Scheduled substance to a nurse employed at a residential facility for administration to a resident at the facility must:
 - (a) state the following particulars of the authorised prescriber issuing the order:
 - (i) name;
 - (ii) business address and telephone number;
 - (iii) health profession; and
 - (b) state the date of issue; and
 - (c) state the name, address and telephone number of the residential facility; and
 - (d) state the resident's name and medical record number; and
 - (e) state the name of the substance, and the dose, form and strength, to be supplied; and
 - (f) state instructions for the administration of the substance; and
 - (g) be signed by the authorised prescriber.
- (2) In addition, a supply order for a Schedule 8 substance of a particular form and strength must not authorise the supply of any other substance, including a Schedule 8 substance of a different form or strength.
- (3) To avoid doubt, a medication chart for a resident may be used as a supply order if it meets the requirements specified in subregulations (1) and (2).

16 Supply order – person in charge of declared place

- (1) For section 92(2) of the Act, a supply order authorising the supply of a Scheduled substance to the person in charge of a declared place must:
 - (a) state the following particulars of the authorised prescriber issuing the order:
 - (i) name;
 - (ii) business address and telephone number;
 - (iii) health profession; and
 - (b) state the date of issue; and
 - (c) state the name, address and telephone number of the declared place; and
 - (d) state the name and address of the person receiving medical treatment at the declared place to whom the substance will be administered; and
 - (e) state the name of the substance, and the dose, form and strength, to be supplied; and
 - (f) state the quantity of the substance to be supplied; and
 - (g) state instructions for the administration of the substance; and
 - (h) be signed by the authorised prescriber.
- (2) In addition, a supply order for a Schedule 8 substance of a particular form and strength must not authorise the supply of any other substance, including a Schedule 8 substance of a different form or strength.

17 Formal requirements for requisitions, prescriptions and administration and supply orders

- (1) This regulation applies to each of the following (the **document**) unless issued electronically:
 - (a) a requisition mentioned in regulation 7;
 - (b) a prescription;
 - (c) an administration order or supply order.
- (2) The document must be written in ink.

- (3) If there are changes to any of the details in the document, the initials of the person who issued the document and the date the change was made must appear beside each change.

Division 2 Dealings to be witnessed

18 Record of supply or administration of Schedule 8 substance

For section 100(1A)(b) of the Act, the Schedule 8 register kept for the ward or department of the hospital in which the patient is receiving treatment, or the residential facility or declared place, is prescribed.

Note for regulation 18

Section 100 of the Act requires certain dealings with Schedule 8 substances to be witnessed.

19 Destruction of Schedule 8 substance

- (1) A person who is authorised under the Act to possess a Schedule 8 substance commits an offence if:
- (a) the person destroys a substance; and
 - (b) the substance is a Schedule 8 substance; and
 - (c) the destruction is not witnessed by one of the following persons:
 - (i) an authorised officer;
 - (ii) a health practitioner;
 - (iii) a veterinarian.

Maximum penalty: 40 penalty units.

- (2) Strict liability applies to subregulation (1)(c).

20 Administration of Schedule 9 substance must be witnessed

- (1) A person who is authorised under the Act to possess a Schedule 9 substance commits an offence if:
- (a) the person administers a substance to a person or animal; and
 - (b) the substance is a Schedule 9 substance; and
 - (c) the administration is not witnessed by another person.

Maximum penalty: 20 penalty units.

- (2) Strict liability applies to subregulation (1)(c).

21 Destruction of Schedule 9 substance

- (1) A person who is authorised under the Act to possess a Schedule 9 substance commits an offence if:
- (a) the person destroys a substance; and
 - (b) the substance is a Schedule 9 substance; and
 - (c) the destruction is not witnessed by an authorised officer.

Maximum penalty: 40 penalty units.

- (2) Strict liability applies to subregulation (1)(c).

Division 3 Storage and transport

Note for Division 3

There are no generally applicable storage requirements for prohibited substances. However, a prohibited substance authorisation may contain conditions regarding storage of the prohibited substance.

22 Storage of Schedule 2 substance by retailer

- (1) The licensee under a retailer licence commits an offence if:
- (a) a Schedule 2 substance is stored at the place in relation to which the licence was issued; and
 - (b) the licensee fails to ensure the substance is stored in a way that restricts public access to it.

Maximum penalty: 30 penalty units.

- (2) Strict liability applies to subregulation (1)(b).

23 Storage of Schedule 3 substance by authority holder

- (1) The holder of a research authorisation or medical kit authorisation commits an offence if:
- (a) the holder possesses a substance; and
 - (b) the substance is a Schedule 3 substance that is in the holder's possession under the authorisation; and

- (c) the holder fails to ensure the substance is stored in a way that prevents unauthorised access to it.

Maximum penalty: 30 penalty units.

- (2) Strict liability applies to subregulation (1)(c).

24 Storage of Schedule 2, 3 or 4 substance at pharmacy

- (1) The pharmacist-in-charge of a pharmacy commits an offence if:

- (a) a Schedule 2 substance that is for retail sale is stored at the pharmacy; and
- (b) the pharmacist-in-charge fails to ensure the substance is stored within 4 m of, or within sight of, the pharmacy's dispensary.

Maximum penalty: 30 penalty units.

- (2) The pharmacist-in-charge of a pharmacy commits an offence if:

- (a) a Schedule 2 substance that is not for retail sale is stored at the pharmacy; and
- (b) the pharmacist-in-charge fails to ensure the substance is stored in a way that restricts public access to it.

Maximum penalty: 30 penalty units.

- (3) The pharmacist-in-charge of a pharmacy commits an offence if:

- (a) a Schedule 3 or 4 substance is stored at the pharmacy; and
- (b) the pharmacist-in-charge fails to ensure the substance is stored:
 - (i) in a part of the pharmacy to which the public does not have access; or
 - (ii) in a way that prevents persons other than a pharmacist, or a person under the direct supervision of a pharmacist, from having access to the substance.

Maximum penalty: 30 penalty units.

- (4) Strict liability applies to subregulations (1)(b), (2)(b) and (3)(b).

25 Storage of Schedule 4 substance by authority holder

(1) The holder of a Schedule 4 authorisation, research authorisation or medical kit authorisation commits an offence if:

- (a) the holder possesses a substance; and
- (b) the substance is a Schedule 4 substance that is in the holder's possession under the authorisation; and
- (c) the holder fails to ensure the substance is stored in a way that prevents unauthorised access to it.

Maximum penalty: 30 penalty units.

(2) Strict liability applies to subregulation (1)(c).

26 Storage of Schedule 4 substance at residential facility or declared place

(1) The nurse in charge of a residential facility commits an offence if:

- (a) a Schedule 4 substance is stored at the facility; and
- (b) disposition of the substance is controlled by the nurse; and
- (c) the nurse fails to ensure the substance is stored in a way that prevents unauthorised access to it.

Maximum penalty: 30 penalty units.

(2) The person in charge of a declared place commits an offence if:

- (a) a Schedule 4 substance is stored at the declared place; and
- (b) disposition of the substance is controlled by the person; and
- (c) the person fails to ensure the substance is stored in a way that prevents unauthorised access to it.

Maximum penalty: 30 penalty units.

(3) Strict liability applies to subregulations (1)(c) and (2)(c).

27 Storage of methylated spirit

(1) A person commits an offence if:

- (a) the person owns a business that sells a substance; and
- (b) the substance is methylated spirit; and

- (c) the person fails to ensure the substance is stored in a part of premises to which the public does not have access.

Maximum penalty: 20 penalty units.

- (2) Strict liability applies to subregulation (1)(c).

28 Storage of Schedule 7 substance by manufacturer or wholesaler

- (1) The holder of a certificate of registration commits an offence if:
 - (a) the holder possesses a substance that is not for immediate use; and
 - (b) the substance is a Schedule 7 substance that is in the holder's possession under the certificate; and
 - (c) the holder fails to ensure that each of the following are satisfied:
 - (i) the substance is stored in a locked container that prevents ready access to the container's contents and is securely attached to a building;
 - (ii) the container is kept securely locked when not in immediate use;
 - (iii) if the container is unlocked by a combination lock – the nominated person for the certificate of registration keeps the combination confidential;
 - (iv) if the container is unlocked by a key – the nominated person keeps personal custody of the key.

Maximum penalty: 30 penalty units.

- (2) Strict liability applies to subregulation (1)(c).

29 Storage of Schedule 7 substance by retailer

- (1) The licensee under a retailer licence commits an offence if:
 - (a) the licensee possesses a substance; and
 - (b) the substance is a Schedule 7 substance that is in the licensee's possession under the licence; and

- (c) the licensee fails to ensure that:
 - (i) if the substance is for retail sale – the substance is stored in a part of the place in relation to which the licence was issued to which the public does not have access; or
 - (ii) otherwise – each of the following are satisfied:
 - (A) the substance is stored in a locked container that prevents ready access to the container's contents and is securely attached to a building;
 - (B) the container is kept securely locked when not in immediate use;
 - (C) if the container is unlocked by a combination lock – the individual who has control of the business activities under the retailer licence (the **business manager**) keeps the combination confidential;
 - (D) if the container is unlocked by a key – the business manager keeps personal custody of the key.

Maximum penalty: 30 penalty units.

- (2) Strict liability applies to subregulation (1)(c).

30 Storage of Schedule 7 substance by authority holder

- (1) The holder of a Schedule 7 authorisation or pest management technician licence commits an offence if:
 - (a) the holder possesses a substance that is not for immediate use; and
 - (b) the substance is a Schedule 7 substance that is in the holder's possession under the authorisation or licence; and
 - (c) the holder fails to ensure that each of the following are satisfied:
 - (i) the substance is stored:
 - (A) if being transported – in a locked container that prevents ready access to the container's contents;
or

- (B) otherwise – in a locked container that prevents ready access to the container's contents and is securely attached to a building;
- (ii) the container is kept securely locked when not in immediate use;
- (iii) if the container is unlocked by a combination lock – the holder and other persons who hold an authority in relation to the substance keep the combination confidential;
- (iv) if the container is unlocked by a key – the holder, or another person who holds an authority in relation to the substance, keeps personal custody of the key.

Maximum penalty: 30 penalty units.

- (2) Strict liability applies to subregulation (1)(c).

31 Storage of Schedule 8 substance

- (1) A person who is authorised under the Act to possess a Schedule 8 substance commits an offence if:
 - (a) the person possesses a substance; and
 - (b) the substance is a Schedule 8 substance; and
 - (c) the person fails to store the substance in accordance with the storage requirements applicable to the person specified in the Schedule 8 Code of Practice.

Maximum penalty: 60 penalty units.

- (2) Strict liability applies to subregulation (1)(c).

- (3) In this regulation:

Schedule 8 Code of Practice means the Code of Practice for Schedule 8 substances made by the CHO under section 244 of the Act, as in force from time to time.

32 Delivery person must not leave certain regulated substances unattended

- (1) A delivery person commits an offence if:
 - (a) the person possesses a substance; and

- (b) the substance is a regulated substance, other than a Schedule 5, 6 or 7 substance, that the person has been engaged by an authorised supplier to transport and deliver; and
- (c) the person leaves the substance unattended, other than in a locked building or vehicle.

Maximum penalty: 40 penalty units.

(2) Strict liability applies to subregulation (1)(c).

(3) In this regulation:

authorised supplier, see section 79(3) of the Act.

delivery person, see section 79(1) of the Act.

Division 4 Packaging and labelling

33 Packaging requirements

- (1) For section 101(1)(c) of the Act, a regulated substance must be packaged in accordance with the container requirements set out in Part 2 of the medicines and poisons standard (the **packaging requirements**).
- (2) However, the packaging requirements do not apply to the extent that the holder of a manufacturer certificate of registration is exempt from compliance with the requirements under a corresponding law.

34 Labelling requirements

- (1) For section 102(1)(c) of the Act, a container of a regulated substance must be labelled in accordance with the label requirements set out in Part 2 of the medicines and poisons standard (the **labelling requirements**).

Note for subregulation (1)

Part 2 of the medicines and poisons standard applies to health practitioners and holders of a manufacturer certificate of registration.

- (2) However, the labelling requirements do not apply to the extent that the holder of a manufacturer certificate of registration is exempt from compliance with the requirements under a corresponding law.

35 Container not to be used for human-use substance

For section 104(1)(b) of the Act, a container of a kind mentioned in paragraph 21, 22 or 23 of the medicines and poisons standard is prescribed.

Division 5 Manufacture, supply and use of paints

36 Paint applied to premises, structures and furniture

For section 110(1) of the Act, a first schedule paint must not be manufactured, supplied or used for application to:

- (a) a roof or other surface to be used for the collection or storage of potable water; or
- (b) furniture; or
- (c) a fence, wall, post, gate or building (including the interior of a building) other than a building that is used only for industrial purposes or mining or as an oil terminal; or
- (d) premises used for the manufacture, processing, preparation, packing or serving of products intended for human or animal consumption.

37 Paint for toys

For section 111(1)(b), (2)(c) and (3)(b) of the Act, a paint manufactured, supplied or used for application to toys must comply with the specification for coating materials in AS/NZS ISO 8124.3:2012 (Safety of toys – Migration of certain elements) as in force from time to time.

38 Paint containing pesticide

- (1) For section 112(b) of the Act, the following pesticides are prescribed:
 - (a) an algicide;
 - (b) an antifouling agent;
 - (c) a bactericide;
 - (d) a fungicide.
- (2) However, subregulation (1) does not apply in relation to a paint for human therapeutic use.

Division 6 Advertising**39 Pharmacist pricelist advertising certain Scheduled substances**

- (1) For section 113(3)(b) of the Act, a pharmacist pricelist is prescribed.
- (2) In this regulation:

pharmacist pricelist means a pricelist published by or for a pharmacist that:

- (a) includes a prescribed substance (other than a Schedule 9 substance) as defined in section 113(4) of the Act; and
- (b) complies with the Price Information Code of Practice, published by the Therapeutic Goods Administration, as in force from time to time.

Part 3 Authorities to deal with regulated substances**40 Additional conditions – certificate of registration**

- (1) For section 144(b) of the Act, the following are prescribed:
 - (a) for a certificate of registration – the "Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8" (effective date 1 April 2011) published by the National Coordinating Committee on Therapeutic Goods, as in force from time to time;
 - (b) for a manufacturer certificate of registration – Part 7 of the "Code of Conduct" published by Medicines Australia, as in force from time to time.

41 Duration of Schedule 8 authorisation for treating child's ADHD

- (1) For section 148(b) of the Act, a Schedule 8 authorisation for dealing with an amphetamine for treating a child for ADHD remains in force until the child becomes an adult.
- (2) In this regulation:

ADHD means attention deficit hyperactivity disorder.

42 Contents of authority

For section 149(b) of the Act, an authority must contain the following information:

- (a) the name of the holder of the authority;
- (b) if the holder is a body corporate – the holder's ACN;
- (c) if the holder will be conducting business under the authority under a business name – the business name;
- (d) the holder's postal address.
- (e) the regulated substance to which the authority applies;
- (f) the dealing with the substance authorised by the authority and, if applicable, the address of the place where the holder is authorised to deal with the substance;
- (g) a unique identifying number;
- (h) the date the authority is issued and the period it remains in force;
- (i) for a certificate of registration – the nominated person.

43 Authority holder to give notice of change of particulars

For section 173(1)(b) of the Act, the following particulars are prescribed:

- (a) the name of the holder of the authority;
- (b) the holder's business name;
- (c) the holder's postal address.

Part 4 Regulated substance registers

Division 1 Maintaining regulated substance registers

Subdivision 1 Pseudoephedrine register

44 Keeping of register

The pharmacist-in-charge of a pharmacy or pharmacy department must keep a register in relation to substances that:

- (a) contain pseudoephedrine; and
- (b) are supplied by retail sale from the pharmacy or pharmacy department.

45 Details to be recorded

The following details must be recorded in the register in relation to each retail sale:

- (a) the date of the sale;
- (b) the name of the substance, and the form, strength and quantity, sold;
- (c) the name and address of the purchaser;
- (d) the type and, if applicable, unique number of the photographic identification of the purchaser produced at the time of sale.

Subdivision 2 Schedule 4 register

46 Keeping of register

Each of the following persons must keep a register in relation to Schedule 4 substances that are supplied or administered under the person's authorisation:

- (a) the holder of a Schedule 4 authorisation;
- (b) the holder of a research authorisation;
- (c) the holder of a medical kit authorisation.

47 Details to be recorded

The following details must be recorded in the register in relation to each supply or administration:

- (a) the nature of the dealing;
- (b) the date of the dealing;
- (c) the name of the substance, and the form, strength and quantity, dealt with;
- (d) if the substance was supplied – the name and address of the person to whom it was supplied;
- (e) if the substance was administered:
 - (i) to a person – the name and address of the person; or
 - (ii) to an animal – the name and address of the person who owns, or is in charge of, the animal.

Subdivision 3 Schedule 7 register

48 Keeping of register

Each of the following persons must keep a register in relation to Schedule 7 substances that are dealt with under the person's authorisation or licence:

- (a) the holder of a Schedule 7 authorisation;
- (b) the holder of a pest management technician licence;
- (c) the licensee under a retailer licence.

49 Details to be recorded

The following details must be recorded in the register in relation to each dealing (other than possession):

- (a) the nature of the dealing;
- (b) the date of the dealing;
- (c) the name of the substance, and the form, strength and quantity, dealt with;
- (d) if the dealing was receiving the substance – the name and address of the supplier;

- (e) if the dealing was supplying the substance – the name, address and, if applicable, authorisation or licence number of the recipient;
- (f) the quantity of the substance held after the dealing.

Subdivision 4 Schedule 8 register

50 Maintenance of register – persons in charge of premises

- (1) A person mentioned in the table below must maintain a register in relation to Schedule 8 substances that are supplied to, or otherwise dealt with, at the place mentioned opposite.

Person	Place
The nurse in charge of a ward or department of a hospital	The ward or department
The nurse in charge of a residential facility	The residential facility
The person in charge of a declared place	The declared place
A doctor	Each premises from which the doctor practises, other than a hospital
A dentist	Each premises from which the dentist practises
A podiatrist	Each premises from which the podiatrist practises
The pharmacist-in-charge of a pharmacy or pharmacy department	The pharmacy or pharmacy department
The person in charge of an ambulance service	The premises from which the ambulance service operates
A nurse	Each premises from which the nurse practises, other than: (a) a hospital, residential facility or declared place; or

	(b) another place from which a doctor, dentist or podiatrist practices.
A midwife	Each premises from which the midwife practises, other than: (a) a hospital or declared place; or (b) another place from which a doctor practices.
A veterinarian	Each premises from which the veterinarian practises

- (2) However, subregulation (1) does not apply to the person in relation to:
- (a) a Schedule 8 substance in a medical kit; or
 - (b) if the person is the nurse in charge of a residential facility – a Schedule 8 substance dispensed in a dose administration aid for a resident of the facility; or
 - (c) if the person is the nurse in charge of a declared place – a Schedule 8 substance dispensed in a dose administration aid for a person receiving medical treatment at the place.
- (3) Only 1 register is to be kept for each place mentioned in subregulation (1).

51 Keeping of register – medical kit holder

The holder of a medical kit authorisation must keep a register in relation to Schedule 8 substances that are dealt with under the authorisation.

52 Keeping of register – other persons

Each of the following persons must keep a register in relation to Schedule 8 substances that are dealt with under the person's certificate or authorisation:

- (a) the holder of a manufacturer certificate of registration;
- (b) the holder of a wholesaler certificate of registration;

- (c) the holder of a Schedule 8 authorisation;
- (d) the holder of a research authorisation.

53 Form of Schedule 8 register

- (1) A Schedule 8 register must contain:
 - (a) a separate page for each form and strength of a Schedule 8 substance; or
 - (b) if the register is kept electronically – a separate record for each form and strength of a Schedule 8 substance.
- (2) However, the CHO may dispense with this requirement in relation to a particular Schedule 8 register.

54 Details to be recorded

- (1) The following details must be recorded in a Schedule 8 register in relation to each dealing with a Schedule 8 substance (other than possession):
 - (a) the nature of the dealing;
 - (b) the date of the dealing;
 - (c) the name of the substance, and the form, strength and quantity, dealt with;
 - (d) if the dealing was receiving the substance – the name and address of the supplier;
 - (e) if the dealing was supplying the substance other than as mentioned in subregulation (2) – the name and address of the recipient;
 - (f) if the dealing was administering the substance other than as mentioned in subregulation (2):
 - (i) the name of:
 - (A) the person to whom it was administered; or
 - (B) the person who owns, or is in charge of, the animal to which it was administered; and
 - (ii) the name of the person who administered it;
 - (g) if the substance was supplied on a prescription – the name of the person who issued the prescription;

- (h) if the dealing was destroying the substance:
 - (i) the name of the person who destroyed the substance;
and
 - (ii) the name of the person who witnessed the destruction;
 - (i) the quantity of the substance held after the dealing.
- (2) In addition, if the dealing was supplying or administering the Schedule 8 substance to a patient of a hospital, a resident of a residential facility or a person receiving medical treatment at a declared place, the following details must be recorded:
- (a) the name of the patient, resident or person;
 - (b) for a patient – the patient's hospital registration number;
 - (c) the time the substance was supplied or administered;
 - (d) the name of the person who authorised the supply or administration;
 - (e) the name of the person who supplied or administered it;
 - (f) the name of the person who witnessed the supply or administration.

Subdivision 5 Schedule 9 register

55 Keeping of register

Each of the following persons must keep a register in relation to Schedule 9 substances that are dealt with under the person's certificate or authorisation:

- (a) the holder of a manufacturer certificate of registration;
- (b) the holder of a wholesaler certificate of registration;
- (c) the holder of a prohibited substance authorisation;
- (d) the holder of a research authorisation.

56 Form of Schedule 9 register

The register must contain:

- (a) a separate page for each form and strength of a Schedule 9 substance; or

- (b) if the register is kept electronically – a separate record for each form and strength of a Schedule 9 substance.

57 Details to be recorded

The following details must be recorded in the register in relation to each dealing (other than possession):

- (a) the nature of the dealing;
- (b) the date of the dealing;
- (c) the name of the substance, and the form, strength and quantity, dealt with;
- (d) if the dealing was receiving the substance – the name and address of the supplier;
- (e) if the dealing was administering the substance:
 - (i) the name of the person to whom it was administered; and
 - (ii) the name of the person who administered it; and
 - (iii) the name of the person who witnessed the administration;
- (f) if the dealing was destroying the substance:
 - (i) the name of the person who destroyed the substance; and
 - (ii) the name of the authorised officer who witnessed the destruction;
- (g) the quantity of the substance held after the dealing.

Subdivision 6 Manufacturer/wholesaler register

58 Keeping of register

The holder of a certificate of registration must keep a register in relation to Schedule 2, 3, 4 and 7 substances that are dealt with under the certificate.

59 Details to be recorded

The following details must be recorded in the register in relation to each dealing (other than possession):

- (a) the nature of the dealing;
- (b) the date of the dealing;
- (c) the name of the substance, and the form, strength and quantity, dealt with;
- (d) if the dealing was receiving the substance – the name and address of the supplier;
- (e) if the dealing was supplying the substance – the name and address and, if applicable, authorisation or licence number of the recipient;
- (f) the quantity of the substance held after the dealing.

Subdivision 7 General requirements

60 Form of register entries

An entry in a regulated substance register must be:

- (a) legible and expressed in the English language; and
- (b) made as soon as practicable after the dealing to which the entry relates happens.

61 Period of retention of registers

A regulated substance register must be kept for at least 2 years after the day on which the last entry is made in the register.

Division 2 Offences relating to regulated substance registers

62 Offence not to maintain register

- (1) A person who is required to maintain a regulated substance register commits an offence if the person:
 - (a) fails to maintain the register; or
 - (b) fails to maintain the register in accordance with the requirements of Division 1.

Maximum penalty: 50 penalty units.

- (2) An offence against subregulation (1) is an offence of strict liability.

63 Offence not to sign entry

- (1) A person commits an offence if the person:
- (a) makes an entry in a regulated substance register; and
 - (b) fails to sign the entry as soon as practicable after it is made.

Maximum penalty: 20 penalty units.

- (2) Strict liability applies to subregulation (1)(b).

64 Offence to make false or misleading entry

A person commits an offence if the person:

- (a) makes an entry in a regulated substance register; and
- (b) knows the entry contains information that is misleading in a material particular or because of the omission of a material particular.

Maximum penalty: 80 penalty units.

65 Offence to change entry

- (1) A person commits an offence if the person cancels, changes, deletes or obliterates an entry in a regulated substance register.

Maximum penalty: 20 penalty units.

- (2) However, subregulation (1) does not apply to a person if the person:

- (a) made the entry in the regulated substance register; and
- (b) changes the entry as permitted under subregulation (3) or (4).

- (3) An entry in a paper-based regulated substance register may be changed by the person signing and dating a marginal note or footnote that gives the correct details.

- (4) An entry in an electronic regulated substance register may be changed by the person attaching or linking, by electronic means, a document that includes the person's signature, the date and the correct details.

66 Offence not to record details of supply of pseudoephedrine

- (1) A person commits an offence if the person:
- (a) supplies, by retail sale from a pharmacy or pharmacy department, a substance that contains pseudoephedrine; and
 - (b) fails to:
 - (i) sight photographic identification of the purchaser; or
 - (ii) record in the regulated substance register for the substance each of the details specified in regulation 45.

Maximum penalty: 20 penalty units.

- (2) Strict liability applies to subregulation (1)(b).

67 Offence not to sign register after certain dealings with Schedule 8 or 9 substance

- (1) A person commits an offence if:
- (a) the person supplies, administers, otherwise uses or destroys a Schedule 8 or 9 substance; and
 - (b) an entry about the dealing is made in the regulated substance register for the substance by a third party; and
 - (c) the person fails to sign the entry in the register as soon as practicable after it is made.

Maximum penalty: 40 penalty units.

- (2) Strict liability applies to subregulation (1)(c).

68 Offence not to sign register after witnessing certain dealings with Schedule 8 or 9 substance

- (1) A person commits an offence if:
- (a) the person witnesses the supply, administration or destruction of a Schedule 8 or 9 substance; and
 - (b) an entry about the dealing that names the person as the witness to the dealing is made in the regulated substance register for the substance by a third party; and

- (c) the person fails to sign the entry in the register as witness as soon as practicable after it is made.

Maximum penalty: 40 penalty units.

- (2) Strict liability applies to subregulation (1)(c).

69 Offence not to ensure witness signs register after certain dealings with Schedule 8 or 9 substance

- (1) A person commits an offence if:

- (a) the person:

- (i) destroys a Schedule 8 substance; or
- (ii) administers or destroys a Schedule 9 substance; and

- (b) an entry about the dealing that names another person as the witness to the dealing is made in the regulated substance register for the substance; and

- (c) the witness fails to sign the entry in the register as soon as practicable after it is made.

Maximum penalty: 40 penalty units.

Note for regulation 69

Section 100 of the Act contains a similar offence in relation to the supply or administration of Schedule 8 substances.

- (2) Strict liability applies to subregulation (1)(c).

70 Offence not to maintain register where substance kept

- (1) A person who is required to maintain a regulated substance register in relation to a regulated substance commits an offence if the person fails to maintain the register:

- (a) at the premises in which the regulated substance is kept; or
- (b) for a Schedule 8 substance in a medical kit – with the medical kit.

Maximum penalty: 20 penalty units.

- (2) An offence against subregulation (1) is an offence of strict liability.

71 Offence not to report possible loss etc. of regulated substance

- (1) A person who is required to maintain a regulated substance register commits an offence if the person:
- (a) becomes aware of a substantial risk that a regulated substance in relation to which the register is maintained has been lost, misappropriated or stolen; and
 - (b) fails to give the CHO written notice about the risk as soon as practicable (but not later than 7 days) after becoming aware of it.

Maximum penalty: 20 penalty units.

- (2) Strict liability applies to subregulation (1)(b).

72 Offence not to report destruction, loss etc. of register

- (1) A person who is required to maintain a regulated substance register commits an offence if:
- (a) the register is damaged in a material respect, destroyed, stolen or lost; and
 - (b) the person fails to give the CHO written notice about the damage, destruction, theft or loss as soon as practicable (but not later than 7 days) after the day it happens.

Maximum penalty: 20 penalty units.

- (2) Strict liability applies to subregulation (1)(b).
- (3) This regulation does not apply in relation to a regulated substance register if the most recent entry in the register is made more than 2 years before the day the register is damaged, stolen, lost or destroyed.
- (4) In this regulation, a regulated substance register is damaged in a material respect if anything required to be entered in the register is missing or cannot be easily read.

Part 5 Other records and notices

Division 1 General requirements

73 Retention of documents relating to receipt or supply of regulated substances

- (1) A health practitioner or veterinarian who, in the course of practising in a health profession or providing veterinary services, receives or supplies a Schedule 4 or 8 substance must keep the original or a copy of each delivery docket or invoice relating to the receipt or supply.
- (2) The holder of an authority, other than a certificate of registration, who receives a regulated substance to which the authority applies must keep the original or a copy of each delivery docket or invoice relating to the receipt.
- (3) The holder of a certificate of registration who receives or supplies a Schedule 2, 3, 4 or 7 substance to which the certificate applies must keep the original or a copy of each delivery docket or invoice relating to the receipt or supply.

74 Retention of prescriptions

The pharmacist-in-charge of a pharmacy or pharmacy department must keep a copy of each prescription that is filled at the pharmacy or pharmacy department.

75 Record of supply or administration of Schedule 4 or 8 substance in clinical or other records

- (1) Subregulation (2) applies to a health practitioner or veterinarian who supplies or administers a Schedule 4 or 8 substance to or for a person or animal (the *patient*) in relation to whom the practitioner or veterinarian keeps clinical records.
- (2) As soon as practicable after the dealing, the health practitioner or veterinarian must record the following details in relation to the dealing in the clinical records of the patient:
 - (a) the nature of the dealing;
 - (b) the date of the dealing;
 - (c) the name of the substance, and the form, strength and quantity, dealt with;

- (d) if the dealing was supplying the substance to someone other than the patient – the name and address of the person to whom it was supplied;
 - (e) if the dealing was supplying the substance on a prescription – the name and address of the person who issued the prescription.
- (3) Subregulation (4) applies to a health practitioner who supplies a Schedule 4 substance to a person in relation to whom the practitioner does not keep clinical records.
- (4) As soon as practicable after the dealing, the health practitioner must record the following details in relation to the dealing in an appropriate record:
- (a) the date of the supply;
 - (b) the name of the substance, and the form, strength and quantity, supplied;
 - (c) the name and address of the person to whom it was supplied;
 - (d) if the substance was supplied on a prescription:
 - (i) the name and address of the person for whom the prescription was issued; and
 - (ii) the name and address of the person who issued the prescription.

76 Form and period of retention of records

- (1) A record that a person is required to make under this Division must be legible and expressed in the English language.
- (2) A record that a person is required under this Division to make or keep must be kept for at least 2 years after the day on which it was made or received.

Division 2 Offences relating to records and notices

77 Offence not to make or keep record

- (1) A person who, under Division 1, is required to make or keep a record commits an offence if the person:
 - (a) fails to make or keep the record; or

- (b) fails to make or keep the record in accordance with the requirements of Division 1.

Maximum penalty: 50 penalty units.

- (2) An offence against subregulation (1) is an offence of strict liability.

78 Offence not to give fraudulent prescription to police

- (1) A pharmacist commits an offence if the pharmacist:
 - (a) receives a prescription; and
 - (b) becomes aware of a substantial risk that the prescription has been forged or fraudulently altered; and
 - (c) fails to give a copy of the prescription to the Commissioner of Police as soon as practicable (but not later than 7 days) after becoming aware of the risk.

Maximum penalty: 80 penalty units.

- (2) Strict liability applies to subregulation (1)(c).

79 Offence not to report supply or administration of Schedule 8 substance at declared place

- (1) A person in charge of a declared place commits an offence if:
 - (a) a Schedule 8 substance is supplied or administered to a person at the declared place; and
 - (b) the person in charge fails to give notice of the supply or administration in the approved form to the CHO within 7 days after the date of supply or administration.

Maximum penalty: 50 penalty units.

- (2) Strict liability applies to subregulation (1)(b).

80 Offence not to report administration of Schedule 8 substance from medical kit

- (1) The holder of a medical kit authorisation commits an offence if:
 - (a) the holder administers a substance to a person; and
 - (b) the substance is a Schedule 8 substance that is in the holder's possession under the authorisation; and

- (c) the holder fails to give notice of the administration in the approved form to the CHO within 7 days after the date of administration.

Maximum penalty: 50 penalty units.

- (2) Strict liability applies to subregulation (1)(c).

Part 6 Legal proceedings

81 Declared provisions

For paragraph (b) of the definition **declared provision** in section 212 of the Act, regulations 22, 23, 25, 27, 28, 29, 30, 62, 64 and 80 are declared provisions.

81A Declared provisions

For section 215(7) of the Act, definition **declared EO liability provision**, paragraph (b), regulation 31 is prescribed.

Part 7 Infringement notice offences

82 Infringement notice offence and prescribed amount payable

- (1) An **infringement notice offence** is an offence against a provision specified in Schedule 1.
- (2) The **prescribed amount** for an infringement notice offence is the amount equal to the monetary value of the number of penalty units specified for the offence in Schedule 1.

83 When infringement notice may be given

If an authorised officer reasonably believes a person has committed an infringement notice offence, the officer may give a notice (an **infringement notice**) to the person.

84 Contents of infringement notice

- (1) The infringement notice must specify the following:
- (a) the name and address of the person, if known;
 - (b) the date the infringement notice is given to the person;
 - (c) the date, time and place of the infringement notice offence;
 - (d) a description of the offence;

- (e) the prescribed amount payable for the offence;
 - (f) the enforcement agency, as defined in the *Fines and Penalties (Recovery) Act*, to whom the prescribed amount is payable.
- (2) The infringement notice must include a statement to the effect of the following:
- (a) the person may expiate the infringement notice offence and avoid any further action in relation to the offence by paying the prescribed amount to the specified enforcement agency within 28 days after the notice is given;
 - (b) the person may elect under section 21 of the *Fines and Penalties (Recovery) Act* to have the matter dealt with by a court instead of under that Act by completing a statement of election and giving it to the specified enforcement agency;
 - (c) if the person does nothing in response to the notice, enforcement action may be taken under the *Fines and Penalties (Recovery) Act*, including (but not limited to) action for the following:
 - (i) suspending the person's licence to drive;
 - (ii) seizing personal property of the person;
 - (iii) deducting an amount from the person's wages or salary;
 - (iv) registering a statutory charge on land owned by the person;
 - (v) making a community work order for the person and imprisonment of the person if the person breaches the order.
- (3) Also, the infringement notice must include an appropriate form for making the statement of election mentioned in subregulation (2)(b).

85 Payment by cheque

If the person tenders a cheque in payment of the prescribed amount, the amount is not taken to have been paid unless the cheque is cleared on first presentation.

86 Withdrawal of infringement notice

- (1) The CHO may withdraw the infringement notice by written notice given to the person.

- (2) The notice must be given:
- (a) within 28 days after the infringement notice is given to the person; and
 - (b) before payment of the prescribed amount.

87 Application of Part

- (1) This Part does not prejudice or affect the start or continuation of proceedings for an infringement notice offence for which an infringement notice has been given unless the offence is expiated.
- (2) Also, this Part does not:
- (a) require an infringement notice to be given; or
 - (b) affect the liability of a person to be prosecuted in a court for an offence for which an infringement notice has not been given; or
 - (c) prevent more than one infringement notice for the same offence being given to a person.
- (3) If more than one infringement notice for the same offence has been given to a person, the person may expiate the offence by paying the prescribed amount in accordance with any of the notices.

Part 8 Administrative matters

88 Content of scheduled substance treatment protocol

For section 254(2) of the Act, a Scheduled substance treatment protocol must state:

- (a) each Scheduled substance to which the protocol applies; and
- (b) the conditions and other restrictions that apply to the possession, supply or administration of each substance.

89 Information in register of authorities

For section 255(3) of the Act, a register of authorities must contain the following particulars for each authority to which it relates:

- (a) the name of the holder of the authority;
- (b) if the holder is a body corporate – the holder's ACN;

- (c) if the holder of the authority will be conducting business under the authority under a business name – the business name;
- (d) the holder's postal address;
- (e) the type of authority;
- (f) the unique identifying number of the authority;
- (g) each regulated substance to which the authority applies;
- (h) the dealing with the substance authorised by the authority and, if applicable, the address of the place where the holder is authorised to deal with the substance;
- (i) the date the authority was issued or renewed and the period it is in force;
- (j) any conditions of the authority imposed by the CHO;
- (k) any suspension or cancellation of the authority and the reasons for it;
- (l) for a certification of registration – the nominated person.

90 Appointed Committee members

For section 265 of the Act, the appointed members of the Committee must be as follows:

- (a) at least 2 doctors with expertise in pain management or rehabilitation;
- (b) at least 2 doctors with experience in general practice;
- (c) at least one doctor who is employed in the Agency and working in the community drugs program managed by the Agency;
- (d) at least one person who:
 - (i) is not a doctor; and
 - (ii) is working in the community drugs program managed by the Agency;
- (e) at least one pharmacist with experience in the community pharmacy practice area;
- (f) at least one pharmacist with experience in the hospital or clinical pharmacy practice area.

91 Fees

The fees specified in Schedule 2 are payable for the matter specified opposite.

Schedule 1 Infringement notice offences and prescribed amounts

regulation 82

Provision	Prescribed amount in penalty units
<i>Medicines, Poisons and Therapeutic Goods Act</i>	
sections 97(2) and (3), 107(1) and 176(1) and (2)	1
<i>Medicines, Poisons and Therapeutic Goods Regulations</i>	
regulations 31(1), 62(1) and 77(1)	3
regulations 19(1), 28(1), 29(1), 30(1), 67(1), 68(1) and 69(1)	2
regulations 27(1), 63(1), 65(1), 66(1), 70(1), 71(1) and 72(1)	1

Schedule 2 Fees

regulation 91

Matter	Fee (revenue units)
1 Application for	
(a) manufacturer certificate of registration	50 plus 100 for each year the certificate will be in force
(b) wholesaler certificate of registration	50 plus 100 for each year the certificate will be in force
(c) retailer licence	50 plus 50 for each year the licence will be in force
(d) Schedule 4 authorisation	50 for each year the authorisation will be in force
(e) Schedule 7 authorisation	50 for each year the authorisation will be in force
(f) pest management technician licence	50 for each year the licence will be in force
(g) Schedule 8 authorisation other than an authorisation for the issue of prescriptions for therapeutic use	50 for each year the authorisation will be in force
(h) prohibited substance authorisation	50 for each year the authorisation will be in force
(i) research authorisation	50 for each year the authorisation will be in force
(j) medical kit authorisation	50 for each year the authorisation will be in force

2	Renewal of	
	(a) manufacturer certificate of registration	100 for each year the certificate will be in force after renewal
	(b) wholesaler certificate of registration	100 for each year the certificate will be in force after renewal
	(c) retailer licence	50 for each year the licence will be in force after renewal
3	Transfer of certificate of registration	50
4	Replacement of authority	50

ENDNOTES
1**KEY**

Key to abbreviations

amd = amended
app = appendix
bl = by-law
ch = Chapter
cl = clause
div = Division
exp = expires/expired
f = forms
Gaz = Gazette
hdg = heading
ins = inserted
lt = long title
nc = not commenced

od = order
om = omitted
pt = Part
r = regulation/rule
rem = remainder
renum = renumbered
rep = repealed
s = section
sch = Schedule
sdiv = Subdivision
SL = Subordinate Legislation
sub = substituted

2**LIST OF LEGISLATION*****Medicines, Poisons and Therapeutic Goods Regulations (SL No. 10, 2014)***

Notified	19 April 2014
Commenced	1 May 2014 (r 2, s 2 <i>Medicines, Poisons and Therapeutic Goods Act 2012</i> (Act No. 13, 2012) and <i>Gaz S22</i> , 30 April 2014, p 12)

Statute Law Amendment (Directors' Liability) Act 2015 (Act No. 26, 2015)

Assent date	18 September 2015
Commenced	14 October 2015 (<i>Gaz G41</i> , 14 October 2015, p 3)

3**LIST OF AMENDMENTS**

r 81A	ins Act No. 26, 2015, s 78
pt 9 hdg	exp Act No. 13, 2012, s 294(5)
rr 92 – 93	exp Act No. 13, 2012, s 294(5)