Australian Capital Territory

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made under the

Medicines, Poisons and Therapeutic Goods Act 2008

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About this republication

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Australian Capital Territory

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Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Regulation 2008

made under the

Medicines, Poisons and Therapeutic Goods Act 2008

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Chapter 1 Preliminary

1 Name of regulation

This regulation is the *Medicines, Poisons and Therapeutic Goods Regulation 2008*.

3 Dictionary

The dictionary at the end of this regulation is part of this regulation.

Note 1 The dictionary at the end of this regulation defines certain terms used in this regulation, and includes references (***signpost definitions***) to other terms defined elsewhere.

For example, the signpost definition '***young detainee***—see the *Children and Young People Act 2008*, section 95.' means that the term 'young detainee' is defined in that section and the definition applies to this regulation.

Note 2 A definition in the dictionary (including a signpost definition) applies to the entire regulation unless the definition, or another provision of the regulation, provides otherwise or the contrary intention otherwise appears (see Legislation Act, s 155 and s 156 (1)).

4 Notes

A note included in this regulation is explanatory and is not part of this regulation.

Note See the Legislation Act, s 127 (1), (4) and (5) for the legal status of notes.

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5 Offences against regulation—application of Criminal Code etc

Other legislation applies in relation to offences against this regulation.

Note 1 *Criminal Code*

The Criminal Code, ch 2 applies to all offences against this regulation (see Code, pt 2.1).

The chapter sets out the general principles of criminal responsibility (including burdens of proof and general defences), and defines terms used for offences to which the Code applies (eg ***conduct***, ***intention***, ***recklessness*** and ***strict liability***).

Note 2 *Penalty units*

The Legislation Act, s 133 deals with the meaning of offence penalties that are expressed in penalty units.

6 Overview of things to which medicines and poisons standard does not apply

(1) The medicines and poisons standard applies to regulated substances (see the Act, pt 3.1 and s 17).

(2) However, the medicines and poisons standard sets out the following things to which it does not apply (unless there is a contrary intention in the standard):

(a) a substance in a preparation or product included in the standard, appendix A (General Exemptions) (see the standard, par 1 (2) (h));

(b) a substance and the reason for its entry in the standard, appendix B (Substances considered not to require control by scheduling) (see the standard, par 1 (2) (h));

(c) a substance to which the standard, appendix G (Dilute Preparations) applies (see the standard, par 1 (2) (i));

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(d) certain low concentrations of substances included in the standard, schedules 1 to 6 if the substance is not also included in schedule 7 or 8 (see the standard, par 1 (2) (j));

(e) certain impurities in pesticides (see the standard, par 1 (2) (k)).

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Chapter 2 Medicines—authorisations generally

Part 2.1 Overview of medicines authorisations

10 General overview of authorisations for medicines

(1) The Act requires that a person must not deal with a medicine in a particular way unless the person is authorised to deal with the medicine.

Example

the Act, s 35 is about obtaining certain substances (which include medicines)

Note 1 The Act, s 19 sets out when a person ***deals*** with a medicine.

Note 2 An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(2) The Act, section 20 sets out when a person is authorised to deal with a medicine.

(3) This regulation authorises certain dealings with medicines.

Note An authorisation is not required to deal with the following:

- a substance excluded from the medicines and poisons standard by the standard, par 1 (2) (see s 6);
- a substance mentioned in the medicines and poisons standard, sch 2, 3, 4 or 8 if none of the schedules apply to the substance because of an exception in the standard (eg Aspirin in packets available from supermarkets).

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(4) An authorisation under this regulation may be subject to limitations.

Examples—s (4)

1 a health practitioner's authorisation is subject to any condition or restriction to which the health practitioner is subject to under the *Health Practitioner Regulation National Law (ACT)* (see s 20)

2 the authorisation of a person to prescribe a medicine is subject to any restriction included in sch 1 in relation to the person (see s 30 (1) (b))

Note For the power to impose other restrictions, see the Act, ch 8.

11 Overview of medicines authorisations under this regulation

(1) Medicines authorisations under this regulation that are specific to health-related occupations are given by the following provisions (and are set out in schedule 1):

(a) section 30 (which is about authorisations under schedule 1 to prescribe medicines);

(b) section 50 (which is about authorisations under schedule 1 to issue requisitions for medicines);

(c) section 60 (which is about authorisations under schedule 1 to issue purchase orders for medicines);

(d) section 110 (which is about authorisations under schedule 1 to supply medicines);

Note ***Supply*** includes dispense on prescription (see Act, s 24).

(e) section 350 (which is about authorisations under schedule 1 for people in health-related occupations to administer medicines);

(f) section 255 (which is about authorisation of approved pharmacists to supply certain medicines without prescription);

(g) section 370 (which is about authorisations under schedule 1 to obtain and possess medicines);

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(h) section 380 (which is about authorisations under schedule 1 to manufacture medicines).

(2) For other authorisations, see the following provisions:

(a) section 70 (which is about authorisation of CHO to issue standing orders for supply of medicines in public health emergencies);

(b) section 71 (which is about authorisation of CHO to issue standing orders for administration of medicines for public health matters);

(c) section 75 (which is about authorisation of doctors to issue standing orders for administration of medicines at institutions);

(d) section 77 (which is about authorisation of CHO to issue standing orders for supply and administration of medicines at walk-in centres);

(e) section 251 (which is about authorisation to supply certain medicines without prescription in emergencies);

(f) section 260 (which is about authorisation to supply medicines to pharmacists for disposal);

(g) section 261 (which is about authorisation to supply medicines to commercial disposal operators for disposal);

(h) section 360 (which is about authorisation for self-administration of medicines);

(i) section 361 (which is about authorisation for the administration of medicines by assistants);

(j) section 371 (which is about authorisation to obtain and possess medicines for certain personal use-related dealings);

(k) section 400 (which is about authorisation to deliver medicines under supply authorities);

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(l) section 401 (which is about authorisation for commercial disposal operators for disposal of medicines);

(m) section 410 (which is about authorisation to supply and administer adrenaline and salbutamol);

(n) section 420 (which is about authorisations for CYP authorised people);

(o) section 421 (which is about authorisations for corrections officers);

(p) section 430 (which is about authorisations for non-controlled medicines research and education);

(q) section 440 (which is about authorisations under controlled medicines research and education program licences);

(r) section 450 (which is about authorisations under first-aid kit licences);

(s) section 460 (which is about authorisations under medicines wholesalers licences);

(t) section 470 (which is about authorisations under opioid dependency treatment licences);

(u) section 480 (which is about authorisations under pharmacy medicines rural communities licences);

(v) section 490 (which is about authorisations for endorsed health practitioners).

12 General overview of authorisation conditions for medicines

(1) The Act, section 44 requires a person who is authorised to deal with a medicine to comply with any condition to which the authorisation is subject.

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Example

Section 31 sets out the authorisation conditions for an authorised person to prescribe a medicine.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(2) The conditions are additional to other restrictions on an authorised person's authority to deal with a medicine.

Example—s (2)

Sch 1 limits the prescription by eligible midwives of medicines that are listed on the pharmaceutical benefits scheme (see sch 1, part 1.5) to eligible midwives who hold a particular authority.

Note Conditions may also be imposed under other provisions of the Act including, for example, s 89 which sets out conditions on licences.

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Part 2.2 Relationship with registration laws

20 Medicines authorisations subject to Health Practitioner Regulation National Law (ACT) restrictions

A health practitioner's authorisation under the Act to deal with a medicine is subject to any condition or other restriction to which the health practitioner is subject under the *Health Practitioner Regulation National Law (ACT)*.

Example

Section 31 places conditions on the prescribing of medicines by a health practitioner authorised to prescribe the medicines. If a particular health practitioner's registration under the *Health Practitioner Regulation National Law (ACT)* is subject to the condition or restriction that the person may not prescribe certain medicines, the health practitioner's authorisation under the *Medicines, Poisons and Therapeutic Goods Act 2008* to prescribe medicines is also subject to that condition or restriction.

Note 1 A reference to an Act includes a reference to the statutory instruments made or in force under the Act, including any regulation (see Legislation Act, s 104).

Note 2 An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

21 Medicines authorisations subject to Veterinary Surgeons Act 2015 restrictions

A veterinary surgeon's authorisation under the Act to deal with a medicine is subject to any condition or other restriction to which the veterinary surgeon is subject under the *Veterinary Surgeons Act 2015*.

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Chapter 3 Medicines—supply authorities

Part 3.1 Prescribing medicines

Division 3.1.1 Authorisation to prescribe medicines

30 Authorisation under sch 1 to prescribe medicines—Act, s 40 (1) (b), (2) (b) and (3) (b)

(1) A person mentioned in schedule 1, column 2 is authorised to prescribe a medicine if—

(a) prescribing the medicine is included in the schedule, column 3 in relation to the person; and

(b) the prescribing is consistent with any restriction for the prescribing mentioned in the schedule, column 3; and

(c) if the prescription is a self-prescription of the medicine—

(i) the person is not a trainee dentist, trainee nurse practitioner, intern doctor or person training to be an eligible midwife; or

(ii) the medicine is not a restricted medicine.

(2) In this section:

restricted medicine means—

(a) an anabolic steroid; or

(b) a designated appendix D medicine; or

(c) a benzodiazepine; or

(d) a controlled medicine.

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31 Authorisation conditions for prescribing medicines—Act, s 44 (1) (b) and (2) (b)

(1) A prescriber's authorisation under section 30 to prescribe a medicine is subject to the following conditions:

(a) the medicine is prescribed in accordance with the Act, section 7 (Appropriate prescription and supply of medicines);

(b) if the prescription is a written prescription—

(i) the prescription complies with section 40 (General requirements for written prescriptions); and

(ii) the prescription (other than a national residential medication chart prescription) includes the particulars mentioned in section 41 on the front of the prescription; and

(iii) if the prescription is a national residential medication chart prescription in a national residential medication chart—the chart includes the particulars mentioned in section 41; and

(iv) if the prescription is faxed by a prescriber to a pharmacist—the prescriber sends the original prescription to the pharmacist not later than 24 hours after the prescriber faxes the prescription to the pharmacist;

Note 1 For the endorsement of faxed prescriptions, see s 41 (1) (m).

Note 2 ***Pharmacist*** does not include an intern pharmacist (see dict).

(c) if the prescription is an oral prescription—

(i) the prescriber believes on reasonable grounds that giving an oral prescription for the medicine is reasonably necessary for the patient's treatment; and

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(ii) if the prescription is for an unusual or dangerous dose of a medicine—the prescription includes a statement telling the person who is to dispense or administer the medicine that the prescription is for an unusual or dangerous dose; and

(iii) the prescription includes the particulars mentioned in section 41; and

(iv) the prescriber sends a written prescription for the medicine to the pharmacist not later than 24 hours after the prescriber gives the oral prescription to the pharmacist;

Note For the endorsement of written prescriptions confirming oral prescriptions, see s 41 (1) (n).

(d) if the medicine is a controlled medicine for human use—

(i) the prescriber complies with the additional requirements under section 32 for prescribing a controlled medicine; and

(ii) if the controlled medicines approval is an oral approval—the prescriber sends the chief health officer a written application for the approval in accordance with section 561 (Requirements for CHO controlled medicines approval applications) not later than 7 days after the day the oral approval is given;

(e) if the medicine is a designated appendix D medicine prescribed for a purpose mentioned in schedule 3 (Designated appendix D medicines—standing approvals), part 3.2, column 3 in relation to the medicine—the prescriber complies with the additional requirements under section 33 in relation to the prescription.

(2) In this section:

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national residential medication chart means a residential medication chart within the meaning of the *National Health (Pharmaceutical Benefits) Regulations 1960* (Cwlth), section 19AA (6) (Item in residential medication chart is prescription), as in force from time to time.

Note The *National Health (Pharmaceutical Benefits) Regulations 1960* (Cwlth) does not need to be notified under the Legislation Act because s 47 (6) does not apply (see s 863).

32 Additional requirements for prescribing controlled medicines for human use

The following are the additional requirements for prescribing a controlled medicine for human use:

(a) the prescriber has a controlled medicines approval to prescribe the medicine;

Note For controlled medicines approvals, see pt 13.1.

(b) if the approval is for a particular form of the medicine—the prescription is for the form of the medicine approved or a bioequivalent form;

Note ***Bioequivalent***—see the dictionary.

(c) if the approval is for a particular strength of the medicine—the prescription is for the strength approved or a weaker strength;

(d) if the approval is for a particular quantity of the medicine—the prescription is for not more than the quantity approved;

(e) the prescriber complies with each condition (if any) of the approval;

(f) if the controlled medicine is dronabinol for human use—

(i) the prescriber also has an authorisation under the *Therapeutic Goods Act 1989* (Cwlth), section 19 to supply the medicine; and

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(ii) the prescriber complies with each condition (if any) of the authorisation.

Example—par (b)

If a slow release form of a medicine is approved, the prescriber is not authorised to prescribe an immediate release form of the medicine.

Example—par (c) and par (d)

If a doctor is given an approval to prescribe 25 morphine 20mg capsules, the doctor may prescribe 5 20mg capsules and 10 15mg capsules. Later, if the approval is still in force, the doctor may prescribe not more than 10 morphine capsules of any strength up to and including 20mg.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

33 Additional requirements for designated appendix D medicines prescriptions for human use

The following are the additional requirements for prescribing a designated appendix D medicine for a purpose mentioned in schedule 3 (Designated appendix D medicines—standing approvals), part 3.2, column 3 in relation to the medicine:

(a) the prescriber has an appendix D medicines approval to prescribe the medicine;

(b) the prescriber complies with each condition (if any) of the approval (including any condition in schedule 3, part 3.2, column 4 in relation to the medicine).

Division 3.1.2 Prescriptions

Note A prescription may provide for a medicine to be dispensed or administered (see Act, dict, def ***prescription***).

40 General requirements for written prescriptions

A written prescription for a medicine must—

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(a) be signed by the prescriber; and

Note The prescription must be signed with the prescriber's usual signature (see Act, dict, def ***signs***).

(b) if the prescriber amends the prescription—be initialled and dated beside the amendment by the prescriber; and

(c) be written in terms and symbols used in ordinary professional practice; and

(d) if the prescription is for an unusual or dangerous dose—include the prescriber's initials beside an underlined reference to the dose.

Note ***Written*** includes in electronic form (see Act, dict).

41 Particulars for prescriptions

(1) A prescription must include the following particulars:

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

(b) the date the prescription is given;

(c) the medicine, and the form, strength and quantity of the medicine, to be dispensed or administered under the prescription;

(d) the name and address of the person for whom the medicine is prescribed;

(e) directions about the use of the medicine, including the dose and regimen of the medicine, that are adequate to allow the medicine to be taken or administered safely;

(f) the number of times the medicine may be dispensed or administered under the prescription;

(g) if the prescription is for a controlled medicine for human use—

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(i) the relevant approval particulars; and

(ii) if the medicine is dronabinol—the relevant TGA authorisation particulars; and

(iii) if the prescription is a repeat prescription—the period that must elapse between each dispensing or administration of the medicine;

(h) if the prescription is for a designated appendix D medicine for a purpose mentioned in schedule 3 (Designated appendix D medicines—standing approvals), part 3.2, column 3 in relation to the medicine—the relevant approval particulars;

(i) if the prescriber is a dentist—the words ‘for dental treatment only’;

(j) if the prescriber is an eligible midwife—the words ‘for midwifery use only’;

(k) if the prescriber is an optometrist—the words ‘for optometry use only’;

(l) if the prescriber is a veterinary surgeon—

(i) the words ‘for animal treatment only’; and

(ii) the species of the animal for which the medicine is to be dispensed; and

(iii) if possible, a way of identifying the animal;

(m) if the prescription is an original of a prescription that was faxed by a prescriber to a pharmacist—the prescription is endorsed with words to the effect that the prescription was faxed to a named pharmacy on a stated date;

(n) if the prescription is a written prescription under section 31 (1) (c) (iv) (which is about oral prescriptions)—the prescription is endorsed with words to the effect that the

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prescription is a confirmation copy of an oral prescription issued to a named pharmacist on a stated date.

(2) However, if the prescription is written for an in-patient at a hospital in the patient's medical records, the prescription need not include any of the following:

(a) the prescriber's professional qualifications and business address and telephone number;

(b) if the medicine prescribed is a controlled medicine or designated appendix D medicine—the relevant approval particulars.

Note 1 ***Hospital*** means a public hospital, private hospital or day hospital and includes a body prescribed by regulation as a hospital (see Act, dict).

Note 2 A ***hospice*** is a hospital (see *The Macquarie Dictionary*, 4th ed).

(3) Also, if the prescription is a national residential medication chart prescription, the prescription need not include either of the following:

(a) the prescriber's professional qualifications;

(b) the quantity of the medicine to be dispensed or administered under the prescription.

(4) In this section:

relevant approval particulars means—

(a) for a controlled medicine—

(i) for an approval under section 556 (Standing approval to prescribe controlled medicines for short-term treatment)—the words 'standing short-term approval'; or

(ii) for an approval under section 557 (Standing interim approval to prescribe buprenorphine and methadone for patients of certain institutions)—the words 'standing opioid dependency treatment approval'; or

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(iii) for an approval under division 13.1.3 (Chief health officer controlled medicines approvals)—the words 'CHO approval number' followed by the identifying number for the approval; or

(b) for a designated appendix D medicine—

(i) for an approval under section 591 (Standing approval to prescribe designated appendix D medicines)—the words 'standing approval' and the specialist area, or the area, in which the prescriber practises; or

(ii) for an approval under section 593 (CHO decisions on applications to prescribe designated appendix D medicines)—the words 'CHO approval number' followed by the identifying number for the approval.

relevant TGA authorisation particulars means the words 'TGA authorisation' followed by—

(a) the identifying number for the authorisation; or

(b) if no identifying number is given for the authorisation—the date of the approval.

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Part 3.2 Requisitioning medicines

Division 3.2.1 Authorisation to issue requisitions

50 Authorisation under sch 1 to issue requisitions for medicines—Act, s 41 (b)

A person mentioned in schedule 1, column 2 is authorised to issue a requisition for a medicine if—

(a) issuing the requisition is included in the schedule, column 3 in relation to the person; and

(b) the issue of the requisition is consistent with any restriction for the issue of the requisition mentioned in the schedule, column 3.

51 Authorisation conditions for issuing requisitions for medicines—Act, s 44 (1) (b) and (2) (b)

A person's authorisation under section 50 to issue a requisition for a medicine is subject to the following conditions:

(a) if the requisition is a written requisition—the requisition complies with section 55 (General requirements for written requisitions) and section 56 (Particulars for requisitions);

(b) if the requisition is an oral requisition—

(i) the person believes on reasonable grounds that issuing the requisition is reasonably necessary for the treatment of a person; and

(ii) the quantity of the medicine requisitioned is not more than the amount reasonably necessary for the person's treatment; and

(iii) the requisition complies with section 56.

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Division 3.2.2 Requisitions

55 General requirements for written requisitions

A written requisition for a medicine must be—

(a) signed by the person (the ***issuer***) issuing the requisition; and

Note The requisition must be signed with the issuer's usual signature (see Act, dict, def ***signs***).

(b) if the issuer amends the requisition—initialled and dated by the issuer beside the amendment.

Note ***Written*** includes in electronic form (see Act, dict).

56 Particulars for requisitions

A requisition must include the following particulars:

(a) the name of the person issuing the requisition;

(b) the capacity in which the person is issuing the requisition;

(c) the date the requisition is issued;

(d) the medicine, and the form, strength and quantity of the medicine, to be supplied on the requisition;

(e) the pharmacy or ward to which the medicine is to be supplied.

Note ***Ward***—see the Act, dictionary.

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Part 3.3 Medicines purchase orders

Division 3.3.1 Authorisation to issue purchase orders

60 Authorisation under sch 1 to issue purchase orders for medicines—Act, s 38 (1) (b) and (2) (a)

A person mentioned in schedule 1, column 2 is authorised to issue a purchase order for a medicine if—

(a) issuing the purchase order is included in the schedule, column 3 in relation to the person; and

(b) the issue of the purchase order is consistent with any restriction for the issue of the purchase order mentioned in the schedule, column 3.

61 Authorisation conditions for issuing purchase orders for medicines—Act, s 44 (1) (b) and (2) (b)

A person's authorisation under section 60 to issue a purchase order for a medicine is subject to the following conditions:

(a) the purchase order complies with section 62 (General requirements for medicines purchase orders—Act, s 38 (2) (c));

Note A purchase order must be in writing (see Act, dict, def ***purchase order***).

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(b) the person must, not later than 24 hours after the person receives the medicine, send the supplier a document signed by the person acknowledging receipt of the medicine.

Example—document

a copy of the supplier's delivery docket signed by the buyer

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

Division 3.3.2 Purchase orders

62 General requirements for medicines purchase orders—Act, s 38 (2) (c)

(1) A purchase order for a medicine must be—

(a) signed by the person (the ***issuer***) issuing the order; and

Note The purchase order must be signed with the issuer's usual signature (see Act, dict, def ***signs***).

(b) if the issuer amends the order—initialled and dated by the issuer beside the amendment.

(2) A purchase order for a medicine must include the following:

(a) the issuer's name and business address and telephone number;

(b) the issuer's authority to issue the order;

(c) the medicine, and the form, strength and quantity of the medicine, to be supplied on the order.

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Part 3.4 Standing orders for medicines

Division 3.4.1 CHO standing orders

70 Authorisation of CHO to issue standing orders for supply of medicines in public health emergencies—Act, s 42 (b)

(1) The chief health officer is authorised to issue a standing order for the supply of a medicine in an emergency relating to public health.

Note 1 ***Supply*** does not include administer (see Act, s 24).

Note 2 A standing order must be in writing (see Act, dict, def ***standing order***).

(2) To remove any doubt, a standing order may be issued under subsection (1) even if no emergency declaration under the *Public Health Act 1997* is in force.

71 Authorisation of CHO to issue standing orders for administration of medicines for public health matters—Act, s 42 (b)

The chief health officer is authorised to issue a standing order for the administration of a medicine in relation to a public health matter.

Note A standing order must be in writing (see Act, dict, def ***standing order***).

72 Particulars for CHO standing orders for administration of medicines for public health matters

A standing order under section 71 must include the following particulars:

(a) a description of the public health matter to which the order relates;

(b) the date of effect of the order and the date (not longer than 2 years after the date of effect) when the order ends;

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(c) the clinical circumstances in which the medicine may be administered;

(d) a description of the people to whom the medicine may be administered;

(e) the medicine's approved name and, if applicable, brand name;

Note ***Approved name***—see the medicines and poisons standard, par 1 (1).

(f) if applicable, the form and strength of the medicine;

(g) the dose and route of administration;

(h) if applicable, the frequency of administration.

Example—par (e) and par (f)

Adrenaline (EpiPen) 300 micrograms in 0.3mL pre-filled syringe

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

Division 3.4.2 Standing orders for institutions

Note ***Institution*** includes a correctional centre and a CYP detention place (see s 652).

75 Authorisation of doctors to issue standing orders for administration of medicines at institutions—Act, s 42 (b)

(1) A doctor is authorised to issue a standing order for the administration of a medicine to patients at an institution if—

(a) a medicines and therapeutics committee for the institution has approved the order; and

(b) the order is signed by the chair of the committee.

Note ***Doctor*** does not include an intern doctor (see dict).

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(2) In this section:

medicines and therapeutics committee, for an institution, means a body—

(a) established by the institution to approve standing orders for the administration of medicines to patients at the institution; and

(b) that includes (but is not limited to) a doctor, nurse and pharmacist.

Note 1 ***Doctor*** and ***pharmacist*** do not include an intern (see dict).

Note 2 ***Nurse*** does not include an enrolled nurse (see Legislation Act, dict, pt 1).

76 Particulars for standing orders for administration of medicines at institutions

A standing order under section 75 must include the following particulars:

(a) an approval number for the order that is different from the number given to each other standing order approved for the institution;

(b) the date of effect of the order and the date (not longer than 2 years after the date of effect) when the order ends;

(c) each ward to which the order applies;

(d) the clinical circumstances in which the medicine may be administered;

(e) a description of the people to whom the medicine may be administered;

(f) the medicine's approved name and, if applicable, brand name;

Note ***Approved name***—see the medicines and poisons standard, par 1 (1).

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(g) if applicable, the form and strength of the medicine;

(h) the dose and route of administration;

(i) if applicable, the frequency of administration.

Example—par (f) and par (g)

Adrenaline (EpiPen) 300 micrograms in 0.3mL pre-filled syringe

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

Division 3.4.3 Standing orders for walk-in centre

77 Authorisation of CHO to issue standing orders for supply and administration of medicines at walk-in centre—Act, s 42 (b)

The chief health officer is authorised to issue a standing order for—

(a) the supply of a medicine at a walk-in centre; and

(b) the administration of a medicine at a walk-in centre.

Note 1 ***Supply*** does not include administer (see Act, s 24).

Note 2 A standing order must be in writing (see Act, dict, def ***standing order***).

78 Particulars for CHO standing orders for supply and administration of medicines at walk-in centre

A standing order under section 77 must include the following particulars:

(a) an approval number for the order that is different from the number given to each other standing order approved for the walk-in centre;

(b) the date of effect of the order and the date (not longer than 2 years after the date of effect) when the order ends;

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(c) each walk-in centre to which the order applies;

(d) the clinical circumstances in which the medicine may be supplied or administered;

(e) a description of the people to whom the medicine may be supplied or administered;

(f) the medicine's approved name and, if applicable, brand name;

Note ***Approved name***—see the medicines and poisons standard, par 1 (1).

(g) if applicable, the form and strength of the medicine;

(h) the dose and route of administration of the medicine;

(i) if applicable, the frequency of administration of the medicine;

(j) if applicable, the maximum duration of supply or administration of the medicine;

(k) if applicable, the maximum quantity of the medicine for supply or administration.

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Part 3.5 Medicines supply authorities generally

80 Cancellation of invalid supply authorities—Act, s 30 (2) (d)

(1) A paper-based supply authority is cancelled by a person if the person—

(a) marks the word ‘cancelled’, and the person’s name and business address, on the front of the supply authority; and

(b) signs and dates the cancellation of the supply authority.

(2) An electronic supply authority is cancelled by a person if the person—

(a) marks the word ‘cancelled’ on the supply authority; and

(b) links an electronic document to the supply authority that includes the person’s name and business address and signature.

81 Information for CHO about controlled medicines supplied on supply authorities—Act, s 31 (1) (b) and (4), def *required information*

(1) A person (the ***supplier***) who supplies a controlled medicine on a supply authority must, not later than 7 days after the day when the medicine is supplied, give the chief health officer the following information in writing:

(a) the supplier’s name, business address and telephone number;

(b) the name of the person who issued the supply authority;

(c) the date of the supply authority;

(d) the name and address of the person to whom the medicine is supplied;

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(e) the date of supply;

(f) the controlled medicine, and the form, strength and quantity of the medicine, supplied.

(2) However, this section does not apply to any of the following who report the supply of a controlled medicine on a supply authority to the Therapeutic Goods Administration:

(a) a medicines wholesalers licence-holder;

(b) a person who is authorised (however described) under a Commonwealth or State law to manufacture controlled medicines or supply controlled medicines by wholesale.

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Chapter 4 Supplying medicines

Part 4.1 Preliminary

100 Overview of supply authorisations for medicines

The following provisions of this chapter authorise a person to supply a medicine:

(a) section 110 (which is about supply authorisations set out in schedule 1, including dispensing on prescription, supply on requisition, purchase order and standing order and supply during consultations);

(b) section 251 (which is about authorisation of pharmacists to supply certain prescription only medicines without a prescription in emergencies);

(c) section 255 (which is about authorisation of approved pharmacists to supply certain medicines without prescription);

(d) section 260 (which is about authorisation to supply medicines to pharmacists for disposal).

Note A person may also be authorised to supply a medicine in a way mentioned in s 11 (2) (Overview of medicines authorisations under this regulation) (including under a licence, see pt 9.5).

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Part 4.2 Medicines—supply authorisations under sch 1

Division 4.2.1 Sch 1 medicines supply authorisations

110 Authorisation under sch 1 to supply medicines—Act, s 26 (1) (b) and (2) (b)

(1) A person mentioned in schedule 1, column 2 is authorised to supply a medicine if—

(a) supplying the medicine is included in the schedule, column 3 in relation to the person; and

(b) the supply is consistent with any restriction for the supply mentioned in the schedule, column 3.

(2) However, a pharmacist is not authorised under schedule 1 to supply a medicine if—

(a) the pharmacist is working for, or providing services to, a corporation when supplying the medicine; and

(b) the corporation is not—

(i) a pharmacist; or

(ii) a complying pharmacy corporation under the *Public Health Act 1997*, part 3B (Pharmacies).

Note ***Supply*** includes dispense (see Act, s 24).

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Division 4.2.2 Dispensing medicines

120 Authorisation conditions for dispensing medicines—Act, s 44 (1) (b) and (2) (b)

(1) A person's authorisation under section 110 to dispense a medicine is subject to the following conditions:

(a) the medicine is dispensed in accordance with the requirements of section 121;

Note Only a pharmacist may dispense a medicine (see sch 1).

(b) if the prescription is dispensed under section 121 (2), the pharmacist notes on the prescription the reasons that the pharmacist was satisfied that it was not practicable for a complying prescription to be issued for the medicine;

(c) if the prescription is changed by a pharmacist at the oral direction of the prescriber—the note of the change complies with section 122;

(d) the medicine is labelled in accordance with section 123;

(e) the dispensed prescription is marked in accordance with section 124;

(f) the dispensing of the prescription is recorded in accordance with section 125;

(g) if the prescription is an oral prescription for the dispensing of the medicine, or is faxed by a prescriber to a pharmacist, and the pharmacist does not receive an original of the prescription within 7 days after the day the prescription is given—the pharmacist must, within 24 hours after the end of the 7-day period, tell the chief health officer, in writing, of the failure to receive the original prescription;

(h) the prescription, if completed, and the record for paragraph (f), are kept at the pharmacy or, if the chief health officer approves

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in writing another place, the place approved by the chief health officer, for at least 2 years after the day the prescription becomes a completed prescription.

(2) However, subsection (1) (d), (e), (f) and (h) do not apply if the prescription is written for an in-patient at a hospital in the patient's medical records.

(3) In this section:

completed—a prescription is ***completed*** when—

(a) for a single prescription—the prescription is dispensed; or

(b) for a repeat prescription—the last repeat of the prescription is dispensed; or

(c) for a national residential medication chart prescription—the prescription is dispensed for the last time.

121 How medicines are dispensed

(1) The following are the requirements for dispensing a medicine:

(a) the prescription is issued by an authorised prescriber;

Note ***Authorised prescriber***—see s (3).

(b) the prescription complies with the applicable provisions of division 3.1.2 (Prescriptions);

(c) the medicine is dispensed in accordance with the prescription (including the prescription as changed by a pharmacist at the oral direction of the prescriber).

Note 1 ***Dispensed in accordance with the prescription***—see s (3).

Note 2 For changes to a prescription by the dispenser, see the Act, s 29 (3).

Note 3 ***Pharmacist*** does not include an intern pharmacist (see dict).

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(2) However, a pharmacist may dispense a prescription that does not include all of the applicable provisions for subsection (1) (b) if—

(a) the prescription is issued by an authorised prescriber; and

(b) the medicine is—

(i) dispensed in accordance with the prescription; and

(ii) if the prescription is changed by a pharmacist at the oral direction of the prescriber—the prescription complies with section 122; and

Note ***Pharmacist*** does not include an intern pharmacist (see dict).

(c) the medicine is supplied in a package that is labelled in accordance with section 123; and

(d) the pharmacist is satisfied that, because of a circumstance affecting the prescriber or the person for whom the medicine is to be dispensed, it is not practicable for a complying prescription to be issued for the medicine.

(3) In this section:

authorised prescriber, in relation to a prescription, means—

(a) for a medicine other than a controlled medicine—a person who is authorised to issue the prescription under the Act or another territory law; and

(b) for a controlled medicine—a person who is authorised to issue the prescription under part 13.1 (Controlled medicines approvals).

Examples—authorised prescribers

1 A NSW registered doctor practising in Queanbeyan is authorised under a NSW law to prescribe medicines. The doctor gives a patient a prescription for a controlled medicine and another prescription for a prescription only medicine. The prescription only medicine can be dispensed in the ACT because the prescription is issued by a person who is authorised under a State

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law to prescribe the medicine. The prescription for the controlled medicine cannot be dispensed in the ACT because the doctor is not registered in the ACT.

2 If the doctor in example 1 is registered in both the ACT and NSW, the prescription for the controlled medicine can be dispensed in the ACT.

3 A special event exemption under the *Health Professionals (Special Events Exemptions) Act 2000* authorises a visiting health professional to prescribe a medicine, including a controlled medicine. A doctor who is a visiting health professional within the meaning of that Act prescribes a controlled medicine. The prescription can be dispensed in the ACT.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

dispensed in accordance with the prescription, for a prescribed medicine, includes dispensing another brand of the medicine that is a bioequivalent form of the prescribed medicine.

Note ***Bioequivalent***—see the dictionary.

122 Noting changes to prescriptions on oral direction of prescriber—Act, s 27 (2) (b) (ii)

The following must be noted, in writing, on the prescription:

(a) the name of the prescriber giving the oral direction to change the prescription;

(b) the change to the prescription;

(c) the date the oral direction is given;

(d) the pharmacist's signature.

Note The notation must be made as soon as possible (see Legislation Act, s 151B).

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123 Labelling dispensed medicines—Act, s 60 (1) (c) (i) and (2) (c) (i)

The dispensed medicine must have a label that includes the following:

(a) the name of the person for whom the medicine is dispensed;

(b) if the prescriber is a dentist—the words 'for dental treatment only';

(c) if the prescriber is an eligible midwife—the words 'for midwifery use only';

(d) if the prescriber is an optometrist—the words 'for optometry use only';

(e) if the prescriber is a veterinary surgeon—

(i) words to the effect of 'for animal treatment only'; and

(ii) the species of the animal for which the medicine is dispensed; and

(iii) if a way of identifying the animal is stated on the prescription—the way of identifying the animal;

(f) the medicine's approved name and brand name;

Note ***Approved name***—see the medicines and poisons standard, par 1 (1).

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

(h) if the package of the dispensed medicine is not a manufacturer's pack—the relevant expiry date for the medicine;

(i) the date the medicine is dispensed;

(j) the name and the business address and telephone number of the pharmacy from which the medicine is dispensed;

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(k) the initials or other identification of the dispensing pharmacist;

(l) a number that is different from the number given to each other prescription dispensed at the pharmacy;

(m) directions about the use of the medicine that are adequate to allow the medicine to be taken or administered safely, including any warning statement in the medicines and poisons standard, appendix K (Drugs required to be labelled with a sedation warning) applying to the medicine;

(n) words to the effect of 'keep out of reach of children'.

Example—par (f) and par (g)

Warfarin tablets (Coumadin) 5mg 50

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

124 Marking dispensed prescriptions

(1) This section does not apply to a prescription for an in-patient at a hospital written in the patient's medical records.

(2) A dispensed paper-based prescription for a medicine must be marked with—

(a) if the prescription is a single prescription, the last repeat of a repeat prescription, or a national residential medication chart prescription dispensed for the last time—the word 'cancelled' on the front of the prescription; and

(b) the prescribed particulars.

(3) A dispensed electronic prescription for a medicine must be marked with—

(a) if the prescription is a single prescription, the last repeat of a repeat prescription, or a national residential medication chart

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prescription dispensed for the last time—the word ‘cancelled’; and

(b) a link to an electronic document containing the prescribed particulars.

(4) In this section:

paper-based prescription includes a faxed copy of a prescription.

prescribed particulars, for a dispensed prescription for a medicine, means—

(a) the date the medicine is dispensed; and

(b) the name and business address of the dispensing pharmacy; and

(c) if another brand of the medicine is dispensed for the prescribed medicine—the brand name of the medicine dispensed; and

(d) for a repeat prescription—the number of the repeat dispensed; and

(e) the prescription’s number under section 123 (l); and

(f) the pharmacist’s initials or signature.

single prescription means a prescription that is not a repeat prescription.

125 Recording dispensing of medicines

The dispensing pharmacist must ensure that a written record is made of the following information in relation to the dispensing of the medicine:

(a) the pharmacist’s name;

(b) the date of the prescription;

(c) the prescriber’s name;

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(d) the date the prescription is dispensed;

(e) for a repeat prescription—the number of the repeat dispensed;

(f) the prescription's number under section 123 (l);

(g) the name and address of the person for whom the medicine is dispensed;

(h) the medicine's approved name and brand name;

Note ***Approved name***—see the medicines and poisons standard, par 1 (1).

(i) the form, strength and quantity of the medicine dispensed.

Note ***Written*** includes in electronic form (see Act, dict).

Division 4.2.3 Supplying medicines on requisitions

Note For authorisation to issue a requisition, see s 50.

130 Authorisation conditions for supplying medicines on requisitions—Act, s 44 (1) (b) and (2) (b)

A person's authorisation under section 110 to supply a medicine on a requisition is subject to the following conditions:

(a) the medicine is supplied in accordance with the requirements under section 131;

(b) the medicine is supplied in a package that is labelled in accordance with section 132;

(c) the filled requisition is marked in accordance with section 133;

(d) the supply is recorded in accordance with section 134;

(e) the filled requisition and record under section 134 are kept at the institution where the medicine is supplied or, if the chief health officer approves in writing another place, the place

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approved by the chief health officer, for at least 2 years after the day the medicine is supplied.

131 Supplying medicines on requisitions

(1) The following are the requirements for the supply of a medicine on a requisition:

(a) the medicine is supplied in accordance with the requisition (including the requisition as changed by the person supplying the medicine at the oral direction of the person issuing the requisition);

Note For changes to a requisition by the person supplying a medicine on a requisition (see Act, s 29 (3)).

(b) if the requisition is a written requisition—the requisition complies with section 55 (General requirements for written requisitions) and section 56 (Particulars for requisitions);

(c) if the requisition is an oral requisition—the requisition complies with section 56.

(2) However, if the requisition does not comply with section 55 or section 56 (as appropriate), a pharmacist may supply the medicine on the requisition if satisfied that it is not practicable for a complying requisition to be issued for the medicine.

Note ***Pharmacist*** does not include an intern pharmacist (see dict).

(3) In this section:

supplied in accordance with the requisition, for a requisitioned medicine, includes supplying another brand of the medicine that is a bioequivalent form of the requisitioned medicine.

Note ***Bioequivalent***—see the dictionary.

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132 Labelling medicines supplied on requisition—Act, s 60 (1) (c) (i) and (2) (c) (i)

The package of a medicine supplied on requisition to a ward for the supply to a patient must have a label that includes the following:

(a) the medicine's approved name or brand name;

Note ***Approved name***—see the medicines and poisons standard, par 1 (1).

(b) the form, strength and quantity of the medicine;

(c) if the package of the medicine is not a manufacturer's pack—

(i) the batch number or numbers of the medicine; and

(ii) the relevant expiry date for the medicine;

(d) the name or other identifier of the pharmacy or ward from which the medicine is supplied;

(e) if the medicine is a controlled medicine—a number that is different from the number given to each other requisition supplied from the pharmacy or ward.

Examples—par (a) and par (b)

1	Warfarin tablets	5mg	50
2	Coumadin tablets	5mg	50

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

133 Marking filled requisitions

(1) A filled paper-based requisition for a medicine must be marked with—

(a) the name or other identifier of the pharmacy or ward from which the medicine is supplied; and

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(b) if the medicine is a controlled medicine—the requisition's number under section 132 (e); and

(c) the supplier's initials or signature.

(2) A filled electronic requisition for a medicine must be marked with a link to an electronic document containing—

(a) the name or other identifier of the pharmacy or ward from which the medicine is supplied; and

(b) if the medicine is a controlled medicine—the requisition's number under section 132 (e); and

(c) the supplier's initials or signature.

(3) However, subsection (1) (a) and (2) (a) do not apply to a requisition filled at a pharmacy at an institution.

(4) In this section:

paper-based requisition includes a faxed copy of a requisition.

134 Recording supply of medicines on requisitions

A person who supplies a medicine to someone else on requisition must make a written record of the following information:

(a) the date of the requisition;

(b) the name of the person who issued the requisition;

(c) the date the requisition is filled;

(d) the medicine, and the form, strength and quantity of the medicine, supplied;

(e) the name or initials of the person supplying the medicine.

Note ***Written*** includes in electronic form (see Act, dict).

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Division 4.2.4 Supplying medicines on purchase orders

Note For authorisation to issue a purchase order, see s 60.

140 Authorisation conditions for supplying medicines on purchase orders—Act, s 44 (1) (b) and (2) (b)

A person's authorisation under section 110 to supply a medicine on a purchase order is subject to the following conditions:

(a) the purchase order is a complying purchase order;

(b) the medicine is supplied in accordance with the requirements of section 141;

(c) the supply is recorded in accordance with section 142;

(d) if the supplier does not receive a document signed by the buyer acknowledging receipt of the medicine within 7 days after the day the medicine is delivered—the supplier must, within 24 hours after the end of the 7-day period, tell the chief health officer, in writing, of the failure to receive the document;

(e) the following are kept at the supplier's business premises or, if the chief health officer approves in writing another place, the place approved by the chief health officer, for at least 2 years after the day the medicine is supplied:

(i) the filled purchase order;

(ii) the delivery acknowledgement under paragraph (d) or section 141 (1) (d) (ii);

(iii) the record for section 142.

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141 Supplying medicines on purchase orders

(1) The following are the requirements for the supply of a medicine on a purchase order:

(a) the medicine is supplied in manufacturer's packs that comply with—

(i) section 501 (Packaging of supplied manufacturer's packs of medicines—Act, s 59 (1) (c) (i) and (2) (c) (i)); or

(ii) an approval under the Act, section 193 (Approval of non-standard packaging and labelling);

(b) the manufacturer's packs are labelled in accordance with—

(i) section 502 (Labelling of supplied manufacturer's packs of medicines—Act, s 60 (1) (c) (i) and (2) (c) (i)); or

(ii) an approval under the Act, section 193;

(c) the manufacturer's packs are securely wrapped and packed;

(d) if the medicine is delivered in person by the supplier to the buyer—

(i) the medicine is delivered to an adult; and

(ii) the delivery is acknowledged by the adult signing and dating a copy of the purchase order;

(e) if the medicine is not delivered in person by the supplier to the buyer—the medicine is delivered to the buyer by a person whose procedures require the delivery of the medicine to be signed for by the buyer or an adult employee of the buyer.

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(2) However, subsection (1) (a), (b) and (c) do not apply in relation to a medicine supplied by a pharmacist to a prescriber who is authorised to supply the medicine during a consultation if the medicine is supplied in a package that is labelled with the following particulars:

(a) the approved name and brand name of the medicine;

Note ***Approved name***—see the medicines and poisons standard, par 1 (1).

(b) the form, strength and quantity of the medicine, supplied;

(c) if the package of the medicine is not a manufacturer's pack—the relevant expiry date for the medicine.

142 Recording supply of medicines on purchase orders

A person who supplies a medicine to someone else on a purchase order must make a written record of the following information:

(a) the date of the order;

(b) the issuer's authority to issue the order;

(c) the name, and the business address and telephone number, of the person to whom the medicine is supplied;

(d) the date the order is supplied;

(e) the medicine, and the form, strength and quantity of the medicine, supplied.

Note ***Written*** includes in electronic form (see Act, dict).

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Division 4.2.5 Supplying medicines on standing orders

Note 1 For the issue of a standing order, see pt 3.4.

Note 2 ***Supply*** does not include administer (see Act, s 24).

150 Authorisation conditions for supplying medicines on standing orders—Act, s 44 (1) (b) and (2) (b)

(1) A person's authorisation under section 110 to supply a medicine on a standing order is subject to the following conditions:

(a) the medicine is supplied in accordance with the requirements of section 151;

(b) the supply is recorded in accordance with section 153;

(c) the record for section 153 is kept at the person's business premises or, if the chief health officer approves in writing another place, the place approved by the chief health officer, for at least 2 years after the day the medicine is supplied;

(d) if the supplier is not the person who would ordinarily have prescribed the medicine for the recipient, the required information is given in writing to—

(i) the prescriber (the ***usual prescriber***) who would ordinarily have prescribed the medicine for the recipient not later than 24 hours after supplying the medicine; or

(ii) if the recipient does not have a usual prescriber—the recipient.

(2) However, subsection (1) (c) and (d) do not apply if the record is made in a patient's medical records.

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(3) In this section:

required information, for the supply of a medicine on a standing order, means—

(a) the supplier's name; and

(b) the date the medicine is supplied; and

(c) the name and address of the person to whom the medicine is supplied; and

(d) the medicine's approved name and brand name; and

(e) the form, strength and quantity of the medicine supplied.

151 Supplying medicines on standing orders

The following are the requirements for the supply of a medicine on a standing order:

(a) the medicine is supplied in accordance with the standing order;

(b) the medicine is supplied in a package that is labelled in accordance with section 152.

152 Labelling medicines supplied on standing order— Act, s 60 (1) (c) (i) and (2) (c) (i)

The package of a medicine supplied on a standing order must have a label that includes the following:

(a) the name of the person to whom the medicine is to be supplied;

(b) the date the medicine is supplied;

(c) the medicine, and the form, strength and quantity of the medicine, supplied;

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(d) if the package of the dispensed medicine is not a manufacturer's pack—

(i) the batch number or numbers of the medicine; and

(ii) the relevant expiry date for the medicine;

(e) the supplier's name, business address and telephone number;

(f) directions about the use of the medicine that are adequate to allow the medicine to be taken or administered safely, including any warning statement in the medicines and poisons standard, appendix K (Drugs required to be labelled with a sedation warning) applying to the medicine;

(g) words to the effect of 'keep out of reach of children'.

153 Recording supply of medicines on standing orders

(1) A person (the ***supplier***) who supplies a medicine to a person (the ***patient***) on a standing order must make a written record of the following information:

(a) the supplier's name;

(b) the patient's name and address;

(c) the date the medicine is supplied;

(d) the medicine's approved name and brand name;

(e) the form, strength and quantity of the medicine;

(f) the date of the standing order.

Note ***Written*** includes in electronic form (see Act, dict).

(2) However, subsection (1) (b) does not apply if the record is made in the patient's medical records.

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Division 4.2.6 Supplying medicines during consultations

Note ***Supply*** does not include administer (see Act, s 24).

160 Authorisation conditions for supplying medicines during consultations—Act, s 44 (1) (b) and (2) (b)

A prescriber's authorisation under section 110 to supply a medicine during a consultation is subject to the following conditions:

(a) the medicine is supplied in accordance with the Act, section 7 (Appropriate prescription and supply of medicines);

(b) if the medicine is a controlled medicine for human use—

(i) the prescriber complies with the additional requirements under section 163 (Additional requirements for supplying controlled medicines for human use during consultations) in relation to the supply; and

(ii) if the medicine is dronabinol—the prescriber has an authorisation under the *Therapeutic Goods Act 1989* (Cwlth), section 19 to supply the medicine; and

Note Dronabinol cannot be prescribed for veterinary use because it is a prohibited substance (see medicines and poisons standard, sch 9, entry for tetrahydrocannabinols).

(iii) the prescriber complies with section 164 (Information for CHO about controlled medicines supplied during consultations—Act, s 31 (2) (b) and (4), def *required information*);

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(c) if the medicine is a designated appendix D medicine prescribed for a purpose mentioned in schedule 3 (Designated appendix D medicines—standing approvals), part 3.2, column 3 in relation to the medicine—

(i) the prescriber has an appendix D medicines approval to prescribe the medicine; and

(ii) the prescriber complies with each condition (if any) of the approval (including any conditions in the schedule, part 3.2, column 4 in relation to the medicine);

(d) the medicine is labelled in accordance with section 161;

(e) the supply is recorded in accordance with section 162;

(f) the record is kept at the prescriber's business premises or, if the chief health officer approves in writing another place, the place approved by the chief health officer, for at least 2 years after the day the medicine is supplied.

161 Labelling medicines supplied during consultations

The supplied medicine must have a label that includes the following:

(a) the name of the person to whom the medicine is supplied;

(b) the date the medicine is supplied;

(c) the prescriber's name, business address and telephone number;

(d) the medicine's approved name or brand name;

Note ***Approved name***—see the medicines and poisons standard, par 1 (1).

(e) the form, strength and quantity of the medicine;

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(f) if the package of the supplied medicine is not a manufacturer's pack—the relevant expiry date for the medicine;

(g) directions about the use of the medicine that are adequate to allow the medicine to be taken or administered safely, including any warning statement in the medicines and poisons standard, appendix K (Drugs required to be labelled with a sedation warning) applying to the medicine;

(h) words to the effect of 'keep out of reach of children';

(i) if the prescriber is a dentist—the words 'for dental treatment only';

(j) if the prescriber is an eligible midwife—the words 'for midwifery use only';

(k) if the prescriber is an optometrist—the words 'for optometry use only';

(l) if the prescriber is a veterinary surgeon—

(i) words to the effect of 'for animal treatment only'; and

(ii) the species of the animal for which the medicine is supplied; and

(iii) if possible, a way of identifying the animal.

Examples—par (d) and par (e)

1	Warfarin tablets	5mg	50
2	Coumadin tablets	5mg	50

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

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162 Recording medicines supplied during consultations

A prescriber who supplies a medicine during a consultation must make a written record of the following information in the medical records of the person to whom, or animal to which, the consultation related:

(a) the date the medicine is supplied;

(b) the medicine's approved name or brand name;

Note ***Approved name***—see the medicines and poisons standard, par 1 (1).

(c) the form, strength and quantity of the medicine;

(d) the directions given to the person for the use of the medicine.

Note ***Written*** includes in electronic form (see Act, dict).

163 Additional requirements for supplying controlled medicines for human use during consultations

The following are the additional requirements for supplying a controlled medicine for human use during a consultation:

(a) the prescriber has a controlled medicines approval to prescribe the medicine;

Note For controlled medicines approvals, see pt 13.1.

(b) if the approval is for a particular form of the medicine—the supply is for the form of the medicine approved or a bioequivalent form;

Note ***Bioequivalent***—see the dictionary.

(c) if the approval is for a particular strength of the medicine—the supply is for the strength approved or a weaker strength;

(d) if the approval is for a particular quantity of the medicine—the supply is for not more than the quantity approved;

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(e) the prescriber complies with each condition (if any) of the approval.

Example—par (b)

If a slow release form of a medicine is approved, the prescriber is not authorised to prescribe an immediate release form of the medicine.

Example—par (c) and par (d)

If a doctor is given an approval to prescribe 25 morphine 20mg capsules, the doctor may prescribe 5 20mg capsules and 10 15mg capsules. Later, if the approval is still in force, the doctor may prescribe not more than 10 morphine capsules of any strength up to and including 20mg.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

164 Information for CHO about controlled medicines supplied during consultations—Act, s 31 (2) (b) and (4), def *required information*

(1) This section applies if a prescriber supplies a controlled medicine for human use during a consultation.

Note ***Supply*** does not include administer (see Act, s 24).

(2) The prescriber must, not later than 7 days after the end of the month when the controlled medicine is supplied, give the chief health officer the following information in writing:

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

(b) the name and address of the person to whom the medicine is supplied;

(c) the date of supply;

(d) the medicine, and the form, strength and quantity of the medicine, supplied.

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Division 4.2.7 Selling pseudoephedrine by retail

170 Meaning of *retail sale*—div 4.2.7

In this division:

retail sale does not include supply on prescription.

171 Authorisation conditions for retail sale of pseudoephedrine—Act, s 44 (1) (b) and (2) (b)

A person's authorisation under section 110 to supply pseudoephedrine is subject to the following conditions if the pseudoephedrine is sold by retail sale:

(a) the pseudoephedrine is supplied in accordance with the Act, section 7 (Appropriate prescription and supply of medicines);

(b) the seller complies with section 172;

(c) the seller makes a record (the ***pseudoephedrine record***) of the required information under section 173;

Note For how the record must be made, see the Act, s 46.

(d) the record is kept at the seller's business premises or, if the chief health officer approves in writing another place, the place approved by the chief health officer, for at least 2 years after the day the sale is made;

(e) if the buyer of the pseudoephedrine asks the seller to see the record during the period it is kept under paragraph (d), the seller—

(i) allows the buyer to see the record within a reasonable period of a request being made by the buyer; and

(ii) if satisfied that the record is incorrect, amends the record;

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(f) the seller complies with—

(i) a request under section 174 (4) (b) (Failure to amend pseudoephedrine sales record); and

(ii) a direction under section 175 (Pseudoephedrine sales record—decision by CHO) to amend the record.

172 Requirement to tell buyer about pseudoephedrine sales record

(1) The authorised person selling pseudoephedrine by retail sale, must tell the buyer the following:

(a) the seller is required to make a record of the sale;

(b) the buyer may refuse to provide information for the record but, if the buyer refuses, the seller must not sell pseudoephedrine to the buyer;

(c) the record may be made available to the following people:

(i) a police officer;

(ii) a public servant who is a member of the administrative unit to which the chief health officer belongs;

(iii) a Commonwealth or State public servant (however described) who is a member of an administrative unit (however described) that administers legislation about medicines;

Note ***State*** includes the Northern Territory (see Legislation Act, dict, pt 1).

(iv) anyone other than the seller who supplies pseudoephedrine to the public in Australia;

(v) the Pharmacy Guild of Australia;

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(d) the buyer has the right to see the record and have any mistake corrected.

Note If a form is approved under the Act, s 198 for this provision, the form must be used.

(2) In this section:

police officer includes a member of a police force (however described) of a State.

173 Required information for pseudoephedrine sales records

(1) The following is the required information for a pseudoephedrine record:

(a) the date of sale;

(b) the brand name, form, strength and quantity of pseudoephedrine sold;

(c) the buyer's name and address;

(d) a unique identification number for the buyer from—

(i) a photo identification document produced to the seller by the buyer; or

(ii) if the buyer does not produce a photo identification document—

(A) the buyer's birth certificate; or

(B) an Australian or New Zealand seniors card for the buyer;

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(e) the kind of identification the buyer produces.

Example—unique identification number

a person's driver licence number

Note 1 If a form is approved under the Act, s 198 for this provision, the form must be used.

Note 2 An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(2) In this section:

Australian student identification card means a card issued to a person who is a student at an Australian secondary or tertiary education institution to identify the person as a student at the institution.

birth certificate, for a person, means—

(a) the person's birth certificate, or a certified extract from the register about the person's birth, under the *Births, Deaths and Marriages Registration Act 1997*; or

(b) a document issued under a law of a State, an external Territory or New Zealand that corresponds to a birth certificate or extract mentioned in paragraph (a) if the document identifies the issuing jurisdiction and states its date of issue.

photo identification document, for a person, means any of the following documents for the person if it is current and contains the person's photograph:

(a) an Australian driver licence or external driver licence within the meaning of the *Road Transport (Driver Licensing) Act 1999*;

(b) a passport, other than an Australian passport;

(c) a proof of age card;

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(d) an Australian student identification card.

proof of age card means a proof of age card issued under—

(a) the *Liquor Act 2010*, section 210 (Proof of age cards); or

(b) the law of a state, an external territory or New Zealand.

174 Failure to amend pseudoephedrine sales record

(1) This section applies if the seller of pseudoephedrine does not amend a pseudoephedrine record in accordance with section 171 (e) (ii) (Authorisation conditions for retail sale of pseudoephedrine—Act, s 44 (1) (b) and (2) (b)).

(2) The buyer may, in writing, apply to the chief health officer for a direction to the seller to make the amendment.

(3) The application must give reasons why the buyer thinks the record is incorrect.

(4) The chief health officer must—

(a) give a copy of the application to the seller; and

(b) ask the seller to—

(i) make the amendment and tell the chief health officer; or

(ii) if the seller is satisfied that the amendment should not be made—send written reasons to the chief health officer not later than 10 working days after the day the seller receives the application why the amendment should not be made.

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175 Pseudoephedrine sales record—decision by CHO

(1) After considering an application under section 174 (2) and any reasons given in accordance with the request under section 174 (4) (b) (ii), the chief health officer must—

(a) direct the seller to amend the pseudoephedrine record—

(i) in accordance with the application; or

(ii) in a stated way other than in accordance with the application; or

(b) refuse the application.

(2) The chief health officer must give the buyer and seller written notice of the decision.

Division 4.2.8 Supplying pharmacist only medicines

180 Authorisation conditions for supply of pharmacist only medicines—Act, s 44 (1) (b) and (2) (b)

(1) This section does not apply to the supply of a pharmacist only medicine—

(a) at an institution; or

(b) on a supply authority.

Note 1 ***Supply*** does not include administer (see Act, s 24).

Note 2 ***Supply authority*** includes a written prescription or requisition or a purchase order or standing order (see Act, s 23).

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(2) A person's authorisation under section 110 to supply a pharmacist only medicine is subject to the following conditions:

(a) the person personally hands the medicine to a customer attending in person;

(b) the person gives the customer adequate instructions, either orally or in writing, for the medicine's use at the time of supply.

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Part 4.3 Authorisation to supply without prescription in emergencies

250 Meaning of *designated prescription only medicine*—pt 4.3

In this part:

designated prescription only medicine means a prescription only medicine other than—

(a) an anabolic steroid; and

(b) a designated appendix D medicine; and

(c) a benzodiazepine.

Note ***Prescription only medicine*** does not include a controlled medicine (see Act, s 11)

251 Authorisation to supply certain medicines without prescription in emergencies—Act, s 26 (1) (b)

A pharmacist is authorised to supply a designated prescription only medicine to someone else without a prescription if the pharmacist is satisfied that—

(a) the person is undergoing treatment essential to the person's health or wellbeing; and

(b) the designated prescription only medicine has previously been prescribed for the person's treatment by a prescriber; and

(c) the person is in immediate need of the medicine to continue the treatment; and

(d) because of an emergency, it is not practicable for the person to obtain a prescription for the medicine from a prescriber.

Note ***Pharmacist*** does not include an intern pharmacist (see dict).

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252 Authorisation conditions for supplying of certain medicines without prescription in emergencies—Act, s 44 (1) (b) and (2) (b)

(1) A pharmacist's authorisation under section 251 to supply a designated prescription only medicine without a prescription is subject to the following conditions:

(a) the quantity supplied is—

(i) if the medicine is a liquid, aerosol, cream, ointment or anovulant tablet packaged in a manufacturer's pack—the smallest manufacturer's pack in which the medicine is generally available; or

(ii) in any other case—not more than the quantity required for 3 days treatment for the person;

(b) the medicine is supplied in a package that is labelled in accordance with section 253;

(c) the supply is recorded in accordance with section 254;

(d) the record of the supply is kept at the pharmacy or, if the chief health officer approves in writing another place, the place approved by the chief health officer, for at least 2 years after the day medicine is supplied;

(e) the pharmacist sends the prescriber who would have ordinarily prescribed the medicine for the recipient the required information for the supply in writing not later than 24 hours after supplying the medicine.

(2) In this section:

required information, for the supply of a designated prescription only medicine, means—

(a) the pharmacist's name; and

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(b) the name, business address and telephone number of the pharmacy from which the medicine is supplied; and

(c) the date the medicine is supplied; and

(d) the name and address of the person to whom the medicine is supplied; and

(e) the medicine's approved name or brand name; and

(f) the form, strength and quantity of the medicine supplied.

253 Labelling medicines supplied without prescription in emergencies—Act, s 60 (1) (c) (i) and (2) (c) (i)

The package of a designated prescription only medicine supplied to a person under section 251 must have a label that includes the following:

(a) the name of the person to whom the medicine is supplied;

(b) the date the medicine is supplied;

(c) the name, business address and telephone number of the pharmacy from which the medicine is supplied;

(d) the initials or other identification of the pharmacist supplying the medicine;

(e) the medicine's approved name and brand name;

Note ***Approved name***—see the medicines and poisons standard, par 1 (1).

(f) the form, strength and quantity of the medicine;

(g) if the package of the supplied medicine is not a manufacturer's pack—the relevant expiry date for the medicine;

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(h) directions about the use of the medicine that are adequate to allow the medicine to be taken or administered safely, including any warning statement in the medicines and poisons standard, appendix K (Drugs required to be labelled with a sedation warning) applying to the medicine;

(i) words to the effect of 'keep out of reach of children'.

Example—par (e) and par (f)

Warfarin tablets (Coumadin) 5mg 3

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

254 Recording medicines supplied without prescription in emergencies

A pharmacist who supplies a designated prescription only medicine to a person under section 251 must make a written record of the following information in relation to the supply of the medicine:

(a) the pharmacist's name;

(b) the name of the prescriber who would ordinarily have prescribed the medicine;

(c) the date the medicine is supplied;

(d) the name and address of the person to whom the medicine is supplied;

(e) the medicine's approved name and brand name;

(f) the form, strength and quantity of the medicine supplied.

Note ***Written*** includes in electronic form (see Act, dict).

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Part 4.3A Authorisation to supply certain medicines without prescription—continued dispensing

255 Authorisation to supply certain medicines without prescription by approved pharmacist––Act, s 185 (1) (g)

An approved pharmacist is authorised to supply a medicine to a person without prescription if—

(a) the medicine is listed as a pharmaceutical benefit under a continued dispensing determination; and

(b) the pharmacist supplies the medicine to the person in accordance with the determination.

256 Labelling certain medicines supplied without prescription by approved pharmacist––Act, s 185 (1) (j)

The medicine supplied to a person under section 255 must have a label that includes the following:

(a) the name of the person to whom the medicine is supplied;

(b) the date the medicine is supplied;

(c) the name, business address and telephone number of the pharmacy from which the medicine is supplied;

(d) the initials or other identification of the pharmacist supplying the medicine;

(e) the medicine's approved name and brand name;

Note ***Approved name***—see the medicines and poisons standard, par 1 (1).

(f) the form, strength and quantity of the medicine;

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(g) if the package of the supplied medicine is not a manufacturer's pack—the relevant expiry date for the medicine;

(h) a number that is different from the number given to any prescription dispensed at the pharmacy;

(i) directions about the use of the medicine that are adequate to allow the medicine to be taken or administered safely, including any warning statement in the medicines and poisons standard, appendix K (Drugs required to be labelled with a sedation warning) applying to the medicine;

(j) words to the effect of 'keep out of reach of children'.

Example—pars (e) and (f)

Microlut 28 tablets (Levonorgestrel) 30mcg 3

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

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Part 4.4 Authorisation to supply medicines for disposal

260 Authorisation to supply medicines to pharmacists for disposal—Act, s 26 (1) (b)

A person is authorised to supply a medicine to a pharmacist for disposal.

Note ***Pharmacist*** does not include an intern pharmacist (see dict).

261 Authorisation to supply medicines to commercial disposal operators for disposal—Act, s 26 (1) (b)

A person is authorised to supply a medicine to another person for disposal if the other person—

(a) holds an environmental authorisation for the disposal of the medicine; or

(b) is an adult acting for a person mentioned in paragraph (a).

Note For related authorisations, see pt 9.1.

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Part 4.5 Wholesale supply of medicines under corresponding laws

270 Conditions for wholesalers supplying medicines under corresponding laws—Act, s 20 (4) (c)

The following conditions apply to a person who supplies medicines by wholesale under a corresponding law:

(a) the person must comply with, and must ensure that the person's agents and employees comply with—

(i) the Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8; and

(ii) the medicines Australia code of conduct;

Note ***Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8*** and ***medicines Australia code of conduct***—see the dictionary.

(b) the person must not supply sample packs of a controlled medicine;

(c) the person must not supply a medicine to someone else (the ***buyer***) unless—

(i) the buyer is authorised to possess the medicine; and

(ii) the supply is in accordance with section 140 (Authorisation conditions for supplying medicines on purchase orders—Act, s 44 (1) (b) and (2) (b));

(d) the person must store medicines—

(i) within the manufacturer's recommended storage temperature range; and

(ii) in any other environmental condition that is necessary to preserve the medicine's stability and therapeutic quality.

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Chapter 5 Administering medicines

Part 5.1 Authorisations for health-related occupations

350 Authorisation under sch 1 for people in health-related occupations to administer medicines—Act, s 37 (1) (b) and (3) (b)

A person mentioned in schedule 1, column 2 is authorised to administer a medicine if—

(a) administering the medicine is included in the schedule, column 3 in relation to the person; and

(b) the administration is consistent with any restriction for the administration mentioned in the schedule, column 3.

Note For authorisation to self-administer a medicine, see s 360.

351 Authorisation conditions for administration of medicines at institutions by people in health-related occupations—Act, s 44 (1) (b) and (2) (b)

(1) An authorisation under section 350 to administer a medicine is subject to the following conditions:

(a) if the medicine is administered under a standing order to a patient at an institution—the administration is recorded in the patient's medical records;

Note ***Institution*** includes a correctional centre and a CYP detention place (see s 652).

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(b) if the medicine is a controlled medicine administered to a patient at an institution—

(i) the medicine is not removed from a storage receptacle until immediately before its administration; and

(ii) the administration is witnessed by a prescribed administration witness or, if a prescribed administration witness is not reasonably available to witness the administration, the administration is witnessed by another person; and

Note The witness must sign the record of the administration as witness (see Act, s 53 (e)).

(iii) the administration is recorded in—

(A) the patient's medical records; and

(B) the applicable controlled medicines register mentioned in section 543 (3) (Making entries in controlled medicines registers—Act, s 51 (1) (b)).

(2) However, subsection (1) (b) does not apply in relation to a controlled medicine dispensed in a dose administration aid for—

(a) a patient at a residential aged care facility or residential disability care facility; or

(b) a detainee at a correctional centre; or

(c) a young detainee at a CYP detention place.

(3) In this section:

prescribed administration witness means a person prescribed under section 544 (Prescribed witnesses for administration of controlled medicines—Act, s 53 (a) and (b)) for the administration of a controlled medicine.

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Part 5.2 Other administration authorisations

360 Authorisation for self-administration etc of medicines—Act, s 37 (2) (b) and (3) (b)

(1) This section applies in relation to a medicine obtained by a person from someone who is authorised to supply the medicine to the person.

(2) The following dealings by the person with the medicine are authorised:

(a) if the person is a prescriber and the medicine is a restricted medicine—self-administration of a medicine prescribed or supplied by another prescriber who is not—

(i) a trainee dentist, trainee nurse practitioner, intern doctor or person training to be an eligible midwife; or

(ii) related to or employed by the person;

(b) if the person is a prescriber and the medicine is not a restricted medicine—self-administration of the medicine;

(c) if the person is not a prescriber and the medicine is supplied for the person's own use—self-administration of the medicine;

(d) if the person is the custodian of an animal and the medicine is supplied for the animal's use—administering the medicine to the animal.

Note ***Custodian***, of an animal—see the dictionary.

(3) In this section:

restricted medicine—see section 30.

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361 Authorisation for administration of medicines by assistants—Act, s 37 (1) (b)

(1) A person (the ***assistant***) is authorised to administer a medicine to someone else (the ***assisted person***) if—

(a) the medicine is obtained by or for the assisted person from someone who is authorised to supply the medicine to the assisted person; and

(b) the medicine is administered in accordance with the directions on the medicine's labelling; and

(c) if the assisted person is not a person under a legal disability—the assisted person asks for the assistant's help to take the medicine; and

(d) if the assisted person is a person under a legal disability—the assistant is authorised by the assisted person's parent or guardian to administer the medicine.

(2) In this section:

impaired decision-making ability—a person has ***impaired decision-making ability*** if the person's decision-making ability is impaired because of a physical, mental, psychological or intellectual condition or state, whether or not the condition or state is a diagnosable illness.

person under a legal disability means—

(a) a child; or

(b) a person with impaired decision-making ability in relation to a matter relating to the person's health.

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Chapter 6 Obtaining and possessing medicines

370 Authorisation under sch 1 to obtain and possess medicines—Act, s 35 (1) (b), (2) (b) and s 36 (b)

(1) A person mentioned in schedule 1, column 2 is authorised to obtain a medicine if obtaining the medicine—

(a) is included in the schedule, column 3 in relation to the person; and

(b) is consistent with any restriction for obtaining the medicine mentioned in the schedule, column 3.

(2) A person mentioned in schedule 1, column 2 is authorised to possess a medicine if—

(a) possessing the medicine is included in the schedule, column 3 in relation to the person; and

(b) the possession is consistent with any restriction for the possession mentioned in the schedule, column 3.

371 Authorisation to obtain and possess medicines for certain personal use-related dealings—Act, s 35 (1) (b), (2) (b) and s 36 (b)

(1) A person is authorised to obtain or possess a medicine if the person obtains the medicine from someone who is authorised to supply the medicine to the person.

(2) Subsection (1) applies in relation to a person whether the medicine is obtained by the person for the person's own use or as an agent for someone else.

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Chapter 7 Manufacturing medicines

380 Authorisation under sch 1 to manufacture medicines—Act, s 33 (b)

A person mentioned in schedule 1, column 2 is authorised to manufacture a medicine if—

(a) manufacturing the medicine is included in the schedule, column 3 in relation to the person; and

(b) the manufacturing is consistent with any restriction for the manufacturing mentioned in the schedule, column 3.

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Chapter 8 Discarding medicines

390 Discarding controlled medicines—Act, s 34 (1) (a)

(1) A controlled medicine must be discarded in accordance with this section.

Note See also the *Drugs of Dependence Act 1989*, div 11.4 about the disposal of seized substances.

(2) A prescribed discarding witness may discard a controlled medicine in the presence of another prescribed discarding witness.

(3) However, a person who is authorised to administer a controlled medicine may discard the residue of the medicine after administration in the presence of a person who is not a prescribed discarding witness if no other prescribed discarding witness is reasonably available to witness its discarding.

(4) A person complies with this section if the person destroys the medicine so that it is unable to be used.

(5) In this section:

prescribed discarding witness means a person prescribed under section 545 (Prescribed witnesses for discarding of controlled medicines—Act, s 54 (a) and (b)) for the discarding of a controlled medicine.

Note A medicine must not be discarded in a way that creates a risk to the health or safety of people or is likely to cause damage to property or the environment (see Act, s 34 (3)).

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Chapter 9 Other medicines authorisations

Part 9.1 Authorisations for delivery people and commercial disposal operators

400 Authorisations to deliver medicines under supply authorities—Act, s 26 (1) (b), (2) (b), s 35 (1) (b), (2) (b) and s 36 (b)

(1) This section applies to an adult (the ***delivery person***), other than a health practitioner, at an institution, who is—

(a) engaged to transport and deliver a medicine supplied on a supply authority; or

(b) acting for a person mentioned in paragraph (a).

Note For health practitioners at institutions, see sch 1, pt 1.4.

(2) The delivery person is authorised to—

(a) obtain and possess the medicine for the purposes of transporting and delivering the medicine as engaged; and

(b) supply the medicine to the entity named as the recipient in the supply authority or the entity's agent.

Examples—delivery person

1 a hospital employee who is not a health practitioner

2 an employee of a courier service

Example—agent

the guardian of a child for a prescription dispensed for the child

Note 1 ***Entity*** includes a person (see Legislation Act, dict, pt 1).

Note 2 An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

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401 Authorisations for commercial disposal operators—Act, s 26 (1) (b) and (2) (b), s 35 (1) (b) and (2) (b) and s 36 (b)

(1) This section applies to a person who—

(a) holds an environmental authorisation for the disposal of a medicine; or

(b) is an adult acting for a person mentioned in paragraph (a).

(2) The person is authorised to obtain and possess the medicine for the purposes of disposing of the medicine as engaged.

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Part 9.2 Emergency supply and administration of adrenaline and salbutamol

410 Authorisations to supply and administer adrenaline and salbutamol—Act, s 26 (1) (b) and s 37 (1) (b)

(1) A person is authorised to do 1 or more of the following for someone else (the ***assisted person***) who is in immediate need of adrenaline or salbutamol:

(a) supply authorised adrenaline or authorised salbutamol to the assisted person;

(b) supply authorised adrenaline or authorised salbutamol to someone else for immediate administration to the assisted person;

(c) administer authorised adrenaline or authorised salbutamol to the assisted person.

(2) In this section:

authorised adrenaline means adrenaline in a single use automatic injector delivering not more than 0.3mg adrenaline.

authorised salbutamol means salbutamol in, or for, a metered inhaler.

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Part 9.3 Medicines authorisations for corrections functions

420 Authorisations for CYP authorised people—Act, s 26 (1) (b), s 35 (1) (b), (2) (b), s 36 (b) and s 37 (1) (b)

A CYP authorised person is authorised, within the scope of the person's employment, to do any of the following in relation to a medicine supplied for a young detainee by a person who is authorised to supply the medicine:

(a) obtain the medicine;

(b) possess the medicine (including possess the medicine outside a CYP detention place for the purpose of administering the medicine to a young detainee while the young detainee is lawfully outside the place);

(c) administer the medicine to the young detainee;

(d) supply the medicine to a person who is authorised to obtain the medicine for the young detainee.

Example—young detainee lawfully outside CYP detention place

the detainee is on local leave escorted by a CYP authorised person

Note 1 ***CYP authorised person*** and ***CYP detention place***—see the dictionary.

Note 2 ***Young detainee***—see the *Children and Young People Act 2008*, s 95.

Note 3 An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

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421 Authorisations for corrections officers—Act, s 26 (1) (b), s 35 (1) (b), (2) (b), s 36 (b) and s 37 (1) (b)

A corrections officer is authorised, within the scope of the officer's employment, to do any of the following in relation to a medicine supplied for a detainee by a person who is authorised to supply the medicine:

(a) obtain the medicine;

(b) possess the medicine (including possess the medicine outside a correctional centre for the purpose of administering the medicine to a detainee while the detainee is lawfully outside the centre);

(c) administer the medicine to the detainee;

(d) supply the medicine to a person who is authorised to obtain the medicine for the detainee.

Note 1 See the example and notes to s 420.

Note 2 ***Detainee***—see the *Corrections Management Act 2007*, s 6.

422 Authorisations for court and police cell custodians—Act, s 26 (1) (b), s 35 (1) (b), (2) (b), s 36 (b) and s 37 (1) (b)

(1) A custodian is authorised, within the scope of the custodian's employment, to do any of the following in relation to a medicine supplied for a person in custody at court cells or police cells by someone who is authorised to supply the medicine:

(a) obtain the medicine at the cells;

(b) possess the medicine at the cells;

(c) administer the medicine to the person in custody at the cells;

(d) supply the medicine to someone who is authorised to obtain the medicine for the person in custody.

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(2) In this section:

court cell—see the *Corrections Management Act 2007*, section 29.

custodian means—

(a) a person in charge of a court cell or police cell; or

(b) a person acting under the direct supervision of the person in charge.

person in custody means—

(a) a detainee; or

(b) a young detainee; or

(c) a person detained at a police cell under the *Corrections Management Act 2007*, section 30; or

(d) a person detained at a court cell under the *Corrections Management Act 2007*, section 33.

police cell—see the *Corrections Management Act 2007*, section 29.

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Part 9.4 Authorisations for medicines research and education program purposes other than controlled medicines

Note A licence is required for research and education programs in relation to controlled medicines (see pt 14.2).

430 Authorisations for non-controlled medicines research and education—Act, s 26 (1) and (2) (b)

(1) A scientifically qualified person employed at a recognised research institution (other than the Canberra Hospital) is authorised to do the following for the purposes of an authorised activity at the institution:

(a) issue a purchase order for a relevant medicine;

(b) obtain on a purchase order a relevant medicine;

(c) possess a relevant medicine;

(d) supply a relevant medicine to a person (a ***relevant person***) who is taking part in the authorised activity at the institution.

Note 1 ***Scientifically qualified person***—see the dictionary.

Note 2 ***Recognised research institution***—see the Act, s 20 (5).

(2) A scientifically qualified person employed at the Canberra Hospital is authorised to do the following for the purposes of an authorised activity at the hospital:

(a) issue a written requisition for a relevant medicine;

(b) obtain on a written requisition a relevant medicine;

(c) possess a relevant medicine;

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(d) supply a relevant medicine to a person (also a ***relevant person***) who is taking part in the authorised activity at the hospital.

(3) A relevant person is authorised to do the following in relation to a relevant medicine for the purposes of an authorised activity:

(a) obtain the medicine from the scientifically qualified person for the activity;

(b) possess the medicine for the purposes of the activity;

(c) supply the medicine to the scientifically qualified person for the activity.

(4) In this section:

authorised activity, in relation to a relevant medicine at a recognised research institution, means the conduct of any of the following if it does not involve the administration of the medicine to a person:

(a) medical or scientific research in relation to the medicine at the institution;

(b) instruction involving the medicine at the institution;

(c) quality control or analysis of the medicine at the institution.

relevant medicine means a medicine other than a controlled medicine.

431 Authorisation conditions for non-controlled medicines research and education—Act, s 44 (1) (b) and (2) (b)

A scientifically qualified person's authorisation under section 430 is subject to the following conditions:

(a) the person has written approval for the conduct of the authorised activity from the person in charge of—

(i) the recognised research institution; or

(ii) a faculty or division of the institution;

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(b) if the recognised research institution employing the person is the Canberra Hospital—

(i) a requisition for the relevant medicine issued by the person complies with section 55 (General requirements for written requisitions) and section 56 (Particulars for requisitions); and

(ii) the requisition is for an amount of the medicine approved in writing by the person in charge; and

(iii) the requisition is for an amount of the medicine used solely for the purpose approved in writing by the person in charge;

(c) if the person is employed at a recognised research institution other than the Canberra Hospital—

(i) a purchase order for the relevant medicine complies with section 62; and

(ii) the purchase order is for an amount of the medicine approved in writing by the person in charge;

(d) the medicine is obtained from someone who is authorised to supply the medicine to the person.

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Part 9.5 Authorisations under medicines licences

Division 9.5.1 Controlled medicines research and education program licence authorisations

Note 1 For authorisation for research and education for other medicines, see pt 9.4.

Note 2 For other provisions about controlled medicines research and education program licences, see pt 14.2.

440 Authorisations under controlled medicines research and education program licences—Act, s 20 (1) (a)

(1) A controlled medicines research and education program licence (other than for a program conducted at the Canberra Hospital) authorises—

(a) the licence-holder to—

(i) issue a purchase order for a controlled medicine (the ***licensed controlled medicine***) stated in the licence for the program stated in the licence; and

(ii) obtain a licensed controlled medicine on a purchase order for the program; and

(iii) possess a licensed controlled medicine for the program at the premises to which the licence relates; and

(iv) supply a licensed controlled medicine to anyone taking part in the program for the program; and

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(b) the program supervisor, and anyone taking part in the program, to deal with the licensed controlled medicine as authorised by the licence at the premises stated in the licence.

(2) A controlled medicines research and education program licence for a program conducted at the Canberra Hospital authorises—

(a) the licence-holder to—

(i) issue a written requisition for a controlled medicine (the ***licensed controlled medicine***) stated in the licence for the program stated in the licence; and

(ii) obtain a licensed controlled medicine on a written requisition for the program; and

(iii) possess a licensed controlled medicine for the program at the premises to which the licence relates; and

(iv) supply a licensed controlled medicine to anyone taking part in the program for the program; and

(b) the program supervisor, and anyone taking part in the program, to deal with the licensed controlled medicine as authorised by the licence at the hospital.

441 Authorisation condition for controlled medicines research and education program licences—Act, s 44 (1) (b) and (2) (b)

A licence-holder's authorisation to obtain a controlled medicine under a controlled medicines research and education program licence is subject to the condition that the medicine is—

(a) if the licence is for a program conducted at the Canberra Hospital—obtained on a requisition that complies with section 55 (General requirements for written requisitions) and section 56 (Particulars for requisitions); or

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(b) in any other case—purchased on a complying purchase order.

Note For licence conditions, see the Act, s 89.

Division 9.5.2 First-aid kit licence authorisations

Note For other provisions about first-aid kit licences, see pt 14.3.

450 Authorisations under first-aid kit licences—Act, s 20 (1) (a)

(1) In this section:

authorised medicine, for a first-aid kit, means—

(a) a medicine stated in the first-aid kit licence for the kit; and

(b) a pharmacy medicine or pharmacist only medicine for the kit.

(2) A first-aid kit licence authorises—

(a) the licence-holder to—

(i) issue a purchase order for an authorised medicine for the first-aid kit; and

(ii) obtain on a purchase order an authorised medicine for the first-aid kit; and

(b) the licence-holder, and anyone else authorised to deal with a medicine by the licence, to—

(i) possess an authorised medicine as part of the first-aid kit for the emergency treatment of a person's medical condition; and

(ii) supply an authorised medicine to someone else who is authorised under the licence to administer the medicine; and

(iii) administer an authorised medicine in the first-aid kit if the person believes on reasonable grounds that the

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administration of the medicine is necessary for the emergency treatment of a person's medical condition.

451 Authorisation condition for first-aid kit licences—Act, s 44 (1) (b) and (2) (b)

A licence-holder's authorisation to obtain a medicine under a first-aid kit licence is subject to the condition that the medicine is purchased on a complying purchase order.

Note For licence conditions, see the Act, s 89.

Division 9.5.3 Wholesalers licence authorisations

Note For other provisions about wholesalers licences, see pt 14.4.

460 Authorisations under medicines wholesalers licences—Act, s 20 (1) (a)

(1) A medicines wholesalers licence authorises the licence-holder to do any of the following in relation to a medicine (the ***licensed medicine***) stated in the licence at the premises (the ***licensed premises***) stated in the licence:

(a) issue a purchase order for a licensed medicine;

(b) obtain a licensed medicine on a purchase order for sale by wholesale from the licensed premises;

(c) possess a licensed medicine for sale by wholesale from the licensed premises;

(d) sell a licensed medicine by wholesale (whether or not for resale) from the licensed premises to—

(i) a person authorised to issue a purchase order for the medicine; or

(ii) someone in another State who may obtain the medicine by wholesale under the law of the other State; or

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(iii) someone in another country who may lawfully obtain the medicine by wholesale in the other country;

Note The medicines must be sold on a purchase order in accordance with s 140 (see s 461).

(e) unless the licensed medicine is a controlled medicine—supply the medicine in accordance with the medicines Australia code of conduct provisions for product starter packs.

Note ***Medicines Australia code of conduct***—see the dictionary.

(2) However, an authorisation under subsection (1) does not apply if the licence states that it does not apply.

(3) Also, subsection (1) (d) (iii) does not apply in relation to a licensed medicine that is a prohibited export under the *Customs Act 1901* (Cwlth).

461 Authorisation conditions for medicines wholesalers licences—Act, s 44 (1) (b) and (2) (b)

A licence-holder's authorisation under a medicines wholesalers licence is subject to the following conditions:

(a) the dealings with a medicine authorised by the licence will be carried out under the supervision of an individual approved under section 616 (1) (Restrictions on issuing of medicines wholesalers licences—Act, s 85 (1) (a));

(b) the licence-holder must comply with, and the licence-holder must ensure that the licence-holder's agents and employees comply with—

(i) the Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8; and

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(ii) the medicines Australia code of conduct;

Note ***Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8*** and ***medicines Australia code of conduct***—see the dictionary.

(c) a medicine obtained under the licence is purchased on a complying purchase order;

(d) a medicine sold under the licence is sold on a complying purchase order in accordance with section 141 (Supplying medicines on purchase orders).

Note For licence conditions, see the Act, s 89.

Division 9.5.4 Opioid dependency treatment licence authorisations

Note For other provisions about opioid dependency treatment licences, see pt 14.5.

470 Authorisations under opioid dependency treatment licences—Act, s 20 (1) (a)

(1) An opioid dependency treatment licence issued to a pharmacist authorises the licence-holder, and any other pharmacist at the community pharmacy (the ***licensed pharmacy***) to which the licence relates, to do any of the following for the purpose of treating a person's drug-dependency:

(a) issue a purchase order for buprenorphine or methadone;

(b) obtain buprenorphine or methadone on a purchase order for administration at the licensed pharmacy;

(c) possess buprenorphine and methadone;

(d) dispense buprenorphine and methadone in accordance with a prescription;

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(e) supply buprenorphine and methadone to a nurse at the licensed pharmacy for administration at the pharmacy under the supervision of a pharmacist;

(f) administer buprenorphine and methadone at the licensed pharmacy in accordance with a prescription (including the prescription as changed by a pharmacist at the oral direction of the prescriber).

(2) An opioid dependency treatment licence issued to a pharmacist authorises a nurse to administer buprenorphine and methadone at the licensed pharmacy under the supervision of a pharmacist and in accordance with a prescription (including the prescription as changed by a pharmacist at the oral direction of the prescriber).

Note 1 ***Nurse*** does not include an enrolled nurse (see Legislation Act, dict, pt 1).

Note 2 ***Pharmacist*** does not include an intern pharmacist (see dict).

(3) To remove any doubt, an authorisation under this section does not, by implication, limit a pharmacist's or nurse's authorisations under schedule 1 (Medicines—health-related occupations authorisations) in relation to other dealings with buprenorphine and methadone.

471 Authorisation condition for opioid dependency treatment licences—Act, s 44 (1) (b) and (2) (b)

(1) A licence-holder's authorisation under an opioid dependency treatment licence is subject to the following conditions:

(a) the licence-holder must ensure that a person to whom buprenorphine or methadone is administered under the licence signs a written acknowledgement in accordance with subsection (2) that the medicine has been administered to the person;

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(b) a purchase order issued by the licence-holder to obtain buprenorphine or methadone under the licence is a complying purchase order.

Note 1 ***Written*** includes in electronic form (see Act, dict).

Note 2 For licence conditions, see the Act, s 89.

(2) For subsection (1) (a), the acknowledgement must include the following:

(a) the approved name or brand name of the medicine administered;

(b) the form, strength and quantity of the medicine administered;

(c) the date the medicine is administered.

Division 9.5.5 Pharmacy medicines rural communities licences

Note For other provisions about pharmacy medicines rural communities licences, see pt 14.6.

480 Authorisations under pharmacy medicines rural communities licences—Act, s 20 (1) (a)

A pharmacy medicines rural communities licence authorises—

(a) the licence-holder to—

(i) issue a purchase order for a pharmacy medicine (the ***licensed medicine***) stated in the licence for retail sale from the premises (the ***licensed premises***) stated in the licence; and

(ii) obtain the licensed medicine on a purchase order for retail sale from the licensed premises; and

(iii) possess the licensed medicine at the licensed premises for retail sale from the licensed premises; and

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(iv) sell the licensed medicine by retail from the licensed premises to customers attending in person at the licensed premises; and

(b) an employee of the licence-holder to—

(i) possess the medicine at the licensed premises for retail sale from the licensed premises; and

(ii) sell the medicine by retail from the licensed premises to customers attending in person at the licensed premises.

Examples—sales to which par (a) (iv) and par (b) (ii) do not apply

sales over the internet or by mail

Note 1 For other requirements in relation to medicines sold under rural communities licences—see s 500 (3), s 502 (4) and s 522.

Note 2 An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

481 Authorisation conditions for pharmacy medicines rural communities licences—Act, s 44 (1) (b) and (2) (b)

A licence-holder's authorisation under a pharmacy medicines rural communities licence is subject to the following conditions:

(a) a pharmacy medicine obtained under the licence is purchased on a complying purchase order;

(b) the pharmacy medicines to which the licence relates are sold in the manufacturer's packs;

(c) the packs are labelled in accordance with—

(i) section 502 (Labelling of supplied manufacturer's packs of medicines—Act, s 60 (1) (c) (i) and (2) (c) (i)); or

(ii) an approval under the Act, section 193 (Approval of non-standard packaging and labelling);

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(d) the pharmacy medicines to which the licence relates are sold from the premises stated in the licence to customers attending in person.

Note For licence conditions, see the Act, s 89.

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Part 9.6 Authorisations for endorsed health practitioners

490 Authorisations for endorsed health practitioners—Act, s 20 (1) (d)

(1) This section applies to a health practitioner whose registration is endorsed under the *Health Practitioner Regulation National Law (ACT)*, section 94 (Endorsement for scheduled medicines).

(2) The health practitioner is authorised to deal with a medicine in accordance with the endorsement.

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Chapter 10 Packaging and labelling of medicines generally

500 When pharmacy medicines and pharmacist only medicines to be supplied in manufacturer's packs—Act, s 59 (1) (c) (i) and (2) (c) (i)

(1) In this section:

health practitioner does not include—

(a) a pharmacist, or intern pharmacist, at a hospital; or

(b) a prescriber who supplies a medicine during a consultation.

supply does not include dispense.

veterinary surgeon does not include a prescriber who supplies a medicine during a consultation.

(2) A health practitioner or employee acting under the direction of a health practitioner, must supply a pharmacy medicine or pharmacist only medicine in a whole manufacturer's pack of the medicine.

(3) A pharmacy medicines rural communities licence-holder, or an employee acting under the direction of the licence-holder, must sell a pharmacy medicine stated in the licence in a whole manufacturer's pack of the medicine.

501 Packaging of supplied manufacturer's packs of medicines—Act, s 59 (1) (c) (i) and (2) (c) (i)

A manufacturer's pack of a medicine supplied must be packaged—

(a) in accordance with the medicines and poisons standard, sections 2.1 (2) to 2.6 (2); or

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(b) in a container in which the medicine may be sold under a corresponding law.

Note A manufacturer's pack of a medicine supplied may also be packaged in accordance with an approval under the Act, s 193 (Approval of non-standard packaging and labelling) (see Act, s 59 (1) (c) (ii) and (2) (c) (ii)).

502 Labelling of supplied manufacturer's packs of medicines—Act, s 60 (1) (c) (i) and (2) (c) (i)

(1) In this section:

supply, a medicine, does not include—

(a) dispense the medicine; or

(b) supply the medicine on a requisition or standing order.

(2) A manufacturer's pack of a supplied medicine must be labelled in accordance with—

(a) the medicines and poisons standard, sections 1.1 (2) to 1.6 (2); or

(b) a corresponding law.

Note A manufacturer's pack of a medicine supplied may also be labelled in accordance with an approval under the Act, s 193 (Approval of non-standard packaging and labelling) (see Act, s 60 (1) (c) (ii) and (2) (c) (ii)).

(3) A manufacturer's pack of a pharmacist only medicine sold by retail at a community pharmacy must be labelled with the pharmacy's name, business address and telephone number.

(4) A manufacturer's pack of a pharmacy medicine sold at premises licensed under a pharmacy medicines rural communities licence must be labelled with the licence-holder's name, business address and telephone number.

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Chapter 11 Storage of medicines

Part 11.1 Preliminary

510 Meaning of *prescribed person*—ch 11

For this chapter, each of the following is a ***prescribed person***:

(a) a dentist, doctor, eligible midwife, nurse practitioner, optometrist, podiatrist or veterinary surgeon;

Note 1 ***Dentist***, ***doctor*** and ***veterinary surgeon*** does not include an intern or trainee (see defs of these terms in dict).

Note 2 ***Nurse practitioner*** does not include a person holding limited or provisional registration to practise as a nurse practitioner (see dict).

(b) a pharmacist responsible for the management of a community pharmacy;

(c) the chief pharmacist at an institution;

(d) a medicines wholesalers licence-holder;

(e) a pharmacy medicines rural communities licence-holder;

(f) an approved analyst;

Note ***Approved analyst***—see the dictionary.

(g) a medicines and poisons inspector (including a police officer);

(h) a controlled medicines research and education program licence-holder;

(i) a person in charge of any of the following:

(i) an ambulance service (whether or not operated by the Commonwealth, the Territory or a State);

(ii) a correctional centre;

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(iii) a CYP detention place;

(iv) a health centre operated by the Territory;

(v) a residential aged care facility without a pharmacy;

(vi) a residential disability care facility without a pharmacy;

(vii) a ward (including an opioid dependency treatment centre operated by the Territory).

Note 1 ***CYP detention place***—see the dictionary.

Note 2 ***Residential aged care facility*** and ***residential disability care facility***—see the Act, dictionary.

Note 3 ***State*** includes a territory (see Legislation Act, dict, pt 1).

511 Meaning of *key*—ch 11

In this chapter:

key includes an electronic swipe card or electronic proximity device.

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Part 11.2 Storage requirements for medicines generally

515 Storage of medicines generally—Act, s 61 (b) and (c)

(1) A prescribed person must ensure that a medicine in the person's possession is stored—

(a) within the manufacturer's recommended storage temperature range; and

(b) in any other environmental condition that is necessary to preserve the medicine's stability and therapeutic quality.

Note ***Possess*** includes having control over disposition (see Act, s 24).

(2) To remove any doubt, this section does not apply to a prescribed person mentioned in section 510 (i) if the person does not have control over the disposition of the medicine.

Example—person not having control over disposition of medicine

a medicine in the personal possession of a resident of a residential aged care facility who is in an independent living unit within the facility

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

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Part 11.3 Additional storage requirements for medicines other than controlled medicines

520 Storage of medicines other than controlled medicines in community pharmacies—Act, s 61 (b) and (c)

(1) The pharmacist responsible for the management of a community pharmacy must ensure that each pharmacy medicine at the pharmacy is stored—

(a) if the medicine is for retail sale—within 4m of, and in sight of, the pharmacy's dispensary; and

(b) in any other case—so that public access to the medicine is restricted.

(2) The pharmacist responsible for the management of a community pharmacy must ensure that each pharmacist only medicine and prescription only medicine at the pharmacy is stored—

(a) in a part of the premises to which the public does not have access; and

(b) so that only a pharmacist, or a person under the direct supervision of a pharmacist, has access to the medicine.

Note ***Pharmacist*** does not include an intern pharmacist (see dict).

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521 Storage of medicines other than controlled medicines by other people—Act, s 61 (b) and (c)

(1) In this section:

prescribed person does not include a pharmacist responsible for the management of a community pharmacy.

(2) A prescribed person must ensure that a medicine (other than a controlled medicine) in the person's possession is stored so that public access to it is restricted.

Note ***Possess*** includes having control over disposition (see Act, s 24).

(3) To remove any doubt, this section does not apply to a prescribed person mentioned in section 510 (i) if the person does not have control over the disposition of the medicine.

Example—person not having control over disposition of medicine

a medicine in the personal possession of a resident of a residential aged care facility who is in an independent living unit within the facility

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

522 Storage of pharmacy medicines by pharmacy medicines rural communities licence-holders—Act, s 61 (b) and (c)

A pharmacy medicines rural communities licence-holder must store a pharmacy medicine for retail sale so that public access to the medicine is restricted.

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Part 11.4 Additional storage requirements for controlled medicines

530 Meaning of *personal custody*—pt 11.4

In this part:

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.

531 Storage of controlled medicines by wholesalers licence-holders—Act, s 61 (b) and (c)

(1) A wholesalers licence-holder must store a controlled medicine in the person's possession (other than a controlled medicine required for immediate supply) in a vault that—

(a) complies with, or is more secure than a vault that complies with, the requirements for a vault in schedule 5, section 5.8 (Requirements for vaults); and

(b) is fitted with an alarm system.

(2) However, if the chief health officer is satisfied that the total amount of controlled medicine held by the licence-holder at any time is not large enough to need to be stored in a vault, the chief health officer may approve, in writing, the storage of the controlled medicine in a safe or strong room.

(3) If the chief health officer gives an approval under subsection (2)—

(a) if the approval is for a safe—the safe must comply with, or be more secure than a safe that complies with, the requirements for a safe in schedule 5, section 5.6 (Requirements for safes); and

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(b) if the approval is for a strong room—the strong room must comply with, or be more secure than a strong room that complies with, the requirements for a strong room in schedule 5, section 5.7 (Requirements for strong rooms); and

(c) the safe or strong room must be fitted with an alarm system.

532 Storage of controlled medicines for certain health-related occupations—Act, s 61 (b) and (c)

(1) In this section:

designated person means—

(a) a dentist, doctor, nurse practitioner or veterinary surgeon (other than a dentist, doctor, nurse practitioner or veterinary surgeon at an institution); or

(b) an ambulance officer employed by the Commonwealth, the Territory or a State; or

(c) a first-aid kit licence-holder.

Note 1 ***Dentist***, ***doctor*** and ***veterinary surgeon*** does not include an intern or trainee (see defs of these terms in dict).

Note 2 ***Nurse practitioner*** does not include a person holding limited or provisional registration to practise as a nurse practitioner (see dict).

Note 3 ***State*** includes a territory (see Legislation Act, dict, pt 1).

(2) A designated person who possesses a controlled medicine must store the controlled medicine as follows:

(a) the person must ensure that the controlled medicine is stored in—

(i) a locked container that prevents ready access to the container's contents and is securely attached to a building; or

(ii) a locked drawer, cupboard, room or vehicle;

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(b) if the medicine is kept in a container that is unlocked by a combination lock—the person must keep the combination confidential;

(c) if the medicine is kept in a container that is unlocked by a key—the person must keep personal custody of the key;

(d) if the medicine is kept in a drawer, cupboard, room or vehicle—the person must keep personal custody of the key to the drawer, cupboard, room or vehicle.

(3) However, subsection (2) does not apply to a controlled medicine if—

(a) the controlled medicine is being carried by a designated person in—

(i) a locked first-aid kit; or

(ii) an unlocked first-aid kit that is in immediate use; and

(b) the person keeps personal custody of the key to the first-aid kit.

533 Storage of controlled medicines by certain other prescribed people—Act, s 61 (b) and (c)

(1) In this section:

excluded person means—

(a) a dentist, doctor, nurse practitioner or veterinary surgeon at an institution; or

(b) the person in charge of a residential aged care facility or residential disability care facility in relation to a controlled medicine dispensed in a dose administration aid for a patient at the facility; or

(c) the person in charge of a correctional centre in relation to a controlled medicine dispensed for a detainee in a dose administration aid; or

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(d) the person in charge of a CYP detention place in relation to a controlled medicine dispensed for a young detainee in a dose administration aid.

Note 1 ***CYP detention place***—see the dictionary.

Note 2 ***Correctional centre***—see the Legislation Act, dictionary, pt 1.

Note 3 ***Detainee***—see the *Corrections Management Act 2007*, s 6.

Note 4 ***Young detainee***—see the *Children and Young People Act 2008*, s 95.

(2) This section applies to a prescribed person, other than an excluded person, in relation to a controlled medicine in the person's possession if the medicine is not for immediate administration.

Note ***Possess*** includes having control over disposition (see Act, s 24).

(3) The person must ensure that—

(a) the controlled medicine is stored in a medicines cabinet, safe, strong room or vault (a ***storage receptacle***) that complies with, or is more secure than a storage receptacle that complies with, the requirements for the receptacle in schedule 5 (Requirements for storage receptacles); and

(b) the storage receptacle is kept securely locked when not in immediate use; and

(c) if the storage receptacle is unlocked by a combination lock—the person keeps the combination confidential; and

(d) if the storage receptacle is unlocked by a key—the person keeps personal custody of the key; and

(e) if the prescribed person is the chief pharmacist at an institution—the storage receptacle is fitted with an alarm system.

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(4) To remove any doubt, this section does not apply to a prescribed person mentioned in section 510 (i) if the person does not have control over the disposition of the medicine.

Example—person not having control over disposition of medicine

a medicine in the personal possession of a resident of a residential aged care facility who is in an independent living unit within the facility

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

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Chapter 12 Controlled medicines registers

540 Keeping of controlled medicines registers by certain people—Act, s 48 (a) and s 50 (1) (b) and (2) (b)

(1) A person mentioned in table 540, column 2 who possesses a controlled medicine must keep a controlled medicines register.

Note Also, a pharmacist responsible for the management of a community pharmacy must keep a controlled medicines register for controlled medicines kept at the pharmacy (see Act, s 48).

(2) However, subsection (1) does not apply to the person in relation to—

(a) a controlled medicine in a first-aid kit kept by the person; or

(b) if the person is the person in charge of a residential aged care facility or residential disability care facility—a controlled medicine dispensed for the patient in a dose administration aid; or

(c) if the person is the person in charge of a correctional centre—a controlled medicine dispensed for a detainee in a dose administration aid; or

(d) if the person is the person in charge of a CYP detention place—a controlled medicine dispensed for a young detainee in a dose administration aid.

Note 1 ***CYP detention place***—see the dictionary.

Note 2 ***Correctional centre***—see the Legislation Act, dictionary, pt 1.

Note 3 ***Detainee***—see the *Corrections Management Act 2007*, s 6.

Note 4 ***Young detainee***—see the *Children and Young People Act 2008*, s 95.

Note 5 For keeping controlled medicines in a first-aid kit, see s 541.

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(3) A person to whom subsection (1) applies must keep a controlled medicines register for a controlled medicine at the place prescribed in table 540, column 3 for the person.

(4) A pharmacist responsible for the management of a community pharmacy at which controlled medicines are kept must keep the controlled medicines register for the controlled medicines at the pharmacy.

Note For the requirement for a controlled medicine register to be kept for a community pharmacy, see the Act, s 48.

Table 540 Keeping controlled medicines registers

column 1 item	column 2 prescribed person	column 3 place where register to be kept
1	person in charge of ambulance service	the premises where the controlled medicine is kept
2	approved analyst	the analyst's laboratory
3	person in charge of correctional centre	the correctional centre
4	person in charge of CYP detention place	the detention place
5	dentist	the dentist's surgery
6	doctor	the doctor's surgery
7	medicines wholesalers licence-holder	the licensed premises under s 460
8	medicines and poisons inspector (other than police officer)	the place directed in writing by the chief health officer
9	person in charge of residential aged care facility without pharmacy	the facility
10	person in charge of residential disability care facility without pharmacy	the facility

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column 1 item	column 2 prescribed person	column 3 place where register to be kept
11	supervisor of program under controlled medicines research and education program licence	the premises where program is being conducted
12	veterinary surgeon	the veterinary surgeon's surgery
13	person in charge of ward (including an opioid dependency treatment centre operated by the Territory)	the ward
14	nurse practitioner	the nurse practitioner's place of practice

541 Keeping of controlled medicines registers by first-aid kit holders—Act, s 48 (a) and s 50 (1) (b) and (2) (b)

(1) In this section:

designated person means—

(a) a dentist, doctor, nurse practitioner or veterinary surgeon; or

(b) an ambulance officer employed by the Commonwealth, the Territory or a State; or

(c) a first-aid kit licence-holder.

Note 1 ***Dentist***, ***doctor*** and ***veterinary surgeon*** does not include an intern or trainee (see defs of these terms in dict).

Note 2 ***Nurse practitioner*** does not include a person holding limited or provisional registration to practise as a nurse practitioner (see dict).

Note 3 ***State*** includes a territory (see Legislation Act, dict, pt 1).

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(2) A designated person who possesses a first-aid kit containing a controlled medicine must keep the controlled medicines register for the controlled medicine with the first-aid kit.

542 Form of controlled medicines registers—Act, s 49 (1) (b) and (2) (b)

(1) Each page in a controlled medicines register must relate to a single form and strength of a controlled medicine.

(2) If a controlled medicines register is kept electronically, a separate record must be used for each form and strength of controlled medicine kept.

543 Making entries in controlled medicines registers—Act, s 51 (1) (b)

(1) The following details for a dealing with a controlled medicine are prescribed:

(a) the nature of the dealing;

(b) the date of the dealing;

(c) the medicine, and the form, strength and quantity of the medicine, dealt with;

(d) if the dealing is receiving the medicine—the name and address of the supplier;

(e) if the dealing is supplying the medicine—the name and address of the person to whom it is supplied;

(f) if the medicine is supplied on a prescription—the prescriber's name and suburb and the prescription's number under section 123 (l) (Labelling dispensed medicines—Act, s 60 (1) (c) (i) and (2) (c) (i));

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(g) if the medicine is supplied on a requisition—the requisition's number under section 132 (e) (Labelling medicines supplied on requisition—Act, s 60 (1) (c) (i) and (2) (c) (i));

(h) if the medicine is supplied on a purchase order—the date of the purchase order;

(i) if the Act, section 53 (Registers—witnessing administration of medicines) applies to the dealing—the name of the person to whom the medicine is administered;

(j) the quantity of the medicine held after the dealing.

(2) However, subsection (1) (i) does not apply in relation to a controlled medicine dispensed in a dose administration aid for—

(a) a patient at a residential aged care facility or residential disability care facility; or

(b) a detainee at a correctional centre; or

(c) a young detainee at a CYP detention place.

(3) A dealing with a controlled medicine must be entered in—

(a) if the dealing happens in a pharmacy at an institution—the controlled medicines register kept at the pharmacy; or

(b) if the dealing happens in a ward at an institution—the controlled medicines register kept at the ward; or

(c) if the person must keep both a controlled medicines register for a first-aid kit and another controlled medicines register—

(i) for a dealing with a controlled medicine to which the first-aid kit relates—the controlled medicines register for the kit; or

(ii) for any other dealing by the person—the other controlled medicines register; or

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(d) in any other case—the controlled medicines register the person must keep.

544 Prescribed witnesses for administration of controlled medicines—Act, s 53 (a) and (b)

The following people are prescribed as witnesses in relation to the administration of a controlled medicine:

(a) if the medicine is administered by an intern doctor—a dentist, doctor, midwife, nurse, nurse practitioner or pharmacist;

(b) if the medicine is administered by a person who is not an intern doctor—

(i) a person prescribed under paragraph (a); or

(ii) an intern doctor or enrolled nurse.

Note ***Dentist***, ***doctor*** and ***pharmacist*** does not include an intern or trainee (see defs of these terms in dict).

545 Prescribed witnesses for discarding of controlled medicines—Act, s 54 (a) and (b)

(1) The following people are prescribed as witnesses in relation to the discarding of a controlled medicine:

(a) an ambulance officer employed by the Commonwealth, the Territory or a State;

(b) an approved analyst;

(c) a dentist;

(d) a doctor;

(e) a medicines and poisons inspector;

(f) a midwife;

(g) a nurse;

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(h) a nurse practitioner;

(i) a pharmacist;

(j) a veterinary surgeon.

Note 1 ***Approved analyst***—see the dictionary.

Note 2 ***Dentist***, ***doctor***, ***pharmacist*** and ***veterinary surgeon*** does not include an intern or trainee (see defs of these terms in dict).

Note 3 ***Nurse*** does not include an enrolled nurse (see Legislation Act, dict, pt 1).

Note 4 See s 390 for the discarding of the residue of a controlled medicine left after administration.

(2) However, a person mentioned in subsection (1) must not be a prescribed witness to the discarding of a controlled medicine if the person is—

(a) related to, a close friend of or employed by the person discarding the medicine; or

(b) the supervisor of the person discarding the medicine; or

(c) supervised by the person discarding the medicine.

546 Changes etc to entries in controlled medicines registers—Act, s 55 (2) (b)

(1) An entry in a paper-based controlled medicines register may be amended by the person who made the entry by—

(a) the person signing and dating a marginal note or footnote that gives the date of the amendment and the amended details; and

(b) if the entry relates to administering a controlled medicine—

(i) the amendment being witnessed by a person prescribed under section 544 (Prescribed witnesses for administration of controlled medicines—Act, s 53 (a) and (b)); and

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(ii) the witness signing the amendment as witness; and

(c) if the entry relates to the discarding of a controlled medicine—

(i) the amendment being witnessed by a person prescribed under section 545 (Prescribed witnesses for discarding of controlled medicines—Act, s 54 (a) and (b)); and

(ii) the witness signing the amendment as witness.

(2) An entry in an electronic controlled medicines register may be amended by the person who made the entry by the person attaching or linking, by electronic means, a document that includes—

(a) the person's signature, the date and the amended details; and

(b) if the entry relates to administering a controlled medicine—the signature as witness of a person prescribed under section 544; and

(c) if the entry relates to the discarding of a controlled medicine—the signature as witness of a person prescribed under section 545.

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Chapter 13 Controlled medicines and appendix D medicines approvals for human use

Part 13.1 Controlled medicines approvals

Note It is a condition of an authorisation to prescribe a controlled medicine for human use that the prescriber has an approval under this part (see s 31 (1) (d)).

Division 13.1.1 Preliminary

550 Meaning of *controlled medicines approval*

In this regulation:

controlled medicines approval means an approval to prescribe a controlled medicine under—

(a) division 13.1.2 (Standing controlled medicines approvals); or

(b) division 13.1.3 (Chief health officer controlled medicines approvals).

551 Meaning of *designated prescriber*—pt 13.1

In this part:

designated prescriber means a prescriber (other than a veterinary surgeon or trainee veterinary surgeon) in relation to whom prescribing a controlled medicine is included in schedule 1, column 3.

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Division 13.1.2 Standing controlled medicines approvals

555 Standing approval to prescribe controlled medicines for hospital in-patients

A designated prescriber is approved to prescribe a controlled medicine for a patient of the prescriber if the patient is an in-patient at a hospital.

Note A ***hospice*** is a hospital (see *The Macquarie Dictionary*, 4th ed).

556 Standing approval to prescribe controlled medicines for short-term treatment

A designated prescriber is approved to prescribe a controlled medicine for a patient of the prescriber if—

(a) the prescriber believes on reasonable grounds that the patient is not a drug-dependant person in relation to a controlled medicine or prohibited substance; and

(b) the prescriber believes on reasonable grounds that the patient has not been prescribed a controlled medicine within the 2-month period before the prescriber prescribes the medicine; and

(c) the prescriber prescribes the controlled medicine for the patient's use for 2 months or less.

Note For long-term prescribing, see div 13.1.3.

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557 Standing interim approval to prescribe buprenorphine and methadone for patients of certain institutions

(1) In this section:

doctor includes an intern doctor acting under the direct supervision of a doctor.

(2) A doctor is approved (the ***interim approval***) to prescribe buprenorphine or methadone if—

(a) the doctor—

(i) is working at a hospital and prescribes the medicine for an outpatient at the hospital; or

(ii) is working at any of the following institutions and prescribes the medicine for a patient of the institution:

(A) a correctional centre;

(B) a CYP detention place;

(C) an opioid dependency treatment centre operated by the Territory; or

Note ***Institution*** includes a correctional centre and a CYP detention place (see s 652).

(iii) prescribes the medicine for a person in police custody; and

(b) the buprenorphine or methadone is prescribed in accordance with the opioid dependency treatment guidelines; and

Note ***Opioid dependency treatment guidelines***—see the dictionary.

(c) the doctor makes an application under section 560 to prescribe the medicine not later than 72 hours after the doctor first prescribes buprenorphine or methadone for the patient.

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(3) The interim approval ends—

(a) if the chief health officer approves the application under division 13.1.3—when the doctor is given notice of the approval; or

(b) if the application under section 560 is withdrawn—on the withdrawal of the application; or

(c) if the chief health officer refuses to approve the application and the 7-day period mentioned in section 565 (2) (Applications for review of unfavourable CHO decisions for approvals) ends without an application for review being made—at the end of the 7-day period; or

(d) if the chief health officer refers the application to the medicines advisory committee or an application is made to the committee under section 565—when the doctor is given notice of the chief health officer's decision under section 573 (Medicines advisory committee—recommendations to CHO).

Division 13.1.3 Chief health officer controlled medicines approvals

560 Applications for CHO controlled medicines approvals

(1) A designated prescriber may apply to the chief health officer for approval to prescribe a controlled medicine.

(2) An application under subsection (1) must—

(a) be for approval to prescribe a controlled medicine for a single individual; and

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(b) be made in a way determined by the chief health officer.

Examples

telephone, email and fax

Note 1 If a form is approved under the Act, s 198 for this provision, the form must be used.

Note 2 An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(3) An application under subsection (1) may be made—

(a) on the applicant's own behalf; or

(b) on the applicant's own behalf and on behalf of 1 or more other named designated prescribers; or

(c) on behalf of a group of designated prescribers that includes the applicant and who practise at the same premises.

Example

the doctors practising at a suburban medical practice so that if a person's usual doctor is unavailable another doctor at the practice can, under the approval, prescribe the controlled medicine

(4) A determination under subsection (2) (b) is a notifiable instrument.

Note A notifiable instrument must be notified under the Legislation Act.

561 Requirements for CHO controlled medicines approval applications

(1) An application by a designated prescriber for an approval to prescribe a controlled medicine for a patient must include the following:

(a) the designated prescriber's name and address;

(b) if the application is made on behalf of a group of designated prescribers—the names of the designated prescribers or a description of the group;

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(c) the medicine, and the form, strength and quantity of the medicine, to be prescribed;

Note For morphine or oxycodone for a terminally ill person, see s (2).

(d) the daily dose of the medicine and, if more than 1 form or strength of the medicine is to be prescribed, the dose for each form or strength;

(e) the patient's name and home address;

(f) the condition from which the patient is suffering that, in the designated prescriber's opinion, requires treatment with the medicine;

(g) whether, in the designated prescriber's opinion, based on reasonable grounds, the patient is a drug-dependent person in relation to a controlled medicine or prohibited substance.

(2) However, for subsection (1) (c), if the controlled medicine is morphine or oxycodone for a person with a terminal illness, the application may be made for all forms, strengths and quantities of the medicine.

(3) To remove any doubt, the application may include any other information the designated prescriber considers relevant.

(4) The chief health officer may ask the designated prescriber for any other information reasonably required to decide the application, including, for example, further information about the patient's treatment.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

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562 CHO decision on applications to prescribe controlled medicines

(1) On application under section 560, the chief health officer must—

(a) approve the application in the terms applied for; or

(b) approve the application in terms different from those applied for; or

(c) refuse to approve the application; or

(d) refer the application to the medicines advisory committee.

Note 1 An approval may include conditions (see s 570).

Note 2 For the form of a controlled medicines approval by the chief health officer, see s 571.

(2) However, the chief health officer need not decide the application if the chief health officer has asked for information under section 561 (4) and the information has not been given.

(3) The chief health officer must give the applicant written notice of the chief health officer's decision not later than 7 days after the day the decision is made.

(4) If the decision is made under subsection (1) (b) or (c), the notice must include information about the applicant's right to seek review of the decision under section 565 (Applications for review of unfavourable CHO decisions for approvals).

563 Restrictions on CHO power to approve applications for approvals

In making a decision under section 562, the chief health officer—

(a) must comply with any guidelines approved under section 574 (Guidelines for CHO decisions on applications); and

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(b) must not approve an application to prescribe all forms, strengths and quantities of morphine or oxycodone for the treatment of a person who is terminally ill unless satisfied—

(i) a specialist has diagnosed the person as being terminally ill; and

(ii) the medicine is for use by the person for therapeutic purposes only; and

(c) must not approve an application to prescribe buprenorphine or methadone to treat a drug-dependent person's drug-dependency unless the applicant is—

(i) a doctor who is working at a hospital, or an institution mentioned in section 557 (2) (a) (ii) (Standing interim approval to prescribe buprenorphine and methadone for patients of certain institutions); or

(ii) an intern doctor who is working at a hospital, or an institution mentioned in section 557 (2) (a) (ii), and who is acting under the direct supervision of a doctor at the hospital or institution; or

(iii) a doctor who is treating a person held in police custody; or

(iv) a doctor who holds an endorsement under section 582 (CHO decisions on applications for endorsement to treat drug-dependency); or

(v) a doctor who is prescribing continuing opioid dependency treatment for up to 5 drug-dependent people if—

(A) the people have already undergone opioid dependency treatment for at least 14 consecutive days (the ***initial treatment***); and

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(B) the initial treatment was prescribed by a doctor holding an endorsement under section 582.

Note ***Doctor*** does not include an intern doctor (see dict).

564 Term of CHO controlled medicines approvals

A controlled medicines approval under this division is for the period (not longer than 1 year) stated in the approval.

565 Applications for review of unfavourable CHO decisions for approvals

(1) This section applies if, under section 562, the chief health officer—

(a) approves an application for a controlled medicines approval in terms different from those applied for; or

(b) refuses to approve the application for an approval.

(2) The applicant for the approval may, not later than 7 days after the day the person receives written notice of the decision, apply to the medicines advisory committee for review of the decision.

(3) The application for review—

(a) must be in writing signed by the applicant; and

(b) must set out the grounds for the application; and

(c) may include any information that the applicant considers appropriate for the review.

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566 Medicines advisory committee—referred applications and review of unfavourable CHO decisions

(1) This section applies to an application—

(a) for approval to prescribe a controlled medicine referred to the medicines advisory committee under section 562 (1) (d); or

(b) under section 565 for review of a decision of the chief health officer on an application for a controlled medicines approval.

(2) The medicines advisory committee may, in writing, ask the applicant to give the committee further information about the treatment of the person to whom the application relates not later than a stated reasonable time.

(3) After considering the application and any further information provided in accordance with a notice under subsection (2), the medicines advisory committee must—

(a) for an application for review of a decision by the chief health officer—

(i) recommend that the chief health officer confirm the decision made; or

(ii) do both of the following:

(A) recommend that the chief health officer revoke the decision made;

(B) make a recommendation under paragraph (b) (i), (ii) or (iii); or

(b) recommend that the chief health officer—

(i) approve the application to prescribe a controlled medicine in the terms applied for; or

(ii) approve the application in terms different from those applied for; or

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(iii) refuse to approve the application.

Note 1 The medicines advisory committee may recommend that the chief health officer include conditions in the approval (see s 570 (2)).

Note 2 The chief health officer must consider the committee's recommendation (see s 573).

(4) A recommendation must be in writing.

567 Amendment and revocation of controlled medicines approvals

(1) The chief health officer may amend or revoke a controlled medicines approval on the chief health officer's own initiative and without consulting the medicines advisory committee.

(2) The medicines advisory committee may recommend that the chief health officer amend or revoke a controlled medicines approval, whether or not the approval was given on the recommendation of the committee.

Note The chief health officer must consider the committee's recommendation (see s 573).

(3) A recommendation must be in writing.

(4) The chief health officer must send the approval-holder written notice of the chief health officer's decision not later than 7 days after the day the decision is made.

(5) If the decision is to amend or revoke a controlled medicines approval under subsection (1), the notice must include information about the approval-holder's right to seek review of the decision under section 568.

(6) In this section:

amend, a controlled medicines approval, includes imposing a condition on, or changing a condition of, the approval.

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568 Application for review of amendment and revocation on CHO initiative

(1) This section applies if the chief health officer amends or revokes a controlled medicines approval under section 567 (1).

(2) The person to whom the approval was given may, not later than 7 days after the day the person is given written notice of the amendment or revocation, apply to the medicines advisory committee for review of the decision.

(3) The application for review—

(a) must be in writing signed by the applicant; and

(b) must set out the grounds for the application; and

(c) may include any information that the applicant considers appropriate for the review.

(4) To remove any doubt, the decision to which the application relates continues to operate despite the making of the application until the day the chief health officer's decision following a recommendation under section 569 (3) takes effect.

569 Medicines advisory committee—review of amendment or revocation on CHO initiative

(1) This section applies if an application is made to the medicines advisory committee under section 568 to review a decision (the ***original decision***) of the chief health officer to amend or revoke a controlled medicines approval.

(2) The medicines advisory committee may, in writing, ask the designated prescriber to give the committee further information about the treatment of the person to whom the application relates not later than a stated reasonable time.

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(3) After considering the application for review and any further information provided in accordance with a notice under subsection (2), the medicines advisory committee must recommend that the chief health officer—

(a) confirm the original decision; or

(b) revoke the original decision; or

(c) revoke the original decision and approve the application as recommended by the committee.

Note 1 The medicines advisory committee may recommend that the chief health officer include conditions in the approval (see s 570 (2)).

Note 2 The chief health officer must consider the committee's recommendation (see s 573).

(4) A recommendation must be in writing.

570 Conditional controlled medicines approvals

(1) The chief health officer may include conditions for the safe or proper use of a controlled medicine in a controlled medicines approval.

(2) The medicines advisory committee may recommend that the chief health officer include conditions for the safe or proper use of a controlled medicine in a controlled medicines approval.

Note The chief health officer must consider the committee's recommendation (see s 573).

571 Form of CHO controlled medicines approvals

(1) A controlled medicines approval given by the chief health officer must include the following:

(a) the name of the controlled medicine to which the approval relates;

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(b) the maximum quantity of the medicine that may be prescribed under the approval;

Note 1 For morphine or oxycodone for a person with a terminal illness, see s (2).

Note 2 For buprenorphine or methadone for a drug-dependent person, see s (3).

(c) the form and strength of the medicine that may be prescribed under the approval;

Note Other forms and strengths may be prescribed in accordance with s 32.

(d) the period when the medicine may be prescribed under the approval or when the approval ends;

(e) an identifying number for the approval;

(f) any condition to which the approval is subject.

Note If the approval is an oral approval, the prescriber must send the chief health officer a written application (see s 31 (1) (d) (ii)).

(2) However, for subsection (1) (b) and (c), if the controlled medicines approval relates to the treatment of a person with a terminal illness, the approval may provide that all forms, strengths and quantities of morphine or oxycodone are approved.

(3) Also, for subsection (1) (b), if the controlled medicines approval relates to the treatment of a drug-dependent person with buprenorphine or methadone for their drug-dependency, the approval may state the maximum daily dose that may be prescribed for the person.

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572 When controlled medicines approvals etc take effect

(1) A controlled medicines approval takes effect when the applicant receives notice of the approval or, if the approval states a later day, on the later day.

(2) An amendment or revocation of a controlled medicines approval takes effect when the approval-holder receives notice of the amendment or revocation or, if the notice of the amendment or revocation states a later day, on the later day.

573 Medicines advisory committee—recommendations to CHO

(1) This section applies if the medicines advisory committee recommends that the chief health officer make a decision in relation to—

(a) an application for a controlled medicines approval; or

(b) a controlled medicines approval; or

(c) an application under section 581 (Applications for CHO endorsement to treat drug-dependency).

(2) The chief health officer must—

(a) make the decision after considering the medicines advisory committee's recommendation; and

(b) send the applicant or approval holder written notice of the decision not later than 7 days after the day the chief health officer makes the decision.

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574 Guidelines for CHO decisions on applications

(1) The medicines advisory committee may give draft guidelines to the chief health officer in relation to decisions on applications under section 560 (Applications for CHO controlled medicines approvals).

(2) The chief health officer may approve a draft guideline.

(3) An approved guideline is a notifiable instrument.

Note A notifiable instrument must be notified under the Legislation Act.

Division 13.1.4 Endorsements to treat drug-dependency

580 Meaning of *endorsement*—div 13.1.4

In this division:

endorsement means an endorsement under section 582 to prescribe buprenorphine and methadone to treat a drug-dependent person's drug-dependency.

Note An endorsement is not required by doctors and certain intern doctors who are working at particular institutions, see s 563 (c).

581 Applications for CHO endorsement to treat drug-dependency

(1) A doctor may, in writing, apply to the chief health officer for an endorsement.

Note ***Doctor*** does not include an intern doctor (see dict).

(2) The application must include the following:

(a) the doctor's name and business address and telephone number;

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(b) the doctor's qualifications and experience in treating drug-dependency.

Note If a form is approved under the Act, s 198 for this provision, the form must be used.

(3) The chief health officer may ask the doctor for any other information reasonably required to decide the application.

582 CHO decisions on applications for endorsement to treat drug-dependency

(1) The chief health officer must give, or refuse to give, an endorsement to a doctor who applies under section 581.

(2) The chief health officer must not give a doctor an endorsement unless satisfied that the doctor has the qualifications and experience to treat drug-dependency.

(3) An endorsement is subject to any condition included in the endorsement by the chief health officer.

(4) The chief health officer must give the doctor written notice of the chief health officer's decision not later than 7 days after the day the decision is made.

(5) If the chief health officer refuses the application, the notice must include information about the doctor's right to seek review of the decision under section 584.

583 Form of CHO endorsements to treat drug-dependency

An endorsement by the chief health officer must include the following:

(a) the doctor's name;

(b) an identifying number for the endorsement;

(c) any condition to which the endorsement is subject.

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584 Medicines advisory committee—review of CHO decisions to refuse endorsements to treat drug-dependency

(1) This section applies if the chief health officer refuses under section 582 to give an endorsement to a doctor.

(2) The doctor may, not later than 28 days after the day the doctor receives written notice of the decision, apply to the medicines advisory committee for review of the decision.

(3) The application for review—

(a) must be in writing signed by the doctor; and

(b) must set out the grounds for the application; and

(c) may include any information that the doctor considers appropriate for the review.

(4) The medicines advisory committee may, in writing, ask the doctor to give the committee further information that the committee reasonably needs to decide the application.

(5) After considering the application and any further information provided in accordance with a notice under subsection (4), the medicines advisory committee must—

(a) recommend that the chief health officer confirm the decision made; or

(b) recommend that the chief health officer revoke the decision made and approve the application as recommended by the committee.

Note The chief health officer must consider the committee's recommendation (see s 573).

(6) A recommendation must be in writing.

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Part 13.2 Appendix D medicines approvals

Note It is a condition of an authorisation to prescribe a designated appendix D medicine for the prescriber to have an approval under this part (see s 33 (a)).

590 Meaning of *appendix D medicines approval*

In this regulation:

appendix D medicines approval means an approval under section 591 or section 593.

591 Standing approval to prescribe designated appendix D medicines

A doctor is approved to prescribe a designated appendix D medicine for a purpose mentioned in schedule 3 (Designated appendix D medicines—standing approvals), part 3.2, column 3 in relation to the medicine if—

(a) the medicine is mentioned in the schedule, part 3.2, column 3 in relation to the doctor; and

(b) if the schedule, part 3.2, column 4 contains a condition in relation to the medicine—the doctor prescribes the medicine in accordance with the condition.

Example—par (b)

If sch 3, pt 3.2, col 4 includes a condition requiring a doctor to advise a woman of child-bearing age to avoid becoming pregnant during or for a certain period after the completion of treatment, the doctor is authorised to prescribe the medicine only if the doctor gives the patient the advice.

Note 1 ***Doctor*** does not include an intern doctor (see dict).

Note 2 An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

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592 Applications for CHO approval to prescribe designated appendix D medicines

(1) A doctor may, in writing, apply to the chief health officer for approval to prescribe a designated appendix D medicine for a purpose mentioned in schedule 3 (Designated appendix D medicines—standing approvals), part 3.2, column 3 in relation to the medicine.

Note ***Doctor*** does not include an intern doctor (see dict).

(2) The application must include the following:

(a) the medicine's name;

(b) the doctor's name, business address and telephone number;

(c) if the doctor is a specialist—the specialist area in which the doctor practises;

(d) if the doctor is not a specialist—the doctor's qualifications and experience in relation to the medicine.

Note If a form is approved under the Act, s 198 for this provision, the form must be used.

(3) The chief health officer may ask the doctor for any other information reasonably required to decide the application.

593 CHO decisions on applications to prescribe designated appendix D medicines

(1) The chief health officer must approve, or refuse to approve, an application by a doctor under section 592 for approval to prescribe a designated appendix D medicine.

(2) An approval under subsection (1) to prescribe a designated appendix D medicine is subject to the following conditions:

(a) that the doctor complies with any conditions in schedule 3, part 3.2, column 4 in relation to the medicine;

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(b) any other condition included in the approval by the chief health officer.

Example—par (a)

If sch 3, pt 3.2, col 4 includes a condition requiring a doctor to advise a woman of child-bearing age to avoid becoming pregnant during or for a certain period after the completion of treatment, the doctor is authorised to prescribe the medicine only if the doctor gives the patient the advice.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(3) For this section, the chief health officer—

(a) must have regard to the specialist area (if any) in which the doctor practises and the requirements (if any) stated in the medicines and poisons standard, appendix D for the medicine to which the application relates; and

(b) may have regard to anything else the chief health officer considers appropriate.

(4) The chief health officer must send the doctor written notice of the chief health officer's decision not later than 7 days after the day the decision is made.

594 Form of CHO appendix D medicines approvals

An appendix D medicines approval given by the chief health officer must include the following:

(a) the doctor's name;

(b) the name of the medicine to which the approval relates;

(c) an identifying number for the approval;

(d) any condition included in the approval by the chief health officer.

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Chapter 14 Medicines licences

Part 14.1 Medicines licences generally

600 Medicines licences that may be issued—Act, s 78 (2)

The following licences for medicines may be issued:

(a) a licence for a program of research or education in relation to a controlled medicine (a ***controlled medicines research and education program licence***);

(b) a licence for medicines for first-aid kits (a ***first-aid kit licence***);

(c) a licence for the supply by wholesale of a medicine (a ***medicines wholesalers licence***);

(d) a licence for the treatment of opioid dependency with buprenorphine or methadone (an ***opioid dependency treatment licence***);

(e) a licence for the sale by retail of pharmacy medicines by a person who is not a pharmacist (a ***pharmacy medicines rural communities licence***).

Note Other medicines licences may also be issued (see Act, s 78 (3)).

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Part 14.2 Controlled medicines research and education program licences

Note For research and education activities in relation to other medicines, see pt 9.4.

605 Applications for controlled medicines research and education program licences

(1) An application for a controlled medicines research and education program licence for a controlled medicine must be in writing, signed by the applicant, and include the following:

(a) the full name, address and academic, professional or other relevant qualifications of—

(i) the person who is to supervise the program; and

(ii) the person who is to conduct the program;

(b) the name of the recognised research institution at or under which the program is proposed to be conducted;

Note ***Recognised research institution***—see the Act, s 20 (5).

(c) whether the program will be conducted at, or under the authority of, the recognised research institution;

(d) the premises where the program will be conducted;

(e) the controlled medicine, and the form and strength of the medicine, for which the licence is sought;

(f) the maximum quantity of the medicine that would be possessed under the licence at any time;

(g) a description of the program, including an explanation of why the program cannot be carried out satisfactorily without the use of the medicine;

(h) the supervision arrangements for the program;

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(i) the period for which the licence is sought.

Note 1 If a form is approved under the Act, s 198 for this provision, the form must be used.

Note 2 A fee may be determined under the Act, s 197 for this provision.

(2) The application must be accompanied by a written approval of the program by the person in charge of—

(a) the recognised research institution; or

(b) a faculty or division of the institution.

606 Restrictions on issuing of controlled medicines research and education program licences—Act, s 85 (1) (a)

The chief health officer must not issue a controlled medicines research and education program licence to a person unless—

(a) the program to which the licence relates will be conducted at, or under the authority of, a recognised research institution; and

(b) the program is approved by a person mentioned in section 605 (2); and

(c) satisfied that the program—

(i) cannot be carried out without the use of the controlled medicine to which the licence application relates; and

(ii) will be adequately supervised.

607 Additional information for controlled medicines research and education program licences—Act, s 88 (1) (k)

The following additional information is prescribed for a controlled medicines research and education program licence:

(a) the research or education program for which the licence is issued;

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(b) the name of the program's supervisor;

(c) the dealings with a controlled medicine authorised by the licence;

(d) the premises where the program will be conducted;

(e) the maximum quantity of the controlled medicine that may be possessed at any time for the program;

(f) the total quantity of the controlled medicine that may be possessed for the program during the period of the licence;

(g) the form and strength of the controlled medicine that may be obtained and possessed for the program.

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Part 14.3 First-aid kit licences

Note This part is not applicable to a health practitioner who is authorised elsewhere under this regulation to possess etc medicines for a first-aid kit.

610 Applications for first-aid kit licences

(1) An application for a first-aid kit licence must be in writing, signed by the applicant, and include the following:

(a) the full name, address and occupation of the applicant;

(b) the full name, address and occupation of each other person proposed to be authorised to deal with a medicine under the licence;

(c) the prescription only medicines and controlled medicines (each of which are ***relevant medicines***), and the form and strength of the relevant medicines, for which the licence is sought;

Note Pharmacy medicines and pharmacist only medicines are authorised for the kit under s 450.

(d) the maximum quantity of the relevant medicines that would be possessed under the licence at any time;

(e) the first-aid services provided, or proposed to be provided, to the community by the applicant;

(f) the situations in which it is proposed the medicines in the first-aid kit will be used;

(g) the period for which the licence is sought.

Note 1 If a form is approved under the Act, s 198 for this provision, the form must be used.

Note 2 A fee may be determined under the Act, s 197 for this provision.

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(2) The application must be accompanied by—

(a) evidence of the qualifications mentioned in section 611 (a) for the applicant and each person included in the application under subsection (1) (b); and

(b) a letter of support from a doctor who will provide medical direction and support to the applicant.

Note ***Doctor*** does not include an intern doctor (see dict).

611 Restrictions on issuing of first-aid kit licences—Act, s 85 (1) (a)

The chief health officer must not issue a first-aid kit licence to a person unless—

(a) each person to be authorised under the licence has successfully completed a course that qualifies the person to be registered as a nurse or employed as an ambulance paramedic; and

(b) the chief health officer is satisfied that the person provides, or will be providing, first-aid services to the community, for example, at a workplace or as part of a privately operated ambulance service approved under the *Emergencies Act 2004*, part 4.6 (Other approved providers); and

(c) the medicines to which the licence application relates are reasonably necessary to provide the first-aid services.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

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612 Additional information for first-aid kit licences—Act, s 88 (1) (k)

(1) The following additional information is prescribed for a first-aid kit licence:

(a) the full name and home address of each person who is authorised to deal with a medicine under the licence;

(b) the maximum quantity of each relevant medicine that may be possessed under the licence at any time;

(c) the total quantity of each relevant medicine that may be possessed during the period of the licence;

(d) the form and strength in which each relevant medicine may be obtained, possessed and administered under the licence.

(2) In this section:

relevant medicines—see section 610.

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Part 14.4 Medicines wholesalers licences

Note This part is applicable to an interstate wholesaler only if the Act, s 20 (4) does not apply to the wholesaler.

615 Applications for medicines wholesalers licences

(1) An application for a medicines wholesalers licence must be in writing, signed by the applicant, and include the following:

(a) the medicines to which the application relates;

(b) the full name of the applicant;

(c) the applicant's ABN (if any);

(d) if the applicant is a corporation—the corporation's ACN;

(e) the location of the premises where the applicant proposes to deal with the medicines under the licence;

(f) the security arrangements proposed for the premises;

(g) the name of an individual who is to supervise the dealings to be authorised under the licence.

Note 1 If a form is approved under the Act, s 198 for this provision, the form must be used.

Note 2 A fee may be determined under the Act, s 197 for this provision.

(2) The application must be accompanied by a plan of the premises that shows—

(a) where it is proposed to store the medicines; and

(b) the location and nature of security devices.

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616 Restrictions on issuing of medicines wholesalers licences—Act, s 85 (1) (a)

(1) The chief health officer must not issue a medicines wholesalers licence to a person unless dealings with medicines under the licence will be supervised by an individual nominated by the applicant and approved, in writing, by the chief health officer.

(2) The chief health officer must not approve the nominated individual unless satisfied that the individual—

(a) is a suitable person to hold a medicines wholesalers licence; and

(b) has qualifications in chemistry, pharmacy or pharmacology or experience appropriate for the sale of medicines.

Note For changes of nominated individuals, see the Act, s 93.

(3) In this section:

suitable person, to hold a licence—see the Act, section 81.

617 Additional information for medicines wholesalers licences—Act, s 88 (1) (k)

The name of the person approved under section 616 (1) to supervise the dealings with medicines authorised by the licence is prescribed for a medicines wholesalers licence.

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Part 14.5 Opioid dependency treatment licences

620 Applications for opioid dependency treatment licences

An application for an opioid dependency treatment licence must be in writing, signed by the applicant, and include the applicant's full name and business address.

Note 1 If a form is approved under the Act, s 198 for this provision, the form must be used.

Note 2 A fee may be determined under the Act, s 197 for this provision.

621 Restriction on issuing of opioid dependency treatment licences—Act, s 85 (1) (a)

The chief health officer must not issue an opioid dependency treatment licence to a person unless the person is a pharmacist at a community pharmacy.

Note ***Pharmacist*** does not include an intern pharmacist (see dict).

622 Witnessing not required for administration under opioid dependency treatment licence—Act, s 190 (1) (a)

The Act, section 53 (e) (Registers—witnessing administration of medicines) does not apply to the administration of buprenorphine or methadone under an opioid dependency treatment licence if section 471 is complied with in relation to the administration.

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Part 14.6 Pharmacy medicines rural communities licences

625 Applications for pharmacy medicines rural communities licences

An application for a pharmacy medicines rural communities licence must—

(a) be in writing signed by the applicant; and

(b) include—

(i) the applicant's full name, business address and telephone number; and

(ii) the pharmacy medicines proposed to be sold under the licence.

Note 1 If a form is approved under the Act, s 198 for this provision, the form must be used.

Note 2 A fee may be determined under the Act, s 197 for this provision.

626 Restrictions on issuing of pharmacy medicines rural communities licences—Act, s 85 (1) (a)

The chief health officer must not issue a pharmacy medicines rural communities licence to a person unless—

(a) the person is carrying on the business of selling goods by retail; and

(b) the premises from which the medicines will be sold under the licence is more than 25km by the shortest practical route to the nearest community pharmacy.

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Chapter 15 Medicines—other provisions

Part 15.1 Opioid dependency treatment guidelines

630 Guidelines for treatment of opioid dependency

(1) The Minister may approve guidelines for the treatment of opioid dependency.

(2) Without limiting subsection (1), approved guidelines may make provision in relation to the prescribing and administration of buprenorphine and methadone to drug-dependent people.

(3) An approval is a notifiable instrument.

Note A notifiable instrument must be notified under the Legislation Act.

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Part 15.2 Medicines advisory committee

Note The medicines advisory committee is established under the Act, s 194.

635 Medicines advisory committee—membership

(1) The medicines advisory committee consists of the following members appointed by the Minister:

(a) a chair;

(b) 6 other members.

Note 1 For the making of appointments (including acting appointments), see the Legislation Act, pt 19.3.

Note 2 Certain Ministerial appointments require consultation with an Assembly committee and are disallowable (see Legislation Act, div 19.3.3).

(2) A person (other than a person mentioned in subsection (3) (d) or (e)) is not eligible for appointment to the medicines advisory committee unless the person is a doctor.

Note ***Doctor*** does not include an intern doctor (see dict).

(3) The medicines advisory committee must include—

(a) at least 1 member who has had experience in the teaching or practice of psychiatry; and

(b) at least 1 member who has had experience in the teaching or practice of pain or addiction medicine; and

(c) at least 1 member who is a general practitioner; and

(d) 1 member who is a pharmacist; and

Note ***Pharmacist*** does not include an intern pharmacist (see dict).

(e) 1 member who represents consumers; and

(f) 1 member nominated by the Australian Capital Territory Branch of the Australian Medical Association.

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(4) However, for subsection (3) only, if the appointment of a member (a ***former member***) is ended before the last day of the period for which the former member was appointed, the medicines advisory committee is taken to still include the former member until the earlier of—

(a) 4 months from the day the former member's appointment ended; or

(b) a member is appointed to replace the former member.

(5) The instrument appointing, or evidencing the appointment of, a medicines advisory committee member must state whether the person is appointed as the chair, or as another member, of the committee.

636 Medicines advisory committee—term of appointments

The appointment of a medicines advisory committee member must be for not longer than 3 years.

Note A person may be reappointed to a position if the person is eligible to be appointed to the position (see Legislation Act, s 208 and dict, pt 1, def ***appoint***).

637 Medicines advisory committee—conditions of appointments

The conditions of appointment of a medicines advisory committee member are the conditions agreed between the Minister and the member, subject to any determination under the *Remuneration Tribunal Act 1995*.

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638 Medicines advisory committee—time and place of meetings

(1) Meetings of the medicines advisory committee are to be held when and where the committee decides.

(2) The chair of the medicines advisory committee may at any time call a meeting.

(3) The chair must give the other members reasonable notice of the time and place of a meeting called by the chair.

(4) The medicines advisory committee may adjourn a proceeding, for any reason it considers appropriate, to a time and place decided by the committee.

639 Medicines advisory committee—presiding member

(1) The chair presides at a meeting of the medicines advisory committee.

(2) If the chair is absent, the member chosen by the members present presides.

640 Medicines advisory committee—quorum

Business may be carried out at a meeting of the medicines advisory committee only if at least 4 members are present.

641 Medicines advisory committee—voting

(1) At a meeting of the medicines advisory committee each member has a vote on each question to be decided.

(2) A question is decided by a majority of the votes of members present and voting but, if the votes are equal, the presiding member has the deciding vote.

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642 Medicines advisory committee—conduct of meetings

(1) The medicines advisory committee may conduct its meetings as the committee considers appropriate.

(2) A meeting of the medicines advisory committee may be held using a method of communication, or a combination of methods of communication, that allows each member taking part to hear what each other member taking part says without the members being in each other's presence.

Examples

a phone link, a satellite link, an internet or intranet link

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(3) A medicines advisory committee member who takes part in a meeting conducted under subsection (2) is taken to be present at the meeting.

(4) A resolution is a valid resolution of the medicines advisory committee, even if it is not passed at a meeting of the committee, if all members agree to the proposed resolution in writing.

Note ***Written*** includes in electronic form (see Act, dict).

(5) The medicines advisory committee must keep minutes of its meetings.

643 Medicines advisory committee—disclosure of interests by members

(1) If a medicines advisory committee member has a material interest in an issue being considered, or about to be considered, by the committee, the member must disclose the nature of the interest at a committee meeting as soon as possible after the relevant facts have come to the member's knowledge.

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(2) The disclosure must be recorded in the medicines advisory committee's minutes and, unless the committee otherwise decides, the member must not—

(a) be present when the medicines advisory committee considers the issue; or

(b) take part in a decision of the committee on the issue.

Example

David, Emile and Fiona are members of the medicines advisory committee. They have an interest in an issue being considered at a committee meeting and they disclose the interest as soon as they become aware of it. David's and Emile's interests are minor but Fiona has a direct financial interest in the issue.

The medicines advisory committee considers the disclosures and decides that because of the nature of the interests:

- David may be present when the committee considers the issue but not take part in the decision
- Emile may be present for the consideration and take part in the decision.

The medicines advisory committee does not make a decision allowing Fiona to be present or take part in the committee's decision. Accordingly, Fiona cannot be present for the consideration of the issue or take part in the decision.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(3) Any other medicines advisory committee member who also has a material interest in the issue must not be present when the committee is considering its decision under subsection (2).

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(4) In deciding under subsection (2) whether a member may be present when the medicines advisory committee decides the issue or take part in a decision of the committee on the issue, and despite section 640 (Medicines advisory committee—quorum), the committee may consist of the members who do not have a material interest in the issue.

Example

if 6 members are present at the meeting and 2 members disclose a material interest, the other 4 members may decide whether the members who made the disclosure can take part in a decision by the committee

(5) In this section:

associate, of a person, means—

(a) the person's business partner; or

(b) a close friend of the person; or

(c) a family member of the person.

executive officer, of a corporation, means a person (however described) who is concerned with, or takes part in, the corporation's management (whether or not the person is a director of the corporation).

indirect interest—without limiting the kind of indirect interest a person may have, a person has an ***indirect interest*** in an issue if any of the following has an interest in the issue:

(a) an associate of the person;

(b) a corporation with not more than 100 members that the person, or an associate of the person, is a member of;

(c) a subsidiary of a corporation mentioned in paragraph (b);

(d) a corporation that the person, or an associate of the person, is an executive officer of;

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(e) the trustee of a trust that the person, or an associate of the person, is a beneficiary of;

(f) a member of a firm or partnership that the person, or an associate of the person, is a member of;

(g) someone else carrying on a business if the person, or an associate of the person, has a direct or indirect right to participate in the profits of the business.

material interest—a medicines advisory committee member has a ***material interest*** in an issue if the member has—

(a) a direct or indirect financial interest in the issue; or

(b) a direct or indirect interest of any other kind if the interest could conflict with the proper exercise of the member's functions in relation to the committee's consideration of the issue.

644 Medicines advisory committee—ending appointments

(1) The Minister may end the appointment of a medicines advisory committee member—

(a) if the member contravenes a territory law; or

(b) for misbehaviour; or

(c) if the member becomes bankrupt or personally insolvent; or

Note ***Bankrupt or personally insolvent***—see the Legislation Act, dictionary, pt 1.

(d) if the member is convicted, in the ACT, of an offence punishable by imprisonment for at least 1 year; or

(e) if the member is convicted outside the ACT, in Australia or elsewhere, of an offence that, if it had been committed in the ACT, would be punishable by imprisonment for at least 1 year; or

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(f) if the member contravenes section 643 (Medicines advisory committee—disclosure of interests by members).

Note A member's appointment also ends if the member resigns (see Legislation Act, s 210).

(2) The Minister must end the appointment of a medicines advisory committee member—

(a) if the member (other than a member mentioned in section 635 (3) (d) or (e)) ceases to be a doctor; or

(b) for a member mentioned in section 635 (3) (d)—if the member ceases to be a pharmacist; or

(c) if, on 3 consecutive occasions, the member fails, without the chair's agreement, to make himself or herself available for a proposed meeting of the committee; or

(d) if the member fails to take all reasonable steps to avoid being placed in a position where a conflict of interest arises during the exercise of the member's functions; or

(e) for physical or mental incapacity, if the incapacity substantially affects the exercise of the member's functions.

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Part 15.3 Other medicines provisions

650 Advertising controlled medicines—Act, s 66 (3) (b)

A pricelist published by a pharmacist that includes a controlled medicine is prescribed if the pricelist complies with the *Price Information Code of Practice*, published by the Therapeutic Goods Administration, as in force from time to time.

Note The Price Information Code of Practice is accessible at www.tga.gov.au.

651 Advertising other medicines

(1) A person commits an offence if—

(a) the person publishes an advertisement; and

(b) the advertisement promotes or encourages the use of a declared medicine.

Maximum penalty: 30 penalty units.

(2) A person commits an offence if—

(a) the person publishes an advertisement; and

(b) the advertisement indicates that someone is willing or authorised to supply a declared medicine.

Maximum penalty: 30 penalty units.

(3) This section does not apply to—

(a) an advertisement for a declared medicine in a publication published primarily for dentists, doctors, pharmacists or veterinary surgeons; or

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(b) a pricelist published by a pharmacist that includes a declared medicine if the pricelist complies with the *Price Information Code of Practice*, published by the Therapeutic Goods Administration, as in force from time to time.

(4) In this section:

advertisement—see the Act, section 66.

declared medicine means—

(a) a pharmacist only medicine other than a pharmacist only medicine to which the medicines and poisons standard, appendix H applies; or

(b) a prescription only medicine.

652 Prescribed institutions—Act, dict, def *institution*, par (b)

The following are prescribed:

(a) a correctional centre;

(b) a CYP detention place.

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Chapter 16 Low and moderate harm poisons

Part 16.1 Preliminary

660 Meaning of *relevant law*—ch 16

In this chapter:

relevant law means—

(a) a corresponding law; or

(b) the *Agricultural and Veterinary Chemicals Act 1994* (Cwlth); or

(c) the *Therapeutic Goods Act 1989* (Cwlth).

Note 1 ***Corresponding law*** includes a law of a State that corresponds, or substantially corresponds, to the Act (see Act, dict).

Note 2 ***State*** includes a territory (see Legislation Act, dict, pt 1).

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Part 16.2 Authorisation to supply low and moderate harm poisons

661 Authorisation to supply low and moderate harm poisons—Act, s 26 (1) (b) and (2) (b)

Anyone is authorised to supply a low harm poison or moderate harm poison.

662 Authorisation condition for supplying low and moderate harm poisons—Act, s 44 (1) (b) and (2) (b)

A person's authorisation under section 661 to supply a low harm poison or moderate harm poison is subject to the following conditions:

(a) the poison is supplied in manufacturer's packs that comply with—

(i) section 665 (Packaging of supplied manufacturer's packs of low and moderate harm poisons—Act, s 59 (1) (c) (i) and (2) (c) (i)); or

(ii) an approval under the Act, section 193 (Approval of non-standard packaging and labelling);

(b) the manufacturer's packs are labelled in accordance with—

(i) section 666 (Labelling of supplied manufacturer's packs of low and moderate harm poisons—Act, s 60 (1) (c) (i) and (2) (c) (i)); or

(ii) an approval under the Act, section 193.

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Part 16.3 Authorisation to manufacture low and moderate harm poisons

663 Authorisation to manufacture low and moderate harm poisons—Act, s 33 (b)

A person is authorised to manufacture a low harm poison or moderate harm poison if the person is authorised to manufacture the poison under a relevant law.

664 Authorisation condition for manufacturing low and moderate harm poisons—Act, s 44 (1) (b) and (2) (b)

A person's authorisation under section 663 to manufacture a low harm poison or moderate harm poison is subject to the condition that, if a condition or restriction applies to the person under the relevant law, the person manufactures the poison in accordance with the condition and restriction.

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Part 16.4 Packaging and labelling of low and moderate harm poisons

665 Packaging of supplied manufacturer's packs of low and moderate harm poisons—Act, s 59 (1) (c) (i) and (2) (c) (i)

(1) A manufacturer's pack of a supplied low harm poison or moderate harm poison must be packaged—

(a) in accordance with the medicines and poisons standard, sections 2.1 (2) to 2.6 (2); or

(b) in a container in which the poison may be sold under a relevant law.

Note A manufacturer's pack of a low or moderate harm poison supplied may also be packaged in accordance with an approval under the Act, s 193 (Approval of non-standard packaging and labelling) (see Act, s 59 (1) (c) (ii) and (2) (c) (ii)).

(2) However, if the poison is camphor or naphthalene for domestic use, it must also be packaged in a way that, in normal use, prevents—

(a) removal of the camphor or naphthalene from the packaging; or

(b) ingestion of the camphor or naphthalene.

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666 Labelling of supplied manufacturer's packs of low and moderate harm poisons—Act, s 60 (1) (c) (i) and (2) (c) (i)

A manufacturer's pack of a supplied low harm poison or moderate harm poison must be labelled in accordance with—

(a) the medicines and poisons standard, sections 1.1 (2) to 1.6 (2); or

(b) a relevant law.

Note A manufacturer's pack of a low or moderate harm poison supplied may also be labelled in accordance with an approval under the Act, s 193 (Approval of non-standard packaging and labelling) (see Act, s 60 (1) (c) (ii) and (2) (c) (ii)).

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Chapter 17 Dangerous poisons authorisations

Part 17.1 Overview of dangerous poisons authorisations

670 General overview of authorisations for dangerous poisons

(1) The Act requires that a person must not deal with a dangerous poison in a particular way unless the person is authorised to deal with the poison.

Example

the Act, s 35 about obtaining certain substances (which include dangerous poisons)

Note 1 The Act, s 19 sets out when a person ***deals*** with a dangerous poison.

Note 2 An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(2) The Act, section 20 sets out when a person is authorised to deal with a dangerous poison.

(3) This regulation authorises certain dealings with dangerous poisons.

Note An authorisation is not required to deal with the following:

- a substance excluded from the medicines and poisons standard by the standard, par 1 (2) (see s 6);
- a substance mentioned in the medicines and poisons standard, sch 7 if the schedule does not apply to the substance because of an exception in the standard.

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(4) An authorisation under this regulation may be subject to limitations.

Example

a purchase order issued by a person mentioned in sch 4, col 2 must comply with s 721 (see s 690 (2) (c))

Note For the power to impose other restrictions, see the Act, ch 8.

671 Overview of dangerous poisons authorisations under this regulation

Dangerous poisons authorisations under this regulation are given by the following provisions:

(a) section 675 (which is about authorisations under dangerous poisons manufacturers licences);

(b) section 680 (which is about authorisations under dangerous poisons research and education program licences);

(c) section 685 (which is about authorisations under dangerous poisons suppliers licences);

(d) section 690 (which is about authorisations for manufacturing and other purposes);

(e) section 692 (which is about authorisation to deliver dangerous poisons under purchase orders);

(f) section 693 (which is about authorisation for commercial disposal operators for disposal of dangerous poisons);

(g) section 695 (which is about authorisations for dangerous poisons research and education programs by scientifically qualified people).

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672 General overview of authorisation conditions for dangerous poisons

(1) The Act, section 44 requires a person who is authorised to deal with a dangerous poison to comply with any condition to which the authorisation is subject.

Example

Section 676 sets out the authorisation conditions for an authorised person to manufacture a dangerous poison.

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(2) The conditions are additional to other restrictions on an authorised person's authority to deal with a dangerous poison.

Note Conditions may also be imposed under other provisions of the Act including, for example, s 89 which sets out conditions on licences.

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Part 17.2 Authorisations under dangerous poisons licences

Division 17.2.1 Dangerous poisons manufacturers licence authorisations

Note For other provisions about dangerous poisons manufacturers licences, see pt 18.2.

675 Authorisations under dangerous poisons manufacturers licences—Act, s 20 (1) (a)

(1) A dangerous poisons manufacturers licence authorises the holder to do any of the following in relation to a dangerous poison (the ***licensed dangerous poison***) stated in the licence at the premises (the ***licensed premises***) stated in the licence:

(a) manufacture the licensed dangerous poison;

(b) possess the licensed dangerous poison for sale by wholesale from the licensed premises;

(c) sell the licensed dangerous poison by wholesale (whether or not for resale) to—

(i) a person authorised to issue a purchase order for the dangerous poison; or

(ii) someone in another State who may obtain the dangerous poison by wholesale under the law of the other State; or

(iii) someone in another country who may lawfully obtain the dangerous poison by wholesale in the other country;

Note The dangerous poison must be sold on a purchase order in accordance with s 720 (see s 676).

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(d) obtain a dangerous poison, other than a licensed dangerous poison, for manufacturing a licensed dangerous poison at the licensed premises;

(e) possess a dangerous poison, other than a licensed dangerous poison, at the licensed premises for manufacturing a licensed dangerous poison.

(2) However, an authorisation under subsection (1) does not apply if the licence states that it does not apply.

(3) Also, subsection (1) (c) (iii) does not apply in relation to a licensed dangerous poison that is a prohibited export under the *Customs Act 1901* (Cwlth).

676 Authorisation conditions for dangerous poisons manufacturers licences—Act, s 44 (1) (b) and (2) (b)

A licence-holder's authorisation under a dangerous poisons manufacturers licence is subject to the following conditions:

(a) the dealings with a dangerous poison authorised by the licence will be carried out under the supervision of an individual approved under section 706 (1) (Restrictions on issuing of dangerous poisons manufacturers licences—Act, s 85 (1) (a));

(b) a dangerous poison obtained under the licence is purchased on a complying purchase order;

(c) a licensed dangerous poison will be supplied for a non-household (including a non-household garden) purpose only;

(d) a dangerous poison sold under the licence will be sold on a purchase order in accordance with section 720 (Supplying dangerous poisons on purchase orders);

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(e) if the supplier does not receive a document signed by the buyer acknowledging receipt of the dangerous poison within 7 days after the day the dangerous poison is delivered—the supplier must, within 24 hours after the end of the 7-day period, tell the chief health officer, in writing, of the failure to receive the document;

(f) the following are kept at the supplier's business premises or, if the chief health officer approves, in writing, another place, the place approved by the chief health officer, for at least 2 years after the day the poison is supplied:

(i) the filled purchase order;

(ii) the delivery acknowledgement under paragraph (e) or section 720 (d) (ii);

(g) the record for section 722 is kept at the supplier's business premises or, if the chief health officer approves, in writing, another place, the place approved by the chief health officer, for at least 5 years after the day the poison is supplied;

(h) if a dangerous poison sold under the licence is liquid containing paraquat—the poison is coloured blue or green and has an offensive smell.

Note For licence conditions, see the Act, s 89.

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Division 17.2.2 Dangerous poisons—research and education program licence authorisations

Note 1 For authorisation for research and education programs by scientifically qualified people, see div 17.3.3.

Note 2 For other provisions about dangerous poisons research and education program licences, see pt 18.3.

680 Authorisations under dangerous poisons research and education program licences—Act, s 20 (1) (a)

A dangerous poisons research and education program licence authorises—

(a) the licence-holder to—

(i) issue a purchase order for a dangerous poison (the ***licensed dangerous poison***) stated in the licence for the program stated in the licence; and

(ii) obtain a licensed dangerous poison on a purchase order for the program; and

(iii) possess a licensed dangerous poison for the program at the premises to which the licence relates; and

(iv) supply a licensed dangerous poison to anyone taking part in the program for the program; and

(b) the program supervisor, and anyone taking part in the program, to deal with the licensed dangerous poison as authorised by the licence at the premises stated in the licence.

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681 Authorisation condition for dangerous poisons research and education program licences—Act, s 44 (1) (b) and (2) (b)

A licence-holder's authorisation to obtain a dangerous poison under a dangerous poisons research and education program licence is subject to the condition that the poison is purchased on a complying purchase order.

Note For licence conditions, see the Act, s 89.

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Division 17.2.3 Dangerous poisons suppliers licence authorisations

Note For other provisions about dangerous poisons suppliers licences, see pt 18.4.

685 Authorisations under dangerous poisons suppliers licences—Act, s 20 (1) (b)

(1) A dangerous poisons suppliers licence authorises the holder to do any of the following in relation to a dangerous poison (the ***licensed dangerous poison***) stated in the licence at the premises (the ***licensed premises***) stated in the licence:

(a) issue a purchase order for a licensed dangerous poison;

(b) obtain a licensed dangerous poison on a purchase order for sale from the licensed premises;

(c) possess a licensed dangerous poison for sale from the licensed premises;

(d) sell a licensed dangerous poison on a purchase order to—

(i) someone authorised to issue a purchase order for the dangerous poison; or

(ii) someone in another State who may obtain the dangerous poison under the law of the other State; or

(iii) someone in another country who may lawfully obtain the dangerous poison in the other country.

Note The dangerous poison must be sold on a purchase order in accordance with s 720 (see s 686).

(2) However, an authorisation under subsection (1) does not apply if the licence states that it does not apply.

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(3) Also, subsection (1) (d) (iii) does not apply in relation to a licensed dangerous poison that is a prohibited export under the *Customs Act 1901* (Cwlth).

686 Authorisation conditions for dangerous poisons suppliers licences—Act, s 44 (1) (b) and (2) (b)

A licence-holder's authorisation under a dangerous poisons suppliers licence is subject to the following conditions:

(a) the dealings with a dangerous poison authorised by the licence will be carried out under the supervision of an individual approved under section 716 (1) (Restrictions on issuing of dangerous poisons suppliers licences—Act, s 85 (1) (a));

(b) a dangerous poison sold under the licence will be sold on a purchase order in accordance with section 720 (Supplying dangerous poisons on purchase orders);

(c) a dangerous poison sold under the licence will be supplied for a non-household (including a non-household garden) purpose only;

(d) if a dangerous poison sold under the licence is subject to the medicines and poisons standard, appendix J (Conditions for availability and use of Schedule 7 poisons), condition 3—the poison will be supplied only to a person who is allowed to use the poison under the condition;

Note Condition 3 relates to a dangerous poison that is not to be used except by or in accordance with the directions of an accredited government vermin control officer.

(e) if the supplier does not receive a document signed by the buyer acknowledging receipt of the dangerous poison within 7 days after the day the dangerous poison is delivered—the supplier must, within 24 hours after the end of the 7-day period, tell the chief health officer, in writing, of the failure to receive the document;

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(f) the following are kept at the supplier's business premises or, if the chief health officer approves, in writing, another place, the place approved by the chief health officer, for at least 2 years after the day the poison is supplied:

(i) the filled purchase order;

(ii) the delivery acknowledgement under paragraph (e) or section 720 (d) (ii);

(g) the record for section 722 is kept at the supplier's business premises or, if the chief health officer approves, in writing, another place, the place approved by the chief health officer, for at least 5 years after the day the poison is supplied;

(h) if a dangerous poison sold under the licence is liquid containing paraquat—the poison is coloured blue or green and has an offensive smell.

Note For licence conditions, see the Act, s 89.

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Part 17.3 Other dangerous poisons authorisations

Division 17.3.1 Authorisations for manufacturing etc purposes

690 Manufacturing etc authorisations for dangerous poisons—Act, s 20 (2) (a)

(1) In this section:

relevant dealing, with a dangerous poison, means any of the following:

(a) issuing a purchase order for the poison;

(b) obtaining the poison;

(c) possessing the poison;

(d) issuing a purchase order for the poison;

(e) discarding the poison.

(2) A person mentioned in schedule 4 (Dangerous poisons—manufacturing etc authorisations), column 2 is authorised for a relevant dealing with a dangerous poison mentioned in column 3 in relation to the person if—

(a) the poison is for a purpose mentioned in column 4 in relation to the person; and

(b) the dealing is consistent with any condition or restriction for the dealing mentioned in column 3; and

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(c) if the dealing is issuing a purchase order for the poison—the purchase order complies with section 721 (General requirements for dangerous poisons purchase orders—Act, s 38 (2) (c)).

Note A purchase order must be in writing (see Act, dict, def ***purchase order***).

Division 17.3.2 Authorisations for delivery people and commercial disposal operators

692 Authorisations to deliver dangerous poisons under purchase orders—Act, s 26 (1) (b) and (2) (b), s 35 (1) (b), (2) (b) and s 36 (b)

(1) This section applies to an adult (the ***delivery person***) who is—

(a) engaged to transport and deliver a dangerous poison supplied on a purchase order; or

(b) acting for a person mentioned in paragraph (a).

(2) The delivery person is authorised to—

(a) obtain and possess the dangerous poison for the purpose of transporting and delivering the dangerous poison as engaged; and

(b) supply the dangerous poison to the entity named as the recipient in the purchase order or the entity's agent.

Example—delivery person

an employee of a courier service

Note 1 ***Entity*** includes a person (see Legislation Act, dict, pt 1).

Note 2 An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

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693 Authorisation to supply dangerous poisons to commercial disposal operator for disposal—Act, s 26 (1) (b)

A person is authorised to supply a dangerous poison for disposal to another person if the other person—

(a) holds an environmental authorisation for the disposal of the dangerous poison; or

(b) is an adult acting for a person mentioned in paragraph (a).

Note For related authorisations, see pt 9.1.

694 Authorisations for commercial disposal operators—Act, s 26 (1) (b) and (2) (b), s 35 (1) (b) and (2) (b) and s 36 (b)

(1) This section applies to a person who—

(a) holds an environmental authorisation for the disposal of a dangerous poison; or

(b) is an adult acting for a person mentioned in paragraph (a).

(2) The person is authorised to obtain and possess the dangerous poison for disposing of the poison as engaged.

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Division 17.3.3 Authorisations for dangerous poisons research and education programs by scientifically qualified people

Note A licence is required for research and education programs in relation to an administration-related dealing for human use (see Act, s 20 (3)).

695 Authorisations for dangerous poisons research and education—Act, s 26 (1) and (2) (b)

(1) A scientifically qualified person employed at a recognised research institution is authorised to do the following for the purposes of an authorised activity at the institution:

(a) issue a purchase order for a dangerous poison;

(b) obtain on a purchase order a dangerous poison;

(c) possess a dangerous poison;

(d) supply a dangerous poison to a person (a ***relevant person***) who is taking part in the authorised activity at the institution.

Note 1 ***Scientifically qualified person***—see the dictionary.

Note 2 ***Recognised research institution***—see the Act, s 20 (5).

(2) A relevant person is authorised to do the following in relation to a dangerous poison for the purposes of an authorised activity:

(a) obtain the poison from the scientifically qualified person for the activity;

(b) possess the poison for the purposes of the activity;

(c) supply the poison to the scientifically qualified person for the activity.

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(3) In this section:

administration-related dealing, in relation to a dangerous poison—see the Act, section 20 (5).

authorised activity, in relation to a dangerous poison at a recognised research institution, means the conduct of any of the following if it does not involve an administration-related dealing of the poison for human use:

(a) medical or scientific research in relation to the poison at the institution;

(b) instruction involving the poison at the institution;

(c) quality control or analysis of the poison at the institution.

696 Authorisation conditions for dangerous poisons research and education—Act, s 44 (1) (b) and (2) (b)

A scientifically qualified person's authorisation under section 695 is subject to the following conditions:

(a) the person has written approval for the conduct of the authorised activity from the person in charge of—

(i) the recognised research institution; or

(ii) a faculty or division of the institution;

(b) a dangerous poison is purchased on a complying purchase order;

(c) the purchase order is for an amount of the poison approved in writing by the person in charge;

(d) the dangerous poison is obtained from someone who is authorised to supply the poison to the person.

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Chapter 18 Dangerous poisons licences

Part 18.1 Dangerous poisons licences generally

700 Dangerous poisons licences that may be issued—Act, s 78 (2)

The following licences for dangerous poisons may be issued:

(a) a licence for the manufacture of a dangerous poison (a ***dangerous poisons manufacturers licence***);

(b) a licence for a program of research or education in relation to a dangerous poison (a ***dangerous poisons research and education program licence***);

(c) a licence for the supply of dangerous poisons (a ***dangerous poisons suppliers licence***).

Note Other dangerous poisons licences may also be issued (see Act, s 78 (3)).

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Part 18.2 Dangerous poisons manufacturers licences

705 Applications for dangerous poisons manufacturers licences

(1) An application for a dangerous poisons manufacturers licence must be in writing, signed by the applicant, and include the following:

(a) the dangerous poisons to which the application relates;

(b) the full name of the applicant;

(c) the applicant's ABN (if any);

(d) if the applicant is a corporation—the corporation's ACN;

(e) the location of the premises where the applicant proposes to deal with the poisons under the licence;

(f) the security arrangements proposed for the premises;

(g) the name of an individual who is to supervise the dealings to be authorised under the licence.

Note 1 If a form is approved under the Act, s 198 for this provision, the form must be used.

Note 2 A fee may be determined under the Act, s 197 for this provision.

(2) The application must be accompanied by a plan of the premises that shows—

(a) each part of the premises where a process in the manufacture of the dangerous poisons is proposed to be carried out and the nature of the process; and

(b) where it is proposed to store the dangerous poisons to which the application relates and any other dangerous poisons obtained for the manufacture of those dangerous poisons; and

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(c) the location and nature of security devices.

706 Restrictions on issuing of dangerous poisons manufacturers licences—Act, s 85 (1) (a)

(1) The chief health officer must not issue a dangerous poisons manufacturers licence to a person unless dealings with dangerous poisons under the licence will be supervised by an individual nominated by the applicant and approved, in writing, by the chief health officer.

(2) The chief health officer must not approve the nominated individual unless satisfied that the individual—

(a) is a suitable person to hold a dangerous poisons manufacturers licence; and

(b) has qualifications in chemistry, pharmacy or pharmacology or experience appropriate for the manufacture of dangerous poisons.

Note For changes of nominated individuals, see the Act, s 93.

(3) In this section:

suitable person, to hold a licence—see the Act, section 81.

707 Additional information for dangerous poisons manufacturers licences—Act, s 88 (1) (k)

The name of the person approved under section 706 (1) to supervise the dealings with dangerous poisons authorised by the licence is prescribed for a dangerous poisons manufacturers licence.

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Part 18.3 Dangerous poisons research and education program licences

710 Applications for dangerous poisons research and education program licences

(1) An application for a dangerous poisons research and education program licence for a dangerous poison must be in writing, signed by the applicant, and include the following:

(a) the full name, address and academic, professional or other relevant qualifications of—

(i) the person who is to supervise the program; and

(ii) the person who is to conduct the program;

(b) the name of the recognised research institution at or under which the program is proposed to be conducted;

Note ***Recognised research institution***—see the Act, s 20 (5).

(c) whether the program will be conducted at, or under the authority of, the recognised research institution;

(d) the premises where the program will be conducted;

(e) the dangerous poison, and the form and strength of the poison, for which the licence is sought;

(f) the maximum quantity of the dangerous poison that would be possessed under the licence at any time;

(g) a description of the program, including an explanation of why the program cannot be carried out satisfactorily without the use of the dangerous poison;

(h) the supervision arrangements for the program;

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(i) the period for which the licence is sought.

Note 1 If a form is approved under the Act, s 198 for this provision, the form must be used.

Note 2 A fee may be determined under the Act, s 197 for this provision.

(2) The application must be accompanied by a written approval of the program by the person in charge of—

(a) the recognised research institution; or

(b) a faculty or division of the institution.

711 Restrictions on issuing of dangerous poisons research and education program licences—Act, s 85 (1) (a)

The chief health officer must not issue a dangerous poisons research and education program licence to a person unless—

(a) the program to which the licence relates will be conducted at, or under the authority of, a recognised research institution; and

(b) the program is approved by a person mentioned in section 710 (2); and

(c) satisfied that the program—

(i) cannot be carried out without the use of the dangerous poison to which the licence application relates; and

(ii) will be adequately supervised.

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712 Additional information for dangerous poisons research and education licences—Act, s 88 (1) (k)

The following additional information is prescribed for a dangerous poisons research and education licence:

(a) the research or education program for which the licence is issued;

(b) the name of the program's supervisor;

(c) the dealings with a dangerous poison authorised by the licence;

(d) the premises where the program will be conducted;

(e) the maximum quantity of the dangerous poison that may be possessed at any time for the program;

(f) the total quantity of the dangerous poison that may be possessed for the program during the period of the licence;

(g) the form and strength of the dangerous poison that may be obtained and possessed for the program.

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Part 18.4 Dangerous poisons suppliers licences

715 Applications for dangerous poisons suppliers licences

(1) An application for a dangerous poisons suppliers licence must be in writing, signed by the applicant, and include the following:

(a) the dangerous poisons to which the application relates;

(b) the full name of the applicant;

(c) the applicant's ABN (if any);

(d) if the applicant is a corporation—the corporation's ACN;

(e) the location of the premises where the applicant proposes to deal with the poisons under the licence;

(f) the security arrangements proposed for the premises;

(g) the name of an individual who is to supervise the dealings to be authorised under the licence.

Note 1 If a form is approved under the Act, s 198 for this provision, the form must be used.

Note 2 A fee may be determined under the Act, s 197 for this provision.

(2) The application must be accompanied by a plan of the premises that shows—

(a) where it is proposed to store the dangerous poisons; and

(b) the location and nature of security devices.

716 Restrictions on issuing of dangerous poisons suppliers licences—Act, s 85 (1) (a)

(1) The chief health officer must not issue a dangerous poisons suppliers licence to a person unless dealings with dangerous poisons

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under the licence will be supervised by an individual nominated by the applicant and approved, in writing, by the chief health officer.

(2) The chief health officer must not approve the nominated individual unless satisfied that the individual—

(a) is a suitable person to hold a dangerous poisons suppliers licence; and

(b) has qualifications in chemistry, pharmacy or pharmacology or experience appropriate for the sale of dangerous poisons.

Note For changes of nominated individuals, see the Act, s 93.

(3) In this section:

suitable person, to hold a licence—see the Act, section 81.

717 Additional information for dangerous poisons suppliers licences—Act, s 88 (1) (k)

The name of the person approved under section 716 (1) to supervise the dealings with dangerous poisons authorised by the licence is prescribed for a dangerous poisons suppliers licence.

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Chapter 19 Dangerous poisons—other provisions

Part 19.1 Dangerous poisons purchase orders

720 Supplying dangerous poisons on purchase orders

The following are the requirements for the supply of a dangerous poison on a purchase order:

(a) the dangerous poison is supplied in manufacturer's packs that comply with—

(i) section 731 (Packaging of supplied manufacturer's packs of dangerous poisons—Act, s 59 (1) (c) (i) and (2) (c) (i)); or

(ii) an approval under the Act, section 193 (Approval of non-standard packaging and labelling);

(b) the manufacturer's packs are labelled in accordance with—

(i) section 732 (Labelling of supplied manufacturer's packs of dangerous poisons—Act, s 60 (1) (c) (i) and (2) (c) (i)); or

(ii) an approval under the Act, section 193;

(c) the manufacturer's packs are securely wrapped and packed;

(d) if the dangerous poison is delivered in person by the supplier to the buyer—

(i) the poison is delivered to an adult; and

(ii) the delivery is acknowledged by the adult signing and dating a copy of the purchase order;

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(e) if the dangerous poison is not delivered in person by the supplier to the buyer—the poison is delivered to the buyer by a person whose procedures require the delivery of the poison to be signed for by the buyer or an adult employee of the buyer.

721 General requirements for dangerous poisons purchase orders—Act, s 38 (2) (c)

(1) A purchase order for a dangerous poison must be—

(a) signed by the person (the ***issuer***) issuing the order; and

Note The purchase order must be signed with the issuer's usual signature (see Act, dict, def ***signs***).

(b) if the issuer amends the order—initialled and dated by the issuer beside the amendment.

(2) A purchase order for a dangerous poison must include the following:

(a) the issuer's name and business address and telephone number;

(b) the issuer's authority to issue the order;

(c) the dangerous poison, and the form, strength and quantity of the poison, to be supplied on the order.

722 Recording supply of dangerous poisons

A person who supplies a dangerous poison on a purchase order to someone else must keep a written record of the supply in accordance with the medicines and poisons standard, section 5.1 (1) and (2).

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Part 19.2 Wholesale supply of dangerous poisons under corresponding laws

725 Conditions for wholesalers supplying dangerous poisons under corresponding laws—Act, s 20 (4) (c)

The following conditions apply to a person who supplies dangerous poisons by wholesale under a corresponding law:

(a) the person must not supply a dangerous poison to someone else (the ***buyer***) unless—

(i) the buyer is authorised to possess the poison; and

(ii) the supply is in accordance with section 686 (Authorisation conditions for dangerous poisons suppliers licences—Act, s 44 (1) (b) and (2) (b));

(b) the poison is supplied for a non-household (including a non-household garden) purpose only;

(c) if the poison is liquid containing paraquat—the poison is coloured blue or green and has an offensive smell.

Note 1 A purchase order must be in writing (see Act, dict, def ***purchase order***).

Note 2 See pt 19.1 for other requirements in relation to supply of dangerous poisons on purchase orders.

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Part 19.3 Packaging and labelling of dangerous poisons

730 Meaning of *relevant law*—pt 19.3

In this part:

relevant law means—

(a) a corresponding law; or

(b) the *Agricultural and Veterinary Chemicals Act 1994* (Cwlth); or

(c) the *Therapeutic Goods Act 1989* (Cwlth).

Note 1 ***Corresponding law*** includes a law of a State that corresponds, or substantially corresponds, to the Act (see Act, dict).

Note 2 ***State*** includes a territory (see Legislation Act, dict, pt 1).

731 Packaging of supplied manufacturer's packs of dangerous poisons—Act, s 59 (1) (c) (i) and (2) (c) (i)

A manufacturer's pack of a supplied dangerous poison must be packaged—

(a) in accordance with the medicines and poisons standard, sections 2.1 (2) to 2.6 (2); or

(b) in a container in which the poison may be sold under a relevant law.

Note A manufacturer's pack of a dangerous poison supplied may also be packaged in accordance with an approval under the Act, s 193 (Approval of non-standard packaging and labelling) (see Act, s 59 (1) (c) (ii) and (2) (c) (ii)).

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732 Labelling of supplied manufacturer's packs of dangerous poisons—Act, s 60 (1) (c) (i) and (2) (c) (i)

A manufacturer's pack of a supplied dangerous poison must be labelled in accordance with—

(a) the medicines and poisons standard, sections 1.1 (2) to 1.6 (2); or

(b) a relevant law.

Note A manufacturer's pack of a dangerous poison supplied may also be labelled in accordance with an approval under the Act, s 193 (Approval of non-standard packaging and labelling) (see Act, s 60 (1) (c) (ii) and (2) (c) (ii)).

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Part 19.4 Storage of dangerous poisons

735 Storage of dangerous poisons—Act, s 61 (b) and (c)

(1) A person mentioned in table 740, column 2 who possesses a dangerous poison is prescribed.

(2) The dangerous poison must be kept in accordance with the medicines and poisons standard, section 3.1 (1) and (2).

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Part 19.5 Dangerous poisons registers

740 Keeping of dangerous poisons registers by certain people—Act, s 48 and s 50 (1) (b) and (2) (b)

(1) A person mentioned in table 740, column 2 who possesses a dangerous poison must keep a dangerous poisons register.

(2) A person to whom subsection (1) applies must keep a dangerous poisons register for a dangerous poison at the place prescribed in table 740, column 3 for the person.

Table 740 Keeping dangerous poisons registers

column 1 item	column 2 prescribed person	column 3 place where register to be kept
1	approved analyst	the analyst's laboratory
2	dangerous poisons manufacturers licence-holder	the licensed premises under s 675
3	dangerous poisons suppliers licence-holder	the licensed premises under s 685
4	medicines and poisons inspector (other than police officer)	the place directed in writing by the chief health officer
5	person mentioned in sch 4, col 2	the person's business premises
6	supervisor of program under dangerous poisons research and education program licence	the premises where program is being conducted
7	supervisor of program under dangerous poisons research and education authorisation under div 17.3.3	the premises where program is being conducted

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741 Form of dangerous poisons registers—Act, s 49 (1) (b)

(1) Each page in a dangerous poisons register must relate to a single form and strength of a dangerous poison.

(2) If a dangerous poisons register is kept electronically, a separate record must be used for each form and strength of dangerous poison kept.

742 Making entries in dangerous poisons registers—Act, s 51 (1) (b)

(1) The following details for a dealing with a dangerous poison are prescribed:

(a) the nature of the dealing;

(b) the date of the dealing;

(c) the poison, and the form, strength and quantity of the poison, dealt with;

(d) if the dealing is receiving the poison—the name and address of the supplier;

(e) if the dealing is supplying the poison—the name and address of the person to whom it is supplied;

(f) if the poison is supplied on a purchase order—the date of the purchase order;

(g) the quantity of the poison held after the dealing.

(2) A dealing with a dangerous poison must be entered in the dangerous poisons register the person must keep.

743 Prescribed witnesses for discarding of dangerous poisons—Act, s 54 (a) and (b)

(1) An adult is prescribed as a witness in relation to the disposal of a dangerous poison.

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(2) However, a person mentioned in subsection (1) must not be a prescribed witness to the discarding of a dangerous poison if the person is—

(a) related to, a close friend of or employed by the person discarding the poison; or

(b) the supervisor of the person discarding the poison; or

(c) supervised by the person discarding the poison.

744 Changes to entries in dangerous poisons registers—Act, s 55 (2) (b)

(1) An entry in a paper-based dangerous poisons register may be amended by the person who made the entry by—

(a) the person signing and dating a marginal note or footnote that gives the date of the amendment and the amended details; and

(b) if the entry relates to disposing of a dangerous poison—

(i) the amendment being witnessed by a person mentioned in section 743; and

(ii) the witness signing the amendment as witness.

(2) An entry in an electronic dangerous poisons register may be amended by the person who made the entry by the person attaching or linking, by electronic means, a document that includes—

(a) the person's signature, the date and the amended details; and

(b) if the entry relates to disposing of a dangerous poison—

(i) the amendment being witnessed by a person mentioned in section 743; and

(ii) the witness signing the amendment as witness.

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Chapter 20 Paints

750 Manufacture, supply and use of paints containing white lead—Act, s 70 (1) (b), (2) (b) and (3) (b)

A paint containing basic lead carbonate (white lead) may be manufactured, supplied or used for application as a mirror backing if the paint—

(a) contains not more than 15% lead in the non-volatile content of the paint; and

(b) is applied not more than 40µm thick; and

(c) is covered by a paint that does not contain lead.

Note µm is the symbol for micron (see *National Measurement Regulations 1999* (Cwlth), sch 1, pt 4).

751 Manufacture, supply and use of paints for certain purposes—Act, s 71 (1) and (3)

(1) A first group 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.

Note ***First group paint***—see the medicines and poisons standard, par 1 (1).

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(2) A paint or tinter mentioned in the medicines and poisons standard, section 7.1 (2) is prescribed.

752 Manufacture, supply and use of paints for toys—Act, s 72 (b)

A paint that complies with the specification requirements for coating materials prescribed by the medicines and poisons standard, section 7.1 (3) may be manufactured, supplied or used for application to toys.

753 Manufacture, supply and use of paints containing pesticides—Act, s 73 (b)

(1) A pesticide mentioned in the medicines and poisons standard, section 7.1 (4) is prescribed.

(2) However, subsection (1) does not apply in relation to a paint for human therapeutic use.

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Chapter 21 Prohibited and schedule 10 substances

Part 21.1 Preliminary

760 Meaning of *prohibited substance*—ch 21

In this chapter:

prohibited substance includes a schedule 10 substance.

Note ***Schedule 10 substance*** and ***prohibited substance***—see the Act, s 13.

761 Prohibited substances licences—Act, s 78 (2)

A licence for a program of research or education in relation to a prohibited substance (a ***prohibited substances research and education program licence***) may be issued.

Note Other prohibited substances licences may also be issued (see Act, s 78 (3)).

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Part 21.2 Prohibited substances research and education program licences

Division 21.2.1 Issue of prohibited substances research and education program licences

765 Applications for prohibited substances research and education program licences

(1) An application for a prohibited substances research and education program licence for a prohibited substance must be in writing, signed by the applicant, and include the following:

(a) the full name, address and academic, professional or other relevant qualifications of—

(i) the person who is to supervise the program; and

(ii) the person who is to conduct the program;

(b) the name of the recognised research institution at or under which the program is proposed to be conducted;

Note ***Recognised research institution***—see the Act, s 20 (5).

(c) whether the program will be conducted at, or under the authority of, the recognised research institution;

(d) the premises where the program will be conducted;

(e) the prohibited substance, and the form and strength of the substance, for which the licence is sought;

(f) the maximum quantity of the prohibited substance that would be possessed under the licence at any time;

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(g) a description of the program, including an explanation of why the program cannot be carried out satisfactorily without the use of the prohibited substance;

(h) the supervision arrangements for the program;

(i) the period for which the licence is sought.

Note 1 If a form is approved under the Act, s 198 for this provision, the form must be used.

Note 2 A fee may be determined under the Act, s 197 for this provision.

(2) The application must be accompanied by a written approval of the program by the person in charge of—

(a) the recognised research institution; or

(b) a faculty or division of the institution.

766 Restrictions on issuing of prohibited substances research and education program licences— Act, s 85 (1) (a)

The chief health officer must not issue a prohibited substances research and education program licence to a person unless—

(a) the program to which the licence relates will be conducted at, or under the authority of, a recognised research institution; and

(b) the program is approved by a person mentioned in section 765 (2); and

(c) satisfied that the program—

(i) cannot be carried out without the use of the prohibited substance to which the licence application relates; and

(ii) will be adequately supervised.

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767 Additional information for prohibited substances research program and education licences—Act, s 88 (1) (k)

The following additional information is prescribed for a prohibited substances research and education licence:

(a) the research or education program for which the licence is issued;

(b) the name of the program's supervisor;

(c) the dealings with a prohibited substance authorised by the licence;

(d) the premises where the program will be conducted;

(e) the maximum quantity of the prohibited substance that may be possessed at any time for the program;

(f) the total quantity of the prohibited substance that may be possessed for the program during the period of the licence;

(g) the form and strength of the prohibited substance that may be obtained and possessed for the program.

Division 21.2.2 Prohibited substances research and education program authorisations

768 Authorisations under prohibited substances research and education program licences—Act, s 20 (1) (a)

A prohibited substances research and education program licence authorises—

(a) the licence-holder to—

(i) issue a purchase order for a prohibited substance (the ***licensed prohibited substance***) stated in the licence for the program stated in the licence; and

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(ii) obtain a licensed prohibited substance on a purchase order for the program; and

(iii) possess a licensed prohibited substance for the program at the premises to which the licence relates; and

(iv) supply a licensed prohibited substance to anyone taking part in the program for the program; and

(b) the program supervisor, and anyone taking part in the program, to deal with the licensed prohibited substance as authorised by the licence at the premises stated in the licence.

769 Authorisation condition for prohibited substances research and education program licences—Act, s 44 (1) (b) and (2) (b)

A licence-holder's authorisation to obtain a prohibited substance under a prohibited substances research and education program licence is subject to the condition that the substance is obtained on a complying purchase order.

Note For licence conditions, see the Act, s 89.

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Division 21.2.3 Other provisions—prohibited substances research and education program licences

770 Approvals of dealings for prohibited substances research and education program licences—Act, s 20 (1) (c)

(1) In this section:

relevant dealing, with a prohibited substance for a prohibited substances research and education program licence, means any of the following:

(a) obtaining the substance;

(b) possessing the substance;

(c) issuing a purchase order for the substance;

(d) supplying the substance on a complying purchase order to the licence-holder.

(2) The chief health officer may approve a person for a relevant dealing with a prohibited substance to which a prohibited substances research and education program licence relates.

(3) An approval—

(a) must be in writing; and

(b) may be conditional; and

(c) may apply for a stated period or until a stated event happens.

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771 Authorisation condition for approval-holders—Act, s 44 (1) (b) and (2) (b)

An approval-holder's authorisation under section 770 is subject to the condition that the following are kept at the approval-holder's business premises or, if the chief health officer approves in writing another place, the place approved by the chief health officer, for at least 2 years after the day a prohibited substance is supplied:

(a) the filled purchase order;

(b) the record for section 773.

772 General requirements for prohibited substances purchase orders—Act, s 38 (2) (c)

(1) A purchase order for a prohibited substance must be—

(a) signed by the person (the ***issuer***) issuing the order; and

Note The purchase order must be signed with the issuer's usual signature (see Act, dict, def ***signs***).

(b) if the issuer amends the order—initialled and dated by the issuer beside the amendment.

(2) A purchase order for a prohibited substance must include the following:

(a) the issuer's name and business address and telephone number;

(b) the issuer's authority to issue the order;

(c) the prohibited substance, and the form, strength and quantity of the substance, to be supplied on the order.

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773 Recording supply of prohibited substances on purchase orders

A person who supplies a prohibited substance to someone else on a purchase order must make a written record of the following information:

(a) the date of the order;

(b) the issuer's authority to issue the order;

(c) the name, and the business address and telephone number, of the person to whom the prohibited substance is supplied;

(d) the date the order is supplied;

(e) the prohibited substance, and the form, strength and quantity of the substance, supplied.

Note ***Written*** includes in electronic form (see Act, dict).

774 Information for CHO about supplied prohibited substances research and education program licences—Act, s 31 (1) (a) (ii), (1) (b), (2) (a) (ii), (2) (b) and (4)

(1) This section applies if a person supplies a prohibited substance to a prohibited substances research and education program licence-holder.

(2) The person must, not later than 7 days after the end of the month when the prohibited substance is supplied, give the chief health officer the following information in writing:

(a) the person's name, business address and telephone number;

(b) the name of the person who issued the supply authority;

(c) the date of the supply authority;

(d) the name and address of the person to whom the substance is supplied;

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(e) the date of supply;

(f) the substance, and the form, strength and quantity of the substance, supplied.

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Part 21.3 Prohibited substances registers

775 Keeping of prohibited substances registers by certain people—Act, s 48 and s 50 (1) (b) and (2) (b)

(1) A person mentioned in table 775, column 2 who possesses a prohibited substance must keep a prohibited substances register.

(2) A person to whom subsection (1) applies must keep a prohibited substances register for a prohibited substance at the place prescribed in table 775, column 3 for the person.

Table 775 Keeping prohibited substances registers

column 1 item	column 2 prescribed person	column 3 place where register to be kept
1	approved analyst	the analyst's laboratory
2	medicines and poisons inspector (other than police officer)	the place directed in writing by the chief health officer
3	supervisor of program under prohibited substances research and education program licence	the premises where program is being conducted

776 Form of prohibited substances registers—Act, s 49 (1) (b)

(1) Each page in a prohibited substances register must relate to a single form and strength of a prohibited substance.

(2) If a prohibited substances register is kept electronically, a separate record must be used for each form and strength of prohibited substance kept.

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777 Making entries in prohibited substances registers—Act, s 51 (1) (b)

(1) The following details for a dealing with a prohibited substance are prescribed:

(a) the nature of the dealing;

(b) the date of the dealing;

(c) the prohibited substance, and the form, strength and quantity of the substance, dealt with;

(d) if the dealing is receiving the substance—the name and address of the supplier;

(e) if the dealing is supplying the substance—the name and address of the person to whom it is supplied;

(f) the quantity of the substance held after the dealing.

(2) A dealing with a prohibited substance must be entered in the prohibited substances register the person must keep.

778 Prescribed witnesses for discarding of prohibited substances—Act, s 54 (a) and (b)

(1) The following people are prescribed as witnesses in relation to the disposal of a prohibited substance:

(a) an approved analyst;

(b) a medicines and poisons inspector.

Note ***Approved analyst***—see the dictionary.

(2) However, a person mentioned in subsection (1) must not be a prescribed witness to the discarding of a prohibited substance if the person is—

(a) related to, a close friend of or employed by the person discarding the substance; or

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(b) the supervisor of the person discarding the substance; or

(c) supervised by the person discarding the substance.

779 Changes to entries in prohibited substances registers—Act, s 55 (2) (b)

(1) An entry in a paper-based prohibited substances register may be amended by the person who made the entry by—

(a) the person signing and dating a marginal note or footnote that gives the date of the amendment and the amended details; and

(b) if the entry relates to disposing of a prohibited substance—

(i) the amendment being witnessed by a person mentioned in section 743; and

(ii) the witness signing the amendment as witness.

(2) An entry in an electronic prohibited substances register may be amended by the person who made the entry by the person attaching or linking, by electronic means, a document that includes—

(a) the person's signature, the date and the amended details; and

(b) if the entry relates to disposing of a prohibited substance—

(i) the amendment being witnessed by a person mentioned in section 743; and

(ii) the witness signing the amendment as witness.

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Chapter 22 Therapeutic goods

800 Definitions—ch 22

In this chapter:

optical device means any of the following:

(a) corrective contact lenses;

(b) corrective lenses for spectacles;

(c) non-corrective contact lenses commonly known as plano contact lenses.

prescription, in relation to an optical device, means a written direction (other than a purchase order) to a person who is authorised to supply the optical device to dispense the optical device.

801 Prescribed regulated therapeutic goods—Act, s 14, def *regulated therapeutic good*, par (b)

Optical devices are prescribed.

802 Authorisation to supply optical devices—Act, s 74 (1) (b) and (2) (b)

(1) To the extent necessary to practise optometry and, if employed, within the scope of employment, an optometrist is authorised to supply optical devices on prescription issued by an optometrist or doctor.

Note ***Supply*** includes dispense (see Act, s 24).

(2) To the extent necessary to practise as an optician and, if employed, within the scope of employment, an optician is authorised to supply optical devices on prescription issued by an optometrist or doctor.

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(3) Within the scope of employment, an employee of an optometrist is authorised to sell and deliver optical devices supplied under subsection (1) or (2).

803 Authorisation conditions for supplying optical devices—Act, s 75 (1) (b)

An optometrist's, and optician's, authorisation under section 802 in relation to optical devices is subject to the following conditions:

(a) the optical devices are supplied on a written prescription by an optometrist or doctor;

(b) if the prescription is for contact lenses (whether corrective or plano)—the prescription is issued not more than 1 year before the date the lenses are supplied;

(c) if the prescription is for corrective lenses for spectacles—the prescription is issued not more than 2 years before the date the lenses are supplied.

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Chapter 23 Notification and review of decisions

850 Meaning of *reviewable decision*—ch 23

In this chapter:

reviewable decision means a decision mentioned in table 850, column 3 under a provision of this regulation mentioned in column 2 in relation to the decision.

Table 850 Reviewable decisions—chief health officer

column 1 item	column 2 section	column 3 decision	column 4 entity
1	120 (1) (h)	refuse approval of other premises	applicant for approval
2	130 (e)	refuse approval of other premises	applicant for approval
3	140 (e)	refuse approval of other premises	applicant for approval
4	150 (1) (c)	refuse approval of other premises	applicant for approval
5	160 (f)	refuse approval of other premises	applicant for approval
6	171 (d)	refuse approval of other premises	applicant for approval
7	175 (1) (a) (ii) and (b)	amend pseudoephedrine record in way other than in accordance with application/refuse application	applicant for amendment
8	252 (1) (d)	refuse approval of other premises	applicant for approval

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column 1 item	column 2 section	column 3 decision	column 4 entity
9	531 (2)	refuse approval to store a controlled medicine in a safe or strongroom	applicant for approval
10	616 (1)	refuse approval of nominated individual for medicines wholesales licence	applicant for licence
11	676 (f)	refuse approval of other premises	applicant for approval
12	686 (f)	refuse approval of other premises	applicant for approval
13	706 (1)	refuse approval of nominated individual for dangerous poisons manufacturers licence	applicant for licence
14	716 (1)	refuse approval of nominated individual for dangerous poisons suppliers licence	applicant for licence
15	771	refuse approval of other premises	applicant for approval

Note For ACAT review of other decisions in relation to licences, see the Act, ch 9 and sch 1.

851 Reviewable decision notices

If a person makes a reviewable decision, the person must give a reviewable decision notice to each entity mentioned in table 850, column 4 in relation to the decision.

Note 1 The person must also take reasonable steps to give a reviewable decision notice to any other person whose interests are affected by the decision (see *ACT Civil and Administrative Tribunal Act 2008*, s 67A).

Note 2 The requirements for reviewable decision notices are prescribed under the *ACT Civil and Administrative Tribunal Act 2008*.

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852 Applications for review

The following may apply to the ACAT for a review of a reviewable decision:

(a) an entity mentioned in table 850, column 4 in relation to the decision;

(b) any other person whose interests are affected by the decision.

Note If a form is approved under the *ACT Civil and Administrative Tribunal Act 2008* for the application, the form must be used.

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Chapter 24 Miscellaneous

860 Authorisations for public employees—Act, s 26 (1) (b), (2) (b), s 35 (1) (b), (2) (b) and s 36 (b)

(1) This section applies to a public employee who is exercising a function under the Act.

Note ***Function*** includes authority, duty and power (see Legislation Act, dict, pt 1).

(2) To the extent necessary to exercise the function and within the scope of employment, the public employee is authorised to do any of the following:

(a) obtain a regulated substance;

(b) possess a regulated substance;

(c) supply a regulated substance or regulated therapeutic good to a person for discarding if the person is authorised to obtain the substance or good;

Example—person authorised to obtain

a person who holds an environmental authorisation for the disposal of the substance (see, eg s 693)

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(d) supply a regulated substance or regulated therapeutic good, for law enforcement purposes, to—

(i) someone else who is authorised to obtain the substance or good; or

(ii) a law enforcement officer.

Note ***Public employee***—see the Legislation Act, dictionary, pt 1.

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(3) In this section:

law enforcement officer—see the Criminal Code, section 700.

861 Other authorisations for public employees— Act, s 20 (1) (a), (2) (a) and s 74 (1) (b)

(1) A public employee is authorised to deal with a regulated substance, or regulated therapeutic good, in accordance with a permit issued by the chief health officer to the employee.

(2) The permit must be in writing and include the following information:

(a) the dealings with regulated substances or regulated therapeutic goods authorised by the permit;

(b) the regulated substances or regulated therapeutic goods to which the permit relates;

(c) the public employee or employees authorised under the permit;

(d) any condition included in the permit by the chief health officer to which the permit is subject;

(e) a unique identifying number;

(f) when the permit ends.

(3) For subsection (2) (c), the permit may identify a public employee authorised under the permit by—

(a) naming the employee; or

(b) nominating the occupant of a position (however described), at a particular time or from time to time.

(4) In this section:

public employee includes a police officer.

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862 Certain containers not to be used for human-use substances—Act, s 63 (1) (b)

A container of a kind mentioned in the medicines and poisons standard, paragraph 21, 22 or 23 is prescribed.

863 Disapplication of Legislation Act, s 47 (6)

The Legislation Act, section 47 (6) does not apply to the following:

(a) the Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8;

(b) the medicines Australia code of conduct;

(c) the *National Health Act 1953* (Cwlth);

(d) the *National Health (Pharmaceutical Benefits) Regulations 1960* (Cwlth);

(e) a continued dispensing determination.

Note 1 An instrument and a law of another jurisdiction mentioned in this section do not need to be notified under the Legislation Act because s 47 (6) does not apply (see Legislation Act, s 47 (7)).

Note 2 A reference to an Act includes a reference to the statutory instruments made or in force under the Act, including any regulation (see Legislation Act, s 104).

Note 3 The Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8 is accessible at www.tga.gov.au.

Note 4 The Medicines Australia Code of Conduct is accessible at www.medicinesaustralia.com.au.

Note 5 A law of another jurisdiction mentioned in this section is accessible at www.comlaw.gov.au.

864 Exemption of piper methysticum (kava)—Act, s 190 (1) (a)

(1) Piper methysticum (kava) in the following forms is exempt from the Act:

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(a) raw or dried whole or peeled rhizome for use in aqueous dispersions or aqueous extracts intended for oral use by humans;

(b) powder made from the dried rhizome for use in aqueous dispersions or aqueous extracts intended for oral use by humans;

(c) preparations for oral use by humans containing aqueous dispersions or aqueous extracts of the raw or dried whole or peeled rhizome;

(d) preparations for oral use by humans containing aqueous dispersions or aqueous extracts of powder made from the dried rhizome.

(2) However, the exemption applies only if—

(a) the kava is prepared, possessed and consumed in accordance with the customs of the Pacific Islands; and

Examples—customs of the Pacific Islands relating to use of kava

1 consuming kava as part of a traditional ceremony, in a kava circle or otherwise

2 serving kava from a traditional bowl

Note An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

(b) the kava is prepared, possessed and consumed in connection with an event declared by the Minister; and

(c) any conditions stated in the declaration are complied with.

(3) The Minister may declare an event only if satisfied it is a public event.

Example

National Multicultural Festival

(4) A declaration may include conditions about any of the following:

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(a) the dates and times when the kava may be prepared or consumed;

(b) the way in which the kava may be prepared or consumed;

(c) the places where the kava may be prepared or consumed;

(d) the minimum age of people who may consume the kava;

(e) signage for the event;

(f) anything else the Minister considers appropriate.

(5) A declaration is a notifiable instrument.

Note A notifiable instrument must be notified under the Legislation Act.

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Schedule 1 Medicines—health-related occupations authorisations

(see s 30, s 50, s 60, s 110, s 350, s 370 and s 380)

Part 1.1 Ambulance services and officers

column 1 item	column 2 person authorised	column 3 authorisation
1	ambulance officer employed by Commonwealth, Territory or State	within scope of employment, do any of the following: (a) obtain medicines; (b) possess medicines; (c) administer medicines.
2	person in charge of ambulance service operated by Commonwealth, Territory or State	within scope of employment, do any of the following: (a) issue purchase orders for medicines; (b) obtain medicines mentioned in par (a); (c) possess medicines mentioned in par (a); (d) supply medicines to ambulance officers in ambulance service.

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Part 1.2 Dentists, dental hygienists, dental therapists and oral health therapists

column 1 item	column 2 person authorised	column 3 authorisation
1	dentist	to the extent necessary to practise dentistry and, if employed, within the scope of employment, do any of the following: (a) issue purchase orders and requisitions for medicines; (b) obtain medicines; (c) possess medicines; (d) administer medicines; (e) prescribe medicines; (f) supply medicines to patients during consultations if labelled in accordance with s 161; (g) supply medicines for administration to patients at dental surgery to people authorised to administer them.

Note ***Dentist*** does not include a trainee dentist (see dict).

2	trainee dentist	to the extent necessary to practise dentistry or undertake training, and under supervision of dentist, do any of the following: (a) obtain medicines from health practitioner authorised to possess them; (b) possess medicines; (c) administer medicines in accordance with prescription (whether or not issued by themself or dentist); (d) prescribe medicines for administration at institution or dental surgery.

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column 1 item	column 2 person authorised	column 3 authorisation
3	dental hygienist	within the scope of employment, to the extent necessary to practice as dental hygienist, and in a structured professional relationship with a dentist, do any of the following: (a) obtain medicines from dentist authorised to possess them; (b) possess medicines mentioned in par (a); (c) administer medicines mentioned in par (a) in accordance with dentist's prescription.
4	dental therapist	within the scope of employment, to the extent necessary to practice as dental therapist, and in a structured professional relationship with a dentist, do any of the following: (a) issue purchase orders and requisitions for medicines for topical dental use and for local anaesthetics; (b) obtain medicines mentioned in par (a); (c) possess medicines mentioned in par (a); (d) administer medicines mentioned in par (a).

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column 1 **item**	**column 2** **person authorised**	**column 3** **authorisation**
5	oral health therapist	within the scope of employment, to the extent necessary to practice as an oral health therapist, and in a structured professional relationship with a dentist, do any of the following: (a) issue purchase orders and requisitions for medicines for topical dental use and for local anaesthetics; (b) obtain medicines mentioned in par (a); (c) possess medicines mentioned in par (a); (d) administer medicines mentioned in par (a).

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Part 1.3 Doctors

column 1 item	column 2 person authorised	column 3 authorisation
1	doctor	to the extent necessary to practise medicine and, if employed, within the scope of employment, do any of the following: (a) issue purchase orders and requisitions for medicines; (b) obtain medicines; (c) possess medicines; (d) administer medicines; (e) prescribe medicines; (f) supply medicines to patients during consultations; (g) supply medicines for administration to patients to people authorised to administer them; (h) supply medicines dispensed for patient to another health practitioner on patient's transfer within institution; (i) supply medicines dispensed for patient to patient on patient's discharge from institution; (j) supply medicines to patients during consultations if labelled in accordance with s 161. *Note* For authorisation to issue standing orders for administration of medicines at institutions, see s 75.

Note ***Doctor*** does not include an intern doctor (see dict).

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column 1 **item**	**column 2** **person authorised**	**column 3** **authorisation**
2	intern doctor	to the extent necessary to practise medicine or undertake training or supervised practice, and under supervision of doctor, do any of the following: (a) obtain medicines from health practitioner authorised to possess them; (b) possess medicines; (c) administer medicines in accordance with prescription (whether or not issued by themself or another prescriber); (d) prescribe medicines for administration at institution or surgery; (e) supply medicines dispensed for patient to another health practitioner on patient's transfer within institution; (f) supply medicines dispensed for patient to patient on patient's discharge from institution.

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Part 1.4 Health practitioners at institutions

column 1 item	column 2 person authorised	column 3 authorisation
1	health practitioner employed at institution	within the scope of employment, do any of the following for the delivery of medicines within the institution to a health practitioner or health professional authorised to obtain the medicines: (a) obtain the medicines; (b) possess the medicines; (c) supply the medicines.

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Part 1.5 Midwives

column 1 item	column 2 person authorised	column 3 authorisation
1	midwife	to the extent necessary to practise midwifery and, if employed, within the scope of employment, do any of the following: (a) issue requisitions for medicines; (b) obtain medicines on requisition; (c) possess medicines; (d) administer medicines in accordance with prescription or standing order; (e) supply medicines in accordance with a standing order issued by chief health officer or a requisition; (f) supply medicines dispensed for patient to another health practitioner on patient's transfer within institution; (g) supply medicines dispensed for patient to patient on patient's discharge from institution.

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column 1 item	column 2 person authorised	column 3 authorisation
2	eligible midwife	to the extent necessary to practise midwifery and, if employed, within the scope of employment, do any of the following: (a) issue requisitions for medicines; (b) obtain medicines; (c) possess medicines; (d) if the midwife is an authorised midwife—prescribe medicines listed on the pharmaceutical benefits scheme for prescribing by an authorised midwife (see *National Health Act 1953* (Cwlth), s 93AA); (e) supply medicines to which par (d) applies to patients during consultations if labelled in accordance with s 161; (f) administer medicines to which par (d) applies in accordance with prescription issued by themself; (g) administer medicines in accordance with prescription issued by another prescriber, or standing order; (h) supply medicines in accordance with a standing order issued by chief health officer or a requisition; (i) supply medicines dispensed for patient to another health practitioner on patient's transfer within institution; (j) supply medicines dispensed for patient to patient on patient's discharge from institution.

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Part 1.6 Nurses

column 1 item	column 2 person authorised	column 3 authorisation
1	nurse	to the extent necessary to practise nursing and, if employed, within the scope of employment, do any of the following: (a) issue requisitions for medicines; (b) obtain medicines on requisition; (c) possess medicines; (d) administer medicines in accordance with prescription or standing order; (e) supply medicines in accordance with a standing order issued by chief health officer or a requisition; (f) supply medicines dispensed for patient to another health practitioner on patient's transfer within institution; (g) supply medicines dispensed for patient to patient on patient's discharge from institution.

Note ***Nurse*** does not include enrolled nurse (see Legislation Act, dict, pt 1).

2	trainee nurse	if successfully completed pharmacology units of nursing studies, to the extent necessary to practise nursing as trainee nurse or undertake training, and under supervision of nurse, nurse practitioner or midwife, do any of the following: (a) obtain medicines from health practitioner authorised to possess them; (b) possess medicines; (c) administer medicines to patients in accordance with prescription.

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column 1 item	column 2 person authorised	column 3 authorisation
3	enrolled nurse	to the extent necessary to practise nursing as enrolled nurse and, if employed, within the scope of employment, do any of the following: (a) obtain medicines from health practitioner authorised to possess them; (b) possess medicines; (c) administer medicines in accordance with prescription.

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column 1 item	column 2 person authorised	column 3 authorisation
4	nurse practitioner	to the extent necessary to practise nursing and, if employed, within the scope of employment, do any of the following: (a) issue requisitions for medicines; (b) obtain medicines; (c) possess medicines; (d) prescribe medicines in accordance with approved scope of practice under the *Health Regulation 2004*, s 11; (e) supply medicines to which par (d) applies to patients during consultations if labelled in accordance with s 161; (f) administer medicines in accordance with prescription (whether or not issued by themself or another prescriber) or standing order; (g) supply medicines in accordance with a standing order issued by chief health officer or a requisition; (h) supply medicines dispensed for patient to another health practitioner on patient's transfer within institution; (i) supply medicines dispensed for patient to patient on patient's discharge from institution.

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Part 1.7 Opioid dependency treatment centres operated by Territory

column 1 item	column 2 person authorised	column 3 authorisation
1	person in charge of opioid dependency treatment centre operated by Territory	to the extent necessary to treat patients of centre and within the scope of employment, do any of the following: (a) issue purchase orders and requisitions for buprenorphine and methadone; (b) obtain buprenorphine and methadone on purchase orders and requisitions; (c) supply buprenorphine and methadone to health practitioners at centre for patients of centre.
2	doctor or nurse at opioid dependency treatment centre operated by Territory	to the extent necessary to treat patients of centre and within the scope of employment, supply buprenorphine and methadone to patients of centre for self-administration outside centre if— (a) supply is in accordance with prescription; and (b) medicine is labelled as if dispensed medicine; and (c) labelled medicine checked by another health practitioner before supply. *Note 1* For authorisation of doctor to issue standing orders for administration of medicines at centre, see s 75. *Note 2* For labelling of dispensed medicines, see s 123.

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Part 1.8 Optometrists

column 1 item	column 2 person authorised	column 3 authorisation
1	optometrist	to the extent necessary to practise optometry and, if employed, within the scope of employment, to deal as follows with medicines mentioned in the medicines and poisons standard, schs 2, 3 and 4: (a) issue purchase orders for the medicines; (b) issue requisitions for the medicines; (c) obtain the medicines; (d) possess the medicines; (e) administer the medicines.

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Part 1.9 Pharmacists and employees

column 1 item	column 2 person authorised	column 3 authorisation
1	pharmacist	to the extent necessary to practise pharmacy and, if employed, within the scope of employment, do any of the following: (a) issue purchase orders and requisitions for medicines; (b) obtain medicines; (c) possess medicines; (d) dispense medicines; (e) administer medicines; (f) manufacture medicines to dispense or supply them on requisition; (g) supply pharmacy medicines; (h) if pharmacist at institution—supply pharmacist only medicines without prescription; (i) if pharmacist at community pharmacy—supply pharmacist only medicines without prescription but in accordance with the Act, s 7; (j) supply medicines on purchase order, requisition or standing order.

Note 1 ***Manufacture***—see the Act, dictionary.

Note 2 ***Pharmacist*** does not include an intern pharmacist (see dict).

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column 1 **item**	**column 2** **person authorised**	**column 3** **authorisation**
2	intern pharmacist	to the extent necessary to practise pharmacy or undertake training or supervised practice, do any of the following: (a) under direct supervision of pharmacist do 1 or more of the following: (i) administer medicines; (ii) if intern pharmacist at institution—supply pharmacist only medicines without prescription; (iii) if intern pharmacist at community pharmacy—supply pharmacist only medicines without prescription but in accordance with the Act, s 7; (iv) to obtain, possess and supply medicines for the purpose of assisting pharmacist to dispense them; (b) under supervision of pharmacist, do 1 or more of the following: (i) obtain medicines; (ii) possess medicines; (iii) supply pharmacy medicines; (iv) supply medicines on requisition.

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column 1 item	column 2 person authorised	column 3 authorisation
3	employee assisting pharmacist employed at hospital	within the scope of employment and under direct supervision of pharmacist, do any of the following: (a) obtain medicines; (b) possess medicines; (c) to obtain, possess and supply medicines for the purpose of assisting pharmacist to dispense them; (d) supply medicines on requisition.
4	employee at a community pharmacy	within the scope of employment and— (a) under supervision of pharmacist, supply— (i) pharmacy medicines; or (ii) pharmacist only medicines supplied in person to customer by pharmacist if supply is for purpose of sale of medicine; or (iii) medicines dispensed at the pharmacy if the delivery or sale is to the person for whom the medicine is prescribed or the person's agent; and (b) under supervision of pharmacist, obtain and possess medicines for purpose of par (a); and (c) under direct supervision of pharmacist, do any of the following for purpose of assisting pharmacist to dispense medicines: (i) obtain the medicines; (ii) possess the medicines.

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Part 1.10 Podiatrists

column 1 item	column 2 person authorised	column 3 authorisation
1	podiatrist	to the extent necessary to practise podiatry and, if employed, within the scope of employment, do any of the following: (a) issue purchase orders and requisitions for adrenaline and local anaesthetics; (b) obtain adrenaline and local anaesthetics; (c) possess adrenaline and local anaesthetics; (d) administer adrenaline and local anaesthetics.

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Part 1.11 Residential care facilities

column 1 item	column 2 person authorised	column 3 authorisation
1	director of nursing for residential aged care facility without pharmacy medical superintendent for residential aged care facility without pharmacy	within the scope of employment, do any of the following: (a) issue purchase orders for following medicines for emergency administration to residents at facility under direction of prescriber: (i) pharmacy medicines, pharmacist only medicines and prescription only medicines; (ii) not more than 5 ampoules, each of 1mL or less, of morphine sulfate, at a concentration of 30mg or less of morphine sulfate per mL; (b) obtain the medicines mentioned in par (a); (c) possess the medicines mentioned in par (a); (d) supply medicines mentioned in par (a) to health practitioner at facility for administration to residents. *Note 1* No authorisation is required for certain dealings with residents' own medicines, see s 371. *Note 2* For the administration of medicines by staff, see s 361. *Note 3* For authorisation of doctor to issue standing orders for administration of medicines at facility, see s 75.

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column 1 **item**	**column 2** **person authorised**	**column 3** **authorisation**
2	director of nursing for residential disability care facility without pharmacy medical superintendent for residential disability care facility without pharmacy	within the scope of employment, do any of the following: (a) issue purchase orders for medicines (other than controlled medicines) for emergency administration to residents at facility under direction of prescriber; (b) obtain the medicines; (c) possess the medicines; (d) supply the medicines to health practitioner at facility for administration to residents. *Note* See the notes to item 1.

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Part 1.12 Sales representatives for medicines manufacturers and wholesalers

column 1 item	column 2 person authorised	column 3 authorisation
1	representative of person authorised (however described) under corresponding law to manufacture medicines representative of medicines wholesalers licence-holder representative of person authorised to supply medicines under the Act, s 20 (4) (which is about wholesalers who do not have a place of business in the ACT)	for purpose of supplying medicines (other than controlled medicines) under medicines Australia code of conduct, and within the scope of employment, do any of the following: (a) obtain manufacturer's packs of medicines (other than controlled medicines) from manufacturer or wholesaler; (b) possess medicines obtained under par (a); (c) supply manufacturer's packs of medicines in accordance with medicines Australia code of conduct.

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Part 1.13 Veterinary surgeons and employees

column 1 item	column 2 person authorised	column 3 authorisation
1	veterinary surgeon	to the extent necessary to practise veterinary medicine and, if employed, within the scope of employment, do any of the following: (a) issue purchase orders for medicines; (b) obtain medicines; (c) possess medicines; (d) administer medicines; (e) prescribe medicines; (f) supply— (i) pharmacy medicines if labelled with words to the effect of 'for animal treatment only'; or (ii) pharmacist only medicines supplied in person by veterinary surgeon, or trainee veterinary surgeon, if labelled with words to the effect of 'for animal treatment only'; or (iii) medicines to custodians of animals during consultations if labelled in accordance with s 161.

Note 1 ***Veterinary surgeon*** does not include a trainee veterinary surgeon (see dict).

Note 2 ***Custodian***, of an animal—see the dictionary.

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column 1 item	column 2 person authorised	column 3 authorisation
2	trainee veterinary surgeon	to the extent necessary to practise veterinary medicine or undertake training, and under supervision of veterinary surgeon, do any of the following: (a) obtain medicines; (b) possess medicines; (c) administer medicines in accordance with prescription (whether or not issued themself or by veterinary surgeon); (d) supply— (i) pharmacy medicines if labelled with words to the effect of ‘for animal treatment only’; or (ii) pharmacist only medicines supplied in person by veterinary surgeon, or trainee veterinary surgeon, if labelled with words to the effect of ‘for animal treatment only’; or (iii) medicines supplied in person by a veterinary surgeon at the surgery if labelled in accordance with s 161; (e) prescribe medicines for administration at veterinary surgery.

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column 1 **item**	**column 2** **person authorised**	**column 3** **authorisation**
3	veterinary surgeon's employee public employee assisting veterinary surgeon who is public employee	within the scope of employment and under supervision of veterinary surgeon, do any of the following: (a) obtain medicines from veterinary surgeon authorised to possess them; (b) possess medicines mentioned in par (a); (c) administer medicines mentioned in par (a) in accordance with veterinary surgeon's prescription; (d) supply pharmacy medicines if labelled with words to the effect of 'for animal treatment only'; (e) supply pharmacist only medicines supplied in person by veterinary surgeon, or trainee veterinary surgeon, if supply is for purpose of sale or delivery of medicine; (f) supply medicines supplied in person by a veterinary surgeon at the place of employment if labelled in accordance with s 161.

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Schedule 3 Designated appendix D medicines—standing approvals

(see s 31, s 33, s 41, s 160, s 591, s 592 and s 593)

Part 3.1 Approval conditions

3.1 Definitions—sch 3

In this schedule:

condition 1, for a doctor prescribing or supplying a designated appendix D medicine to a woman of child-bearing age, means the doctor must ensure that the possibility of pregnancy by the woman has been excluded prior to commencement of treatment.

condition 2, for a doctor prescribing or supplying a designated appendix D medicine to a woman of child-bearing age, means the doctor must advise the woman to avoid becoming pregnant during, or for a period of 1 month after the completion of, treatment.

condition 3, for a doctor prescribing or supplying a designated appendix D medicine to a woman of child-bearing age, means the doctor must advise the woman to avoid becoming pregnant during, or for a period of 3 months after the completion of, treatment.

condition 4, for a doctor prescribing or supplying a designated appendix D medicine to a woman of child-bearing age, means the doctor must advise the woman to avoid becoming pregnant during, or for a period of 24 months after the completion of, treatment.

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Part 3.2 Standing approvals for designated appendix D medicines

column 1 item	column 2 doctor	column 3 medicine	column 4 conditions (if any)
1	specialist practising in specialist area of dermatology	acitretin for human use alefacept for human use bexarotene for human use etretinate for human use isotretinoin for human oral use thalidomide for human use	conditions 1 and 4 conditions 1 and 2 conditions 1 and 4 conditions 1 and 2 conditions 1 and 2
2	specialist practising in specialist area of endocrinology, gynaecology or obstetrics	clomiphene for human use corifollitropin alfa for human use cyclofenil for human use dinoprost for human use dinoprostone for human use follitropin alpha (recombinant human follicle-stimulating hormone) for human use follitropin beta (recombinant human follicle-stimulating hormone) for human use luteinising hormone for human use urofollitropin (human follicle-stimulating hormone) for human use	

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column 1 item	column 2 doctor	column 3 medicine	column 4 conditions (if any)
3	specialist practising in specialist area of mental health doctor employed by Territory and working under supervision of chief psychiatrist under *Mental Health (Treatment and Care) Act 1994*	clozapine for human use	
4	specialist physician	ambrisentan for human use acitretin for human use etretinate for human use bexarotene for human use bosentan for human use isotretinoin for human oral use lenalidomide for human use sitaxentan for human use teriparatide for human use thalidomide for human use tretinoin for human oral use	conditions 1 and 3 conditions 1 and 4 conditions 1 and 4 conditions 1 and 2 conditions 1 and 3 conditions 1 and 2 conditions 1 and 2 conditions 1 and 3 conditions 1 and 2 conditions 1 and 2
5	specialist practising in specialist area of neurology or rehabilitation	nabiximols for human use	
6	specialist practising in specialist area of neurology, paediatrics or sleep medicine	sodium oxybate for human use	

Note ***Specialist*** includes a doctor training in a specialist area—see the dictionary.

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Schedule 4 Dangerous poisons—manufacturing etc authorisations

(see s 690)

column 1 item	column 2 people	column 3 dangerous poison	column 4 prescribed purpose
1	manufacturers of glass	arsenic	manufacturing glass
	metallurgists		manufacturing alloys
2	manufacturers of dyes or pharmaceuticals	benzene	manufacturing dyes or pharmaceuticals
	manufacturers of lacquers, linoleum, protective cloths or varnishes		manufacturing lacquers, linoleum, protective cloths or varnishes
3	manufacturers of chemicals or pharmaceuticals	carbon tetrachloride	manufacturing chemicals or pharmaceuticals
	manufacturers of lacquers, paints or varnishes		manufacturing lacquers, paints or varnishes
4	managers of swimming pools, other than domestic swimming pools	chlorine	purifying water in pools
	manufacturers of chemicals, plastics or synthetic rubber		manufacturing chemicals, plastics or synthetic rubber
	metallurgists		cleaning metals
	people working at sewage treatment centres		treating sewage at treatment centres
	people working at water treatment centres		purifying water at treatment centres
5	electroplaters	cyanides	electroplating

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column 1 item	column 2 people	column 3 dangerous poison	column 4 prescribed purpose
	jewellers		manufacturing gold jewellery
	miners		extracting or processing gold
6	manufacturers of lacquers, paints or varnishes	epichlorohydrin	manufacturing lacquers, paints or varnishes
7	manufacturers of chemicals or detergents	ethylene oxide	manufacturing chemicals or detergents
	sterilising technologists		sterilising surgical instruments
8	glass workers	hydrofluoric acid	etching glass
	masons		cleaning building materials
	metal workers		cleaning or etching metals
	miners		extracting or processing gold
	potters		cleaning ceramics
9	manufacturers of lamps, mirrors or scientific instruments	mercury	manufacturing of lamps, mirrors or scientific instruments
	manufacturers of mercury salts or organic compounds		manufacturing mercury salts or organic compounds
	miners		extracting metals from ores
10	manufacturers of plastics	4, 4’-methylenebis [2-chloroaniline] (MOCA)	manufacturing plastics

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column 1 item	column 2 people	column 3 dangerous poison	column 4 prescribed purpose
11	manufacturers of detergents, lubricants or organic compounds	propylene oxide	manufacturing detergents, lubricants or organic compounds
12	manufacturers of organic compounds, paints, rust removers or varnishes	tetrachloroethane	manufacturing organic compounds, paints, rust removers or varnishes
13	manufacturers of dyes	ortho-tolidine	manufacturing dyes
14	manufacturers of disinfectants, household cleaners or industrial deodorants	trichloroisocyanuric acid	manufacturing disinfectants, household cleaners or industrial deodorants

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Schedule 5 Requirements for storage receptacles

(see s 531 and s 533)

Part 5.1 Medicines cabinets

5.1 Medicines cabinets—general requirements

A medicines cabinet must be constructed to prevent ready access to the cabinet's contents by cutting, sawing or unbolting.

5.2 Medicines cabinets—body requirements

(1) The body of a medicines cabinet must be constructed of a single layer of black mild steel plate at least 10mm thick and with continuous welding of all joints.

(2) The body must have, for installation—

(a) 4 suitably sized holes in the cabinet's back plate; or

(b) 2 suitably sized holes in the back plate and 2 suitably sized holes in the cabinet's base.

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5.3 Medicines cabinets—door requirements

(1) The door of a medicines cabinet must be constructed of black mild steel plate at least 10mm thick.

(2) When the medicines cabinet door is closed, the door must—

(a) fit flush with the cabinet; and

(b) have a clearance around the door of not more than 1.5mm.

(3) The door must be fitted with a fixed locking bar, welded to the inside face of the door near the hinge edge, that engages in a rebate in the cabinet when closed.

(4) The hinges on the door must be—

(a) constructed of heavy duty steel; and

(b) continuous welded to the door and body of the cabinet.

5.4 Medicines cabinets—lock requirements

(1) A medicines cabinet lock must be—

(a) a 6-lever pick-proof lock; or

(b) a lock mechanism of a level of security equal to, or greater than, a 6-lever pick-proof lock.

(2) The lock must be securely attached to the inside face of the door.

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5.5 Medicines cabinets—mounting requirements

(1) A medicines cabinet must be—

(a) embedded in a floor of reinforced concrete of at least 10mpa compressive strength; or

(b) securely fixed to a wall or floor (or both) in accordance with this section.

(2) If the wall and floor are brick or concrete, the medicines cabinet must be fixed to the wall or floor (or both) by at least 4 expanding bolts.

(3) If the wall is timber, but the floor is brick or concrete, the medicines cabinet must be fixed—

(a) to the floor by at least 4 expanding bolts; and

(b) to the wall by at least 2 coach screws into the studs as close to the top of the wall face as is possible.

(4) If the wall and floor are timber, the medicines cabinet must be fixed to the timber frame of the wall or floor in a way that will ensure that the cabinet cannot be removed from the floor or wall within 30 minutes.

(5) The bolts and coach screws must be at least 10mm in diameter.

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Part 5.2 Safes, strong rooms and vaults

5.6 Requirements for safes

(1) A safe must be constructed to prevent ready access to the safe's contents by cutting, sawing or unbolting.

(2) When locked, a safe must reasonably be expected to resist attempts to gain entry by tools, torch or explosives for at least 30 minutes.

(3) A safe—

(a) may be freestanding if it weighs more than 350kg; or

(b) must be securely attached to, or embedded in, a concrete floor or a concrete or brick wall in a way that will ensure that the cabinet cannot be removed from the floor or wall within 30 minutes.

5.7 Requirements for strong rooms

(1) The walls, floor and ceiling of a strong room must be brick or concrete.

(2) The strong room must be fitted with a door.

(3) When locked, the strong room must reasonably be expected to resist attempts to gain entry by tools, torch or explosives for at least 1 hour.

5.8 Requirements for vaults

(1) The walls, floor and ceiling of a vault must be reinforced concrete.

(2) The vault must be fitted with a door.

(3) When locked, the vault must reasonably be expected to resist attempts to gain entry by tools, torch or explosives for at least 1 hour.

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Dictionary

(see s 3)

Note 1 The Legislation Act contains definitions and other provisions relevant to this regulation.

Note 2 For example, the Legislation Act, dict, pt 1, defines the following terms:

- AS/NZS (see s 164 (2))
- child
- correctional centre
- doctor
- enrolled nurse
- home address
- nurse
- nurse practitioner
- optometrist
- public employee
- reviewable decision notice.

Note 3 Terms used in this regulation have the same meaning that they have in the *Medicines, Poisons and Therapeutic Goods Act 2008* (see Legislation Act, s 148). For example, the following terms are defined in the *Medicines, Poisons and Therapeutic Goods Act 2008*, dictionary:

- controlled medicine (see s 11)
- dangerous poison (see s 12)
- deals, with a regulated substance (see s 19)
- deals, with a regulated therapeutic good (see s 21)
- health practitioner
- hospital
- institution
- medicines and poisons standard (see s 15)
- prescription only medicine (see s 11)
- prohibited substance (see s 13)
- purchase order

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- regulated substance (see s 10)
- residential aged care facility
- signs
- supply (see s 24)
- supply authority (see s 23)
- ward
- written.

appendix D medicines approval—see section 590.

approved analyst means—

(a) an analyst appointed under the *Public Health Act 1997*, section 15 who is authorised under that Act to exercise a function under the Act; or

(b) an analyst appointed or authorised under another territory law or a law of the Commonwealth, a State or another Territory.

approved pharmacist—see the *National Health Act 1953* (Cwlth), section 84 (1), as in force from time to time.

Note The *National Health Act 1953* (Cwlth) does not need to be notified under the Legislation Act because s 47 (6) does not apply (see s 863).

Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8 means the *Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8* prepared by the National Coordinating Committee on Therapeutic Goods, as in force from time to time.

Note The Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 and 8 is accessible at www.tga.gov.au.

authorised midwife—see the *National Health Act 1953* (Cwlth), section 84 (1), definition of ***authorised midwife.***

bioequivalent—a form of a substance is the ***bioequivalent*** of another form of the substance if the forms are physiologically equivalent in their clinical effect.

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chief pharmacist, for an institution with a pharmacy, means the pharmacist having the supervision of all other pharmacists employed at the institution.

CHO means chief health officer.

community pharmacy means a pharmacy at a place other than an institution.

complying purchase order means—

(a) for a medicine—a purchase order that complies with section 62; or

(b) for a dangerous poison—a purchase order that complies with section 721; or

(c) for a schedule 10 substance or prohibited substance—see section 772.

condition 1, for a doctor prescribing or supplying a designated appendix D medicine to a woman of child-bearing age, for schedule 3 (Designated appendix D medicines—standing approvals)—see schedule 3, section 3.1.

condition 2, for a doctor prescribing or supplying a designated appendix D medicine to a woman of child-bearing age, for schedule 3—see schedule 3, section 3.1.

condition 3, for a doctor prescribing or supplying a designated appendix D medicine to a woman of child-bearing age, for schedule 3—see schedule 3, section 3.1.

condition 4, for a doctor prescribing or supplying a designated appendix D medicine to a woman of child-bearing age, for schedule 3—see schedule 3, section 3.1.

continued dispensing determination means a determination made by the Minister under the *National Health Act 1953* (Cwlth), section 89A (When pharmaceutical benefits may be supplied by approved pharmacists without prescription), as in force from time to

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time, about the supply of a pharmaceutical benefit to a person by an approved pharmacist without a prescription.

Note See the *National Health (Continued Dispensing) Determination 2012* (Cwlth). The determination does not need to be notified under the Legislation Act because s 47 (6) does not apply (see s 863).

controlled medicines approval—see section 550.

controlled medicines register means a register for controlled medicines.

controlled medicines research and education program licence—see section 600.

custodian, of an animal, means—

(a) an adult who has lawful custody of the animal; or

(b) if the animal is owned by a child or a person with a guardian—a parent or guardian of the child or person.

CYP authorised person—see the *Children and Young People Act 2008*, dictionary, definition of ***authorised person***.

CYP detention place means a detention place under the *Children and Young People Act 2008*.

dangerous poisons manufacturers licence—see section 700.

dangerous poisons register means a register for dangerous poisons.

dangerous poisons research and education program licence—see section 700.

dangerous poisons suppliers licence—see section 700.

day hospital means a facility where a person is admitted for surgical or medical treatment and discharged on the same day.

dentist does not include a trainee dentist.

Note See the definition of ***trainee***.

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designated appendix D medicine means a medicine listed in schedule 3, (Designated appendix D medicines—standing approvals), part 3.2, column 3.

Note The medicines are included in the medicines and poisons standard, appendix D.

designated prescriber, for part 13.1 (Controlled medicines approvals)—see section 551.

designated prescription only medicine, for part 4.3 (Authorisation to supply without prescription in emergencies)—see section 250.

detainee—see the *Corrections Management Act 2007*, section 6.

disability care means care that is provided to a person with a disability in a residential facility in which the person is also provided with accommodation that includes—

(a) appropriate staff to meet the nursing and personal care needs of the person; and

(b) meals and cleaning services; and

(c) furnishings, furniture and equipment for the provision of the care and accommodation.

doctor does not include an intern doctor.

Note See the definition of ***intern***.

drug-dependent person, in relation to a controlled medicine or prohibited substance, means a person with a condition—

(a) who, as a result of the administration of the medicine or substance, demonstrates, in relation to the person's use of the medicine or substance—

(i) impaired control; or

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(ii) drug-seeking behaviour that suggests impaired control; and

(b) who, as a result of the cessation of the administration of the medicine or substance, is likely to experience symptoms of mental or physical distress or disorder.

eligible midwife—see the *National Health Act 1953* (Cwlth), section 84AAE**.**

endorsement, for division 13.1.4 (Endorsements to treat drug-dependency)—see section 580.

environmental authorisation means—

(a) an environmental authorisation under the *Environment Protection Act 1997*; or

(b) an authorisation (however described) under a Commonwealth or State law that corresponds to the environmental authorisation mentioned in paragraph (a).

first-aid kit includes a portable bag or container of medicines and other medical supplies kept by a person for health care or emergency treatment.

first-aid kit licence—see section 600.

health profession includes—

(a) a health profession under the *Health Practitioner Regulation National Law (ACT)*, section 5; and

(b) the veterinary surgeons profession under the *Veterinary Surgeons Act 2015*.

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in-patient, at an institution, includes—

(a) a patient being treated at an emergency department of the institution; and

(b) for a correctional centre—a detainee; and

(c) for a CYP detention place—a young detainee.

Note A correctional centre and a CYP detention place is an institution (see s 652).

intern, in relation to a doctor or pharmacist, means—

(a) for a doctor—a person holding limited or provisional registration to practise in the medical profession under the *Health Practitioner Regulation National Law (ACT)*, for the purpose of undertaking a period of supervised practice that the person has started; and

(b) for a pharmacist—a person holding limited or provisional registration to practise in the pharmacy profession under the *Health Practitioner Regulation National Law (ACT)*, for the purpose of undertaking a period of supervised practice or course of training, or both, to allow the person to be registered to practice without supervision.

key, for chapter 11 (Storage of medicines)—see section 511.

manufacturer's pack means a primary pack for a medicine that is supplied by a manufacturer.

Note See the definition of ***primary pack***.

medical records includes—

(a) for a person at an institution—the person's clinical records and a medication chart for the person at the institution; and

(b) for a person who is not at an institution and is being treated by a prescriber—any record the prescriber keeps about the person.

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medicines Australia code of conduct means the *Medicines Australia Code of Conduct*, authorised by the Australian Competition and Consumer Commission, as in force from time to time.

Note The Medicines Australia Code of Conduct is accessible at www.medicinesaustralia.com.au.

medicines wholesalers licence—see section 600.

national residential medication chart prescription means a medication chart prescription within the meaning of the *National Health (Pharmaceutical Benefits) Regulations 1960* (Cwlth), section 19AA (Item in residential medication chart is prescription), as in force from time to time.

Note The *National Health (Pharmaceutical Benefits) Regulations 1960* (Cwlth) does not need to be notified under the Legislation Act because s 47 (6) does not apply (see s 863).

nurse practitioner, for chapter 11 and chapter 12, does not include a person holding limited or provisional registration to practise as a nurse practitioner.

opioid dependency treatment guidelines means the guidelines approved under section 630 (Guidelines for treatment of opioid dependency).

opioid dependency treatment licence—see section 600.

optical device, for chapter 22 (Therapeutic goods)—see section 800.

personal custody, of a key by a person, for part 11.4 (Additional storage requirements for controlled medicines)—see section 530.

pharmaceutical benefit—see the *National Health Act 1953* (Cwlth), section 84 (1), as in force from time to time.

Note The *National Health Act 1953* (Cwlth) does not need to be notified under the Legislation Act because s 47 (6) does not apply (see s 863).

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pharmaceutical benefits scheme means the scheme for the supply of pharmaceutical benefits established under the *National Health Act 1953* (Cwlth), part 7.

pharmacist does not include an intern pharmacist.

Note See the definition of ***intern***.

pharmacy medicines rural communities licence—see section 600.

prescribed person, for chapter 11 (Storage of medicines)—see section 510.

prescriber, in relation to a medicine, means a person in relation to whom prescribing the medicine is included in schedule 1, column 3 in relation to the person.

prescription, in relation to an optical device, for chapter 22 (Therapeutic Goods)—see section 800.

Note ***Prescription***, in relation to a medicine—see the Act, dictionary.

primary pack means the pack in which a regulated substance and its immediate container or immediate wrapper or measure pack are presented for sale or supply.

Note This is the same as the definition in the medicines and poisons standard, par 1 (l), and is included because of its relationship to the meaning of ***manufacturer's pack***. Other terms defined in the standard have the same meaning in this regulation, see the Act, s 16 (1).

prohibited substance, for chapter 21 (Prohibited and schedule 10 substances)—see section 760.

prohibited substances register means a register for prohibited substances.

prohibited substances research and education program licence—see section 761.

pseudoephedrine record—see section 171 (c).

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recognised research institution—see the Act, section 20 (5).

relevant expiry date, for a medicine, means—

(a) if the medicine is from 1 batch—the expiry date for the batch; or

(b) if the medicine is from more than 1 batch—the expiry date that is closest to the date of dispensing.

relevant law—

(a) for chapter 16 (Low and moderate harm poisons)—see section 660; and

(b) for part 19.3 (Packaging and labelling of dangerous poisons)—see section 730.

requisition includes issue a requisition.

reviewable decision, for chapter 23 (Notification and review of decisions)—see section 850.

retail sale, for division 4.2.7 (Selling pseudoephedrine by retail)—see section 170.

schedule 1—a reference to ***schedule 1*** includes a reference to a provision of the schedule.

scientifically qualified person means—

(a) a dentist, doctor, pharmacist, or veterinary surgeon; or

(b) a person who has been awarded a doctorate for scientific studies by the person.

Note ***Dentist***, ***doctor***, ***pharmacist*** and ***veterinary surgeon*** does not include an intern or trainee (see defs of these terms).

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scope of employment includes scope of engagement as a contractor.

specialist means—

(a) a person holding specialist registration to practise in the medical profession under the *Health Practitioner Regulation National Law (ACT)*; or

(b) a person holding limited or provisional registration to practise in the medical profession under the *Health Practitioner Regulation National Law (ACT)*, for the purpose of undertaking a period of supervised practice under the supervision of a person mentioned in paragraph (a), the successful completion of which means that the person is eligible for specialist registration under that Law.

specialist area, for a health profession, means a recognised speciality under the *Health Practitioner Regulation National Law (ACT)*.

terminal illness—a person has a ***terminal illness*** if a specialist diagnoses the person as having a terminal illness and estimates the person's life expectancy to be less than 1 year.

Note ***Specialist*** includes a doctor training in a specialist area (see def ***specialist***).

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trainee, in relation to a health practitioner (other than a doctor or pharmacist), means a person holding limited or provisional registration to practise in a health profession under the *Health Practitioner Regulation National Law (ACT)* for the purpose of undertaking a period of supervised practice or course of training, or both, to allow the person to be registered to practise without supervision.

Examples—references to trainee

- trainee dentist
- trainee nurse

Note 1 For doctors and pharmacists, see the definition of ***intern***.

Note 2 An example is part of the regulation, is not exhaustive and may extend, but does not limit, the meaning of the provision in which it appears (see Legislation Act, s 126 and s 132).

veterinary surgeon does not include a trainee veterinary surgeon.

Note See the definition of ***trainee***.

walk-in centre means a non-residential facility operated by the Territory for the treatment and care for people with minor illness or injury.

young detainee—see the *Children and Young People Act 2008*, section 95.

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Endnotes

1 About the endnotes

Amending and modifying laws are annotated in the legislation history and the amendment history. Current modifications are not included in the republished law but are set out in the endnotes.

Not all editorial amendments made under the *Legislation Act 2001*, part 11.3 are annotated in the amendment history. Full details of any amendments can be obtained from the Parliamentary Counsel's Office.

Uncommenced amending laws are not included in the republished law. The details of these laws are underlined in the legislation history. Uncommenced expiries are underlined in the legislation history and amendment history.

If all the provisions of the law have been renumbered, a table of renumbered provisions gives details of previous and current numbering.

The endnotes also include a table of earlier republications.

2 Abbreviation key

A = Act
AF = Approved form
am = amended
amdt = amendment
AR = Assembly resolution
ch = chapter
CN = Commencement notice
def = definition
DI = Disallowable instrument
dict = dictionary
disallowed = disallowed by the Legislative Assembly
div = division
exp = expires/expired
Gaz = gazette
hdg = heading
IA = Interpretation Act 1967
ins = inserted/added
LA = Legislation Act 2001
LR = legislation register
LRA = Legislation (Republication) Act 1996
mod = modified/modification
NI = Notifiable instrument
o = order
om = omitted/repealed
ord = ordinance
orig = original
par = paragraph/subparagraph
pres = present
prev = previous
(prev...) = previously
pt = part
r = rule/subrule
reloc = relocated
renum = renumbered
R[X] = Republication No
RI = reissue
s = section/subsection
sch = schedule
sdiv = subdivision
SL = Subordinate law
sub = substituted
<u>underlining</u> = whole or part not commenced or to be expired

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3 Legislation history

Medicines, Poisons and Therapeutic Goods Regulation 2008 SL2008-42

notified LR 15 September 2008
s 1, s 2 commenced 15 September 2008 (LA s 75 (1))
remainder commenced 14 February 2009 (s 2 and see Medicines, Poisons and Therapeutic Goods Act 2008 A2008-26, s 2 and LA s 79)

as amended by

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2009 (No 1) SL2009-27

notified LR 5 June 2009
s 1, s 2 commenced 5 June 2009 (LA s 75 (1))
remainder commenced 6 June 2009 (s 2)

Statute Law Amendment Act 2009 (No 2) A2009-49 sch 3 pt 3.51

notified LR 26 November 2009
s 1, s 2 commenced 26 November 2009 (LA s 75 (1))
sch 3 pt 3.51 commenced 17 December 2009 (s 2)

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2010 (No 1) SL2010-1

notified LR 21 January 2010
s 1, s 2 commenced 21 January 2010 (LA s 75 (1))
remainder commenced 22 January 2010 (s 2)

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2010 (No 2) SL2010-2

notified LR 21 January 2010
s 1, s 2 commenced 21 January 2010 (LA s 75 (1))
remainder commenced 22 January 2010 (s 2)

Health Practitioner Regulation National Law (ACT) Act 2010 A2010-10 sch 2 pt 2.15

notified LR 31 March 2010
s 1, s 2 commenced 31 March 2010 (LA s 75 (1))
sch 2 pt 2.15 commenced 1 July 2010 (s 2 (1) (a))

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Medicines, Poisons and Therapeutic Goods Amendment Regulation 2010 (No 3) SL2010-16

notified LR 10 May 2010
s 1, s 2 commenced 10 May 2010 (LA s 75 (1))
sch 1 commenced 1 July 2010 (s 2 (2) and see Health Practitioner Regulation National Law (ACT) Act 2010 A2010-10 s 2 (1) (a))
remainder commenced 11 May 2010 (s 2 (1))

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2010 (No 4) SL2010-20

notified LR 3 June 2010
s 1, s 2 commenced 3 June 2010 (LA s 75 (1))
remainder commenced 1 July 2010 (s 2 and see Health Practitioner Regulation National Law (ACT) Act 2010 A2010-10 s 2 (1) (a))

Liquor (Consequential Amendments) Act 2010 A2010-43 sch 1 pt 1.14

notified LR 8 November 2010
s 1, s 2 commenced 8 November 2010 (LA s 75 (1))
sch 1 pt 1.14 commenced 1 December 2010 (s 2 (4) and see Liquor Act 2010 A2010-35, s 2 (3) (as am by A2010-43 amdt 1.19) and CN2010-14)

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2010 (No 5) SL2010-45

notified LR 22 November 2010
s 1, s 2 commenced 22 November 2010 (LA s 75 (1))
remainder commenced 23 November 2010 (s 2)

Justice and Community Safety Legislation Amendment Act 2010 (No 4) A2010-50 sch 1 pt 1.6

notified LR 14 December 2010
s 1, s 2 commenced 14 December 2010 (LA s 75 (1))
sch 1 pt 1.6 commenced 21 December 2010 (s 2 (1))

Statute Law Amendment Act 2011 (No 3) A2011-52 sch 1 pt 1.5

notified LR 28 November 2011
s 1, s 2 commenced 28 November 2011 (LA s 75 (1))
sch 1 pt 1.5 commenced 12 December 2011 (s 2)

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Medicines, Poisons and Therapeutic Goods Amendment Regulation 2012 (No 1) SL2012-5

notified LR 9 February 2012
s 1, s 2 commenced 9 February 2012 (LA s 75 (1))
remainder commenced 10 February 2012 (s 2)

Medicines, Poisons and Therapeutic Goods (Prescribing Authorisation—Optometrists) Amendment Regulation 2012 (No 1) SL2012-34

notified LR 2 August 2012
s 1, s 2 commenced 2 August 2012 (LA s 75 (1))
remainder commenced 3 August 2012 (s 2)

Medicines, Poisons and Therapeutic Goods (Kava Exemption) Amendment Regulation 2013 (No 1) SL2013-1

notified LR 25 January 2013
s 1, s 2 commenced 25 January 2013 (LA s 75 (1))
remainder commenced 26 January 2013 (s 2)

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2013 (No 1) SL2013-24

notified LR 29 August 2013
s 1, s 2 commenced 29 August 2013 (LA s 75 (1))
remainder commenced 1 September 2013 (s 2)

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2013 (No 2) SL2013-28

notified LR 4 November 2013
s 1, s 2 commenced 4 November 2013 (LA s 75 (1))
remainder commenced 5 November 2013 (s 2)

Statute Law Amendment Act 2013 (No 2) A2013-44 sch 1 pt 1.3

notified LR 11 November 2013
s 1, s 2 commenced 11 November 2013 (LA s 75 (1))
sch 1 pt 1.3 commenced 25 November 2013 (s 2)

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Medicines, Poisons and Therapeutic Goods Amendment Regulation 2014 (No 1) SL2014-23

notified LR 25 September 2014
s 1, s 2 commenced 25 September 2014 (LA s 75 (1))
s 11 commenced 1 October 2014 (s 2 (2))
remainder commenced 26 September 2014 (s 2 (1))

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2014 (No 2) SL2014-26

notified LR 22 October 2014
s 1, s 2 commenced 22 October 2014 (LA s 75 (1))
remainder commenced 23 October 2014 (s 2)

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2015 (No 1) SL2015-19

notified LR 21 May 2015
s 1, s 2 commenced 21 May 2015 (LA s 75 (1))
s 5 commenced 21 July 2015 (s 2 (2))
remainder commenced 22 May 2015 (s 2 (1))

Veterinary Surgeons Act 2015 A2015-29 sch 2 pt 2.10

notified LR 20 August 2015
s 1, s 2 commenced 20 August 2015 (LA s 75 (1))
sch 2 pt 2.10 commenced 1 December 2015 (s 2 (1) and CN2015-22)

Mental Health Act 2015 A2015-38 sch 2 pt 2.4 div 2.4.11

notified LR 7 October 2015
s 1, s 2 commenced 7 October 2015 (LA s 75 (1))
sch 2 pt 2.4 div 2.4.11 commences 1 March 2016 (s 2 (1) and see Mental Health (Treatment and Care) Amendment Act 2014 A2014-51, s 2 (as am by A2015-38 amdt 2.54))

Authorised by the ACT Parliamentary Counsel—also accessible at www.legislation.act.gov.au

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2015 (No 2) SL2015-36

notified LR 23 November 2015
s 1, s 2 commenced 23 November 2015 (LA s 75 (1))
remainder commenced 24 November 2015 (s 2)

Statute Law Amendment Act 2015 (No 2) A2015-50 sch 1 pt 1.3, sch 3 pt 3.24

notified LR 25 November 2015
s 1, s 2 commenced 25 November 2015 (LA s 75 (1))
sch 1 pt 1.3, sch 3 pt 3.24 commenced 9 December 2015 (s 2)

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4 Amendment history

Commencement

s 2 om LA s 89 (4)

Dictionary

s 3 am A2015-29 amdt 2.73

General overview of authorisations for medicines

s 10 am A2010-10 amdt 2.85

Overview of medicines authorisations under this regulation

s 11 am SL2010-2 s 4; pars renum R4 LA; SL2013-28 s 4; pars renum R17 LA; SL2014-23 s 11; SL2015-19 s 4

General overview of authorisation conditions for medicines

s 12 am SL2012-34 s 4

Relationship with registration laws

pt 2.2 hdg sub A2010-10 amdt 2.86

Medicines authorisations subject to Health Practitioner Regulation National Law (ACT) restrictions

s 20 sub A2010-10 amdt 2.86
am A2015-29 amdt 2.74

Medicines authorisations subject to Veterinary Surgeons Act 2015 restrictions

s 21 ins A2010-10 amdt 2.86
sub A2015-29 amdt 2.75

Authorisation under sch 1 to prescribe medicines—Act, s 40 (1) (b), (2) (b) and (3) (b)

s 30 am SL2010-45 s 4

Authorisation conditions for prescribing medicines—Act, s 44 (1) (b) and (2) (b)

s 31 am SL2013-28 ss 5-7; pars renum R17 LA

Particulars for prescriptions

s 41 am SL2010-1 s 4; SL2010-45 s 5; pars renum R8 LA; SL2013–28 s 8; ss renum R17 LA

Standing orders for walk-in centre

div 3.4.3 hdg ins SL2010-2 s 5

Authorisation of CHO to issue standing orders for supply and administration of medicines at walk-in centre—Act, s 42 (b)

s 77 ins SL2010-2 s 5

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Particulars for CHO standing orders for supply and administration of medicines at walk-in centre
s 78 ins SL2010-2 s 5

Information for CHO about controlled medicines supplied on supply authorities—Act, s 31 (1) (b) and (4), def *required information*
s 81 am SL2015-19 s 5

Overview of supply authorisations for medicines
s 100 am SL2013–28 s 9; pars renum R17 LA

Authorisation under sch 1 to supply medicines—Act, s 26 (1) (b) and (2) (b)
s 110 am A2010-10 amdt 2.87; A2013-44 amdt 1.31

Authorisation conditions for dispensing medicines—Act, s 44 (1) (b) and (2) (b)
s 120 am SL2013–28 s 10

How medicines are dispensed
s 121 am A2010-10 amdt 2.88, amdt 2.89; A2015-50 amdt 3.126

Labelling dispensed medicines—Act, s 60 (1) (c) (i) and (2) (c) (i)
s 123 am SL2010-45 s 6; pars renum R8 LA

Marking dispensed prescriptions
s 124 am SL2013–28 s 11, s 12

Labelling medicines supplied during consultations
s 161 am SL2010-45 s 7; pars renum R8 LA

Required information for pseudoephedrine sales records
s 173 am A2010-43 amdt 1.57

Authorisation to supply certain medicines without prescription—continued dispensing
pt 4.3A ins SL2013–28 s 13

Authorisation to supply certain medicines without prescription by approved pharmacist––Act, s 185 (1) (g)
s 255 ins SL2013–28 s 13

Labelling certain medicines supplied without prescription by approved pharmacist––Act, s 185 (1) (j)
s 256 ins SL2013–28 s 13

Conditions for wholesalers supplying medicines under corresponding laws—Act, s 20 (4) (c)
s 270 am SL2014-23 s 4, s 5

Authorisation for self-administration etc of medicines—Act, s 37 (2) (b) and (3) (b)
s 360 am SL2010-45 s 8

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Authorisations to deliver medicines under supply authorities—Act, s 26 (1) (b), (2) (b), s 35 (1) (b), (2) (b) and s 36 (b)
s 400 am A2010-10 amdts 2.90-2.92; A2015-29 amdts 2.76-2.78

Authorisation conditions for medicines wholesalers licences—Act, s 44 (1) (b) and (2) (b)
s 461 am SL2014-23 s 6, s 7

Authorisations for endorsed health practitioners
pt 9.6 hdg ins SL2015-19 s 6

Authorisations for endorsed health practitioners—Act, s 20 (1) (d)
s 490 ins SL2015-19 s 6

When pharmacy medicines and pharmacist only medicines to be supplied in manufacturer's packs—Act, s 59 (1) (c) (i) and (2) (c) (i)
s 500 am A2010-10 amdt 2.93; A2015-29 amdts 2.79-2.81

Packaging of supplied manufacturer's packs of medicines—Act, s 59 (1) (c) (i) and (2) (c) (i)
s 501 am A2015-50 amdt 1.10

Labelling of supplied manufacturer's packs of medicines—Act, s 60 (1) (c) (i) and (2) (c) (i)
s 502 am A2015-50 amdt 1.11

Meaning of *prescribed person*—ch 11
s 510 am SL2010-16 s 4, s 5, amdt 1.1; SL2010-45 s 9

Storage of controlled medicines for certain health-related occupations—Act, s 61 (b) and (c)
s 532 am SL2010-16 s 6, s 7, amdt 1.1

Storage of controlled medicines by certain other prescribed people—Act, s 61 (b) and (c)
s 533 am SL2010-16 s 8

Keeping of controlled medicines registers by certain people—Act, s 48 (a) and s 50 (1) (b) and (2) (b)
s 540 table 540 am SL2010-16 s 9

Keeping of controlled medicines registers by first-aid kit holders—Act, s 48 (a) and s 50 (1) (b) and (2) (b)
s 541 am SL2010-16 s 10, s 11, amdt 1.1

Prescribed witnesses for administration of controlled medicines—Act, s 53 (a) and (b)
s 544 am SL2010-20 s 4

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Standing interim approval to prescribe buprenorphine and methadone for patients of certain institutions

s 557 hdg sub SL2010-1 s 5
s 557 am SL2010-1 s 6; pars renum R4 LA; SL2014-26 s 4

Restrictions on CHO power to approve applications for approvals

s 563 am SL2010-1 s 7; SL2014-26 s 5

Medicines advisory committee—referred applications and review of unfavourable CHO decisions

s 566 am SL2014-26 s 6

Amendment and revocation of controlled medicines approvals

s 567 am SL2014-26 s 7

Application for review of amendment and revocation on CHO initiative

s 568 am SL2014-26 s 8

Medicines advisory committee—review of amendment or revocation on CHO initiative

s 569 am SL2014-26 s 9

Conditional controlled medicines approvals

s 570 am SL2014-26 s 10

Medicines advisory committee—recommendations to CHO

s 573 hdg sub SL2014-26 s 11
s 573 am SL2014-26 s 12, s 13

Guidelines for CHO decisions on applications

s 574 sub SL2014-26 s 14

Medicines advisory committee—review of CHO decisions to refuse endorsements to treat drug-dependency

s 584 am SL2014-26 s 15

First-aid kit licences

pt 14.3 hdg note am A2010-10 amdt 2.104; A2015-29 amdt 2.82

Additional information for first-aid kit licences—Act, s 88 (1) (k)

s 612 am A2009-49 amdt 3.121

Medicines advisory committee—membership

s 635 am SL2014-26 ss 16-19; ss and pars renum R21 LA

Medicines advisory committee—quorum

s 640 am SL2014-26 s 20

Medicines advisory committee—disclosure of interests by members

s 643 am SL2014-26 s 21, s 22

Medicines advisory committee—ending appointments

s 644 am A2011-52 amdt 1.8; SL2014-26 s 23; pars renum R21 LA

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Advertising controlled medicines—Act, s 66 (3) (b)
s 650 am SL2014-23 s 8

Packaging of supplied manufacturer's packs of low and moderate harm poisons—Act, s 59 (1) (c) (i) and (2) (c) (i)
s 665 am A2015-50 amdt 1.12

Labelling of supplied manufacturer's packs of low and moderate harm poisons—Act, s 60 (1) (c) (i) and (2) (c) (i)
s 666 am A2015-50 amdt 1.13

Authorisation conditions for dangerous poisons manufacturers licences—Act, s 44 (1) (b) and (2) (b)
s 676 am A2015-50 amdt 1.14; pars renum R26 LA

Authorisation conditions for dangerous poisons suppliers licences—Act, s 44 (1) (b) and (2) (b)
s 686 am A2015-50 amdt 1.14; pars renum R26 LA

Recording supply of dangerous poisons
s 722 sub A2015-50 amdt 1.15

Packaging of supplied manufacturer's packs of dangerous poisons—Act, s 59 (1) (c) (i) and (2) (c) (i)
s 731 am A2015-50 amdt 1.16

Labelling of supplied manufacturer's packs of dangerous poisons—Act, s 60 (1) (c) (i) and (2) (c) (i)
s 732 am A2015-50 amdt 1.17

Storage of dangerous poisons—Act, s 61 (b) and (c)
s 735 am A2015-50 amdt 1.18

Manufacture, supply and use of paints for certain purposes—Act, s 71 (1) and (3)
s 751 am A2015-50 amdt 1.19, amdt 1.20

Manufacture, supply and use of paints for toys—Act, s 72 (b)
s 752 am SL2013–28 s 14, s 15
sub A2015-50 amdt 1.21

Manufacture, supply and use of paints containing pesticides—Act, s 73 (b)
s 753 sub A2015-50 amdt 1.22

Prohibited and schedule 10 substances
ch 21 hdg am A2015-50 amdt 1.23

Meaning of *prohibited substance*—ch 21
s 760 am A2015-50 amdt 1.24, amdt 1.25

Meaning of *reviewable decision*—ch 23
s 850 am SL2009-27 s 4

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Reviewable decision notices
s 851 sub SL2009-27 s 5

Applications for review
s 852 sub SL2009-27 s 5

Other authorisations for public employees—Act, s 20 (1) (a), (2) (a) and s 74 (1) (b)
s 861 am SL2010-45 s 10

Displacement of Legislation Act, s 47 (6)
s 863 am SL2012-34 s 5, s 6
sub SL2013–28 s 16
am SL2014-23 s 9, s 10; pars renum R19 LA; SL2015-19 s 7; pars renum R22 LA; A2015-50 amdt 1.26, amdt 1.27; pars renum R26 LA

Exemption of piper methysticum (kava)—Act, s 190 (1) (a)
s 864 om LA s 89 (3)
ins SL2012-5 s 4
exp 12 February 2012 (s 864 (3))
ins SL2013-1 s 4

Transitional
ch 30 hdg exp 31 March 2010 (s 1008)

Definitions—ch 30
s 1000 exp 31 March 2010 (s 1008)
def ***DODA*** exp 31 March 2010 (s 1008)
def ***PADA*** exp 31 March 2010 (s 1008)

DODA wholesaler's licences—Act, s 520 (2)
s 1001 exp 31 March 2010 (s 1008)

Poisons Act licences—Act, s 520 (2)
s 1002 exp 31 March 2010 (s 1008)

PADA licences—Act, s 520 (2)
s 1003 exp 31 March 2010 (s 1008)

DODA authorisations—Act, s 522 (2)
s 1004 exp 31 March 2010 (s 1008)

PADA authorisations—Act, s 522 (2)
s 1005 exp 31 March 2010 (s 1008)

Public Health (Prohibited Drugs) Act authorisations—Act, s 522 (2)
s 1006 exp 31 March 2010 (s 1008)

DODA approvals to prescribe drugs of dependence—Act, s 531 (2)
s 1007 exp 31 March 2010 (s 1008)

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Expiry—ch 30

s 1008	exp 31 March 2010 (s 1008)

Modification of Act

ch 31 hdg	ins SL2009-27 s 6 om A2010-50 amdt 1.13

Modification of Act, ch 14—Act, s 501 (2)

s 1100	ins SL2009-27 s 6 om A2010-50 amdt 1.13

Expiry—ch 31

s 1110	ins SL2009-27 s 6 om A2010-50 amdt 1.13

Dentists, dental hygienists, dental therapists and oral health therapists

sch 1 pt 1.2 hdg	sub SL2015-36 s 4
sch 1 pt 1.2	am A2010-10 amdt 2.104; SL2015-36 s 5, s 6

Doctors

sch 1 pt 1.3	am A2010-10 amdt 2.104

Health practitioners at institutions

sch 1 pt 1.4 hdg	sub A2015-29 amdt 2.83
sch 1 pt 1.4	sub A2010-10 amdt 2.94 am A2015-29 amdt 2.84

Midwives

sch 1 pt 1.5	am A2010-10 amdt 2.104; SL2010-45 s 11; A2015-29 amdt 2.85

Nurses

sch 1 pt 1.6	am SL2010-16 s 12; A2010-10 amdt 2.104; SL2010-20 s 5; items renum R7 LA

Opioid dependency treatment centres operated by Territory

sch 1 pt 1.7	am A2010-10 amdt 2.104

Optometrists

sch 1 pt 1.8	am A2010-10 amdt 2.95; SL2012-34 s 7; SL2015-19 s 8

Residential care facilities

sch 1 pt 1.11	am A2010-10 amdt 2.104

Optometry medicines

sch 2	am A2010-10 amdt 2.96 om SL2012-34 s 8

Designated appendix D medicines—standing approvals

sch 3	am SL2010-45 s 12; SL2013-24 s 4, s 5; SL2014-23 s 11

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Health Professionals Regulation 2004

sch 6 om LA s 89 (3)

Modification—Crimes Act 1900

sch 10 ins SL2009-27 s 7
om A2010-50 amdt 1.14

Dictionary

dict am SL2009-27 s 8; A2009-49 amdt 3.122; A2010-10 amdt 2.97, amdt 2.98; SL2013–28 s 17
def ***approved pharmacist*** ins SL2013–28 s 18
def ***Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8*** ins SL2014-23 s 12
def ***Australian code of good wholesaling practice for therapeutic goods for human use*** om SL2014-23 s 13
def ***authorised midwife*** ins SL2010-45 s 13
def ***chief pharmacist*** reloc from Medicines, Poisons and Therapeutic Goods Act 2008 dict by A2013-44 amdt 3.110
def ***complying purchase order*** am A2015-50 amdt 1.28
def ***continued dispensing determination*** ins SL2013–28 s 18
def ***drug-dependent person*** reloc from Medicines, Poisons and Therapeutic Goods Act 2008 dict by A2013-44 amdt 3.112
def ***eligible midwife*** ins SL2010-45 s 13
def ***enrolled nurse*** om SL2010-20 s 6
def ***enrolled nurse (medications)*** sub A2010-10 amdt 2.99
om SL2010-20 s 7
def ***health profession*** sub A2010-10 amdt 2.100
sub A2015-29 amdt 2.86
def ***health professional*** om A2015-29 amdt 2.87
def ***intern*** sub A2010-10 amdt 2.101
def ***medicines Australia code of conduct*** am SL2014-23 s 14
def ***national list*** ins SL2012-34 s 9
om SL2015-19 s 9
def ***national residential medication chart prescription*** ins SL2013–28 s 18
def ***nurse practitioner*** ins SL2010-16 s 13
am SL2010-16 amdt 1.1
def ***Optometry endorsement scheduled medicines registration standard*** ins SL2012-34 s 9; SL2014-23 s 15
om SL2015-19 s 9
def ***pharmaceutical benefit*** ins SL2013–28 s 18
def ***pharmaceutical benefits scheme*** ins SL2010-45 s 13
def ***prohibited substance*** am A2015-50 amdt 1.29
def ***specialist*** sub A2010-10 amdt 2.102

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def ***specialist area*** sub A2010-10 amdt 2.102
sub A2015-29 amdt 2.88
def ***trainee*** am A2010-10 amdt 2.103
sub A2015-29 amdt 2.89
def ***walk-in centre*** ins SL2010-2 s 6

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5 Earlier republications

Some earlier republications were not numbered. The number in column 1 refers to the publication order.

Since 12 September 2001 every authorised republication has been published in electronic pdf format on the ACT legislation register. A selection of authorised republications have also been published in printed format. These republications are marked with an asterisk (*) in column 1. Electronic and printed versions of an authorised republication are identical.

Republication No and date	Effective	Last amendment made by	Republication for
R1 14 Feb 2009	14 Feb 2009– 5 June 2009	not amended	new regulation
R2 6 June 2009	6 June 2009– 16 Dec 2009	SL2009-27	amendments by SL2009-27
R3 17 Dec 2009	17 Dec 2009– 21 Jan 2010	A2009-49	amendments by A2009-49
R4 22 Jan 2010	22 Jan 2010– 31 Mar 2010	SL2010-2	amendments by SL2010-1 and SL2010-2
R5 1 Apr 2010	1 Apr 2010– 10 May 2010	A2010-10	commenced expiry
R6 11 May 2010	11 May 2010– 30 June 2010	SL2010-16	amendments by SL2010-16
R7 1 July 2010	1 July 2010– 22 Nov 2010	SL2010-20	amendments by A2010-10, SL2010-16 and SL2010-20
R8 23 Nov 2010	23 Nov 2010– 30 Nov 2010	SL2010-45	amendments by SL2010-45
R9 1 Dec 2010	1 Dec 2010– 20 Dec 2010	SL2010-45	amendments by A2010-43
R10 21 Dec 2010	21 Dec 2010– 11 Dec 2011	A2010-50	amendments by A2010-50
R11 12 Dec 2011	12 Dec 2011– 9 Feb 2012	A2011-52	amendments by A2011-52

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5 Earlier republications

Republication No and date	Effective	Last amendment made by	Republication for
R12 10 Feb 2012	10 Feb 2012– 12 Feb 2012	SL2012-5	amendments by SL2012-5
R13 13 Feb 2012	13 Feb 2012– 2 Aug 2012	SL2012-5	expiry of provision (s 864)
R14 3 Aug 2013	3 Aug 2013– 25 Jan 2013	SL2012-34	amendments by SL2012-34
R15 26 Jan 2013	26 Jan 2013– 31 Aug 2013	SL2013-1	amendments by SL2013-1
R16 1 Sept 2013	1 Sept 2013– 4 Nov 2013	SL2013-24	amendments by SL2013-24
R17 5 Nov 2013	5 Nov 2013– 24 Nov 2013	SL2013-28	amendments by SL2013-28
R18 25 Nov 2013	25 Nov 2013– 25 Sept 2013	A2013-44	relocation of provisions from A2008-26 and other amendments by A2013-44
R19 26 Sept 2014	26 Sept 2014– 30 Sept 2014	SL2014-23	amendments by SL2014-23
R20 1 Oct 2014	1 Oct 2014– 22 Oct 2014	SL2014-23	amendments by SL2014-23
R21 23 Oct 2014	23 Oct 2014– 21 May 2015	SL2014-26	amendments by SL2014-26
R22 22 May 2015	22 May 2015– 20 July 2015	SL2015-19	amendments by SL2015-19
R23 21 July 2015	21 July 2015– 23 Nov 2015	SL2015-19	amendments by SL2015-19
R24 24 Nov 2015	24 Nov 2015– 30 Nov 2015	SL2015-36	amendments by SL2015-36
R25 1 Dec 2015	1 Dec 2015– 8 Dec 2015	SL2015-36	amendments by A2015-29

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