



Australian Capital Territory

# **Medicines, Poisons and Therapeutic Goods Act 2008**

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## About this republication

### The republished law

This is a republication of the *Medicines, Poisons and Therapeutic Goods Act 2008* (including any amendment made under the *Legislation Act 2001*, part 11.3 (Editorial changes)) as in force on 12 December 2011. It also includes any commencement, amendment, repeal or expiry affecting this republished law to 12 December 2011.

The legislation history and amendment history of the republished law are set out in endnotes 3 and 4.

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- authorised republications to which the *Legislation Act 2001* applies
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### Editorial changes

The *Legislation Act 2001*, part 11.3 authorises the Parliamentary Counsel to make editorial amendments and other changes of a formal nature when preparing a law for republication. Editorial changes do not change the effect of the law, but have effect as if they had been made by an Act commencing on the republication date (see *Legislation Act 2001*, s 115 and s 117). The changes are made if the Parliamentary Counsel considers they are desirable to bring the law into line, or more closely into line, with current legislative drafting practice.

This republication includes amendments made under part 11.3 (see endnote 1).

### Uncommenced provisions and amendments

If a provision of the republished law has not commenced, the symbol **U** appears immediately before the provision heading. Any uncommenced amendments that affect this republished law are accessible on the ACT legislation register ([www.legislation.act.gov.au](http://www.legislation.act.gov.au)). For more information, see the home page for this law on the register.

### Modifications

If a provision of the republished law is affected by a current modification, the symbol **M** appears immediately before the provision heading. The text of the modifying provision appears in the endnotes. For the legal status of modifications, see the *Legislation Act 2001*, section 95.

### Penalties

At the republication date, the value of a penalty unit for an offence against this law is \$110 for an individual and \$550 for a corporation (see *Legislation Act 2001*, s 133).



Australian Capital Territory

# Medicines, Poisons and Therapeutic Goods Act 2008

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Australian Capital Territory

# Medicines, Poisons and Therapeutic Goods Act 2008

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An Act to consolidate and reform the law relating to regulated substances and regulated therapeutic goods, to give effect to the medicines and poisons standard, and for other purposes

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## Chapter 1 Preliminary

### 1 Name of Act

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

### 3 Dictionary

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

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

For example, the signpost definition '*health professional*—see the *Health Professionals Act 2004*, section 14.' means that the term 'health professional' is defined in that section and the definition applies to this Act.

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

### 4 Notes

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

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



## 5 Offences against Act—application of Criminal Code etc

Other legislation applies in relation to offences against this Act.

*Note 1 Criminal Code*

The Criminal Code, ch 2 applies to all offences against this Act (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.

## Chapter 2 Operation of Act

### 6 Objects

- (1) The main object of this Act is to promote and protect public health and safety by minimising—
  - (a) accidental and deliberate poisonings by regulated substances; and
  - (b) medicinal misadventures related to regulated substances; and
  - (c) the diversion of regulated substances for abuse; and
  - (d) the manufacture of regulated substances that are subject to abuse; and
  - (e) harm from regulated therapeutic goods.
- (2) The objects of this Act also include ensuring that—
  - (a) consumers of prescription medicines have adequate information and the understanding necessary to allow them to use the medicines safely and effectively; and
  - (b) consumers of non-prescription medicines have adequate information and the understanding to allow them to select the most appropriate medicines for their condition and to use the medicines safely and effectively, taking into account the condition of their health.
- (3) In regulating the dealings of health professionals or health practitioners with regulated substances, the chief health officer may, but need not, choose to take disciplinary action rather than pursuing prosecutions under this Act if the chief health officer believes it would be in the public interest to do so.
- (4) In this section:  
***non-prescription medicine*** means a medicine other than a prescription medicine.

*prescription medicine* means a prescription only medicine or controlled medicine.

## **7 Appropriate prescription and supply of medicines**

- (1) A health professional or a health practitioner who prescribes or supplies a medicine must ensure that the prescription or supply of the medicine is for a quantity and purpose that is consistent with the recognised therapeutic standard of what is appropriate in the circumstances.
- (2) Subsection (1) does not apply to wholesale supply.

## **8 Obligations under other territory laws**

The obligations under this Act are additional to the obligations under any other territory law unless this Act, or the other law, provides otherwise.

### **Example**

If there is an obligation under the *Dangerous Substances Act 2004* and under this Act in relation to a particular substance, both obligations must be complied with in relation to the substance unless either Act provides otherwise.

*Note* An example is part of the Act, 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).

## **9 Inconsistency between Act and medicines and poisons standard**

This Act prevails if there is an inconsistency between this Act and the medicines and poisons standard.

*Note* 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).

## Chapter 3      Important concepts

### Part 3.1      Substances to which Act applies

#### 10      **Meaning of *regulated substance*—Act**

In this Act:

*regulated substance* means a medicine, poison, prohibited substance or appendix C substance.

#### 11      **Medicine-related definitions**

(1) In this Act:

*medicine* means—

- (a) a pharmacy medicine; or
- (b) a pharmacist only medicine; or
- (c) a prescription only medicine; or
- (d) a controlled medicine.

(2) In this Act:

*controlled medicine* means a substance to which the medicines and poisons standard, schedule 8 applies.

*Note*      Schedule 8 medicines are prescription medicines that have additional restrictions to reduce misuse or dependence. The schedule includes some derivatives of the scheduled medicines (see s 16 (2)).

*pharmacist only medicine* means a substance to which the medicines and poisons standard, schedule 3 applies.

*Note*      Schedule 3 medicines are medicines that require advice from a pharmacist to be used safely. The schedule includes some derivatives of the scheduled medicines (see s 16 (2)).

***pharmacy medicine*** means a substance to which the medicines and poisons standard, schedule 2 applies.

*Note* Schedule 2 medicines are medicines that may require advice from a pharmacist to be used safely. The schedule includes some derivatives of the scheduled medicines (see s 16 (2)).

***prescription only medicine*** means a substance to which the medicines and poisons standard, schedule 4 applies.

*Note* Schedule 4 medicines are medicines (including prescription animal remedies) that are available from a pharmacy on prescription. The schedule includes some derivatives of the scheduled medicines (see s 16 (2)).

## 12 Poison-related definitions

(1) In this Act:

***poison*** means—

- (a) a low harm poison; or
- (b) a moderate harm poison; or
- (c) a dangerous poison.

(2) In this Act:

***dangerous poison*** means a substance to which the medicines and poisons standard, schedule 7 applies.

*Note* Schedule 7 applies to substances with a high potential for causing harm. The schedule includes some derivatives of the scheduled substances (see s 16 (2)).

***low harm poison*** means a substance to which the medicines and poisons standard, schedule 5 applies.

*Note* Schedule 5 applies to substances with a low potential for causing harm. The schedule includes some derivatives of the scheduled substances (see s 16 (2)).

***moderate harm poison*** means a substance to which the medicines and poisons standard, schedule 6 applies.

*Note* Schedule 6 applies to substances with a moderate potential for causing harm. The schedule includes some derivatives of the scheduled substances (see s 16 (2)).

### 13 **Meaning of *appendix C substance* and *prohibited substance*—Act**

In this Act:

***appendix C substance*** means a substance to which the medicines and poisons standard, appendix C applies.

*Note* Appendix C substances are substances, other than those in sch 9, the sale, supply and use of which is prohibited because of the degree of danger to health they represent. The appendix includes some derivatives of the substances to which the appendix applies (see s 16 (2)).

***prohibited substance*** means a substance to which the medicines and poisons standard, schedule 9 applies.

*Note* Schedule 9 substances are generally illegal substances that are subject to abuse. They include some derivatives of the scheduled substances (see s 16 (2)).

## Part 3.2                      Therapeutic goods to which Act applies

### 14                      Meaning of *regulated therapeutic good*—Act

In this Act:

*regulated therapeutic good* means—

- (a) any of the following within the meaning of the *Therapeutic Goods Act 1989* (Cwlth) as prescribed by regulation:
  - (i) a therapeutic good (other than a regulated substance);
  - (ii) a medical device;
  - (iii) a therapeutic device; or
- (b) anything else (other than a regulated substance) prescribed by regulation.

## Part 3.3 Medicines and poisons standard

### 15 Meaning of *medicines and poisons standard*—Act

- (1) In this Act:

*medicines and poisons standard* means the poisons standard, as in force from time to time and as modified by regulation (if any).

*Note* For the public availability and inspection of a copy of the medicines and poisons standard, see s 18.

- (2) For subsection (1), but subject to any modification prescribed by regulation—

(a) an amendment of a current poisons standard takes effect on the date notified under the *Therapeutic Goods Act 1989* (Cwlth), section 52D (4) (b); and

(b) a new poisons standard takes effect on the date of effect notified under the *Therapeutic Goods Act 1989* (Cwlth), section 52D (3) (b).

- (3) In this section:

*current poisons standard*—see the *Therapeutic Goods Act 1989* (Cwlth), section 52A, definition of *current Poisons Standard*.

*new poisons standard* means a document prepared under the *Therapeutic Goods Act 1989* (Cwlth), section 52D (2) (b).

*poisons standard* means a document made under the *Therapeutic Goods Act 1989* (Cwlth), section 52D (2).



## 16 Interpretation provisions in medicines and poisons standard—application to Act

- (1) A term defined in the medicines and poisons standard (other than the definition of *poison*) has the same meaning in this Act.

*Note* The medicines and poisons standard uses the term ‘poison’ for any substance or preparation (whether it is a medicine, poison or prohibited substance) included in a schedule to the standard (see medicines and poisons standard, pt 1, def *poison*).

- (2) A provision of the medicines and poisons standard relating to the interpretation of the standard applies in the interpretation of this Act.

### Example

If the medicines and poisons standard provides that, subject to stated exceptions, a reference to a substance in a schedule or appendix to the standard includes every salt, active principle or derivative of the substance, then a reference to the substance in this Act includes, subject to the exceptions, a reference to each salt, active principle or derivative of the substance.

*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 Act, 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).

## 17 When medicines and poisons standard *applies* to substances

For this Act, a schedule or appendix of the medicines and poisons standard *applies* to a substance in a circumstance if—

- (a) the substance is included in the schedule or appendix; and
- (b) either—
- (i) an exclusion in the standard does not, in the circumstance, exclude the substance from the operation of the schedule or appendix; or

- (ii) if a restriction is mentioned in the standard for the substance—the restriction applies in relation to the substance in the circumstance.

**Example—par (b) (ii)**

Substance X is included in sch 4 (Prescription only medicine) of the medicines and poisons standard. Its listing is followed by the restriction ‘for human therapeutic use’. Substance X is not included in another schedule or an appendix of the standard. The standard applies to substance X only for human therapeutic use.

*Note 1* See also s 9 (Inconsistency between Act and medicines and poisons standard).

*Note 2* An example is part of the Act, 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).

## **18 Inspection of medicines and poisons standard**

The chief health officer must ensure that a copy of the medicines and poisons standard (including any amendments of the standard) is made available for inspection free of charge to the public on business days at reasonable times at an office administered by the chief health officer.

## Part 3.4 Other important concepts

### 19 Meaning of *deals* with a regulated substance—Act

- (1) For this Act, a person *deals* with a regulated substance if the person does 1 or more of the following:
- (a) manufactures the substance;
  - (b) obtains the substance;
  - (c) possesses the substance;
  - (d) supplies the substance;
  - (e) administers the substance;
  - (f) discards the substance;
  - (g) issues a purchase order for the substance;
  - (h) if the substance is a medicine—
    - (i) prescribes the medicine; or
    - (ii) issues a requisition or standing order for the medicine;
  - (i) if the substance is a dangerous poison, prohibited substance or appendix C substance—gives a written or oral direction to—
    - (i) supply the poison or substance for administration to a person; or
    - (ii) administer the poison or substance to a person.

- (2) For this Act, a person also *deals* with a regulated substance if the regulated substance otherwise comes into, or goes out of, the person's possession, including, for example, if the person loses or finds the regulated substance or the substance is stolen from the person.

*Note* An example is part of the Act, 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).

## 20 When *authorised* to deal with regulated substances

- (1) For this Act, a person is *authorised* to deal with a medicine, low harm poison or moderate harm poison if—

- (a) the person has a licence or permit under a Commonwealth Act, this Act or another territory law that authorises the dealing; or

*Note* A reference to an Act includes a reference to statutory instruments made or in force under the Act, including any regulation and any law or instrument applied, adopted or incorporated by the Act (see Legislation Act, s 104).

- (b) the person may or must deal with the medicine or poison under a Commonwealth Act, this Act or another territory law; or
- (c) the chief health officer approves the dealing under a regulation; or
- (d) the dealing is otherwise authorised by regulation.

### Examples of Commonwealth Acts—pars (a) and (b)

*Customs (Prohibited Imports) Regulations 1956, Narcotic Drugs Act 1967 and Therapeutic Goods Act 1989*

### Examples of when person may or must deal with medicines—par (b)

- 1 the person is a dentist and a regulation allows dentists to administer the medicine

2 the person is authorised under the *Health Professionals (Special Events Exemptions) Act 2000*, s 10 (1) to issue a written prescription for the medicine

*Note 1* For the supply of a regulated substance by wholesale, see s (4).

*Note 2* An example is part of the Act, 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) For this Act, a person is **authorised** to deal with a dangerous poison, prohibited substance or appendix C substance if—

(a) the person may or must deal with the poison or substance under a Commonwealth Act, this Act or another territory law; or

(b) the person has a licence under this Act that authorises the dealing.

(3) However, for subsection (2), a person is **authorised** for an administration-related dealing with a dangerous poison, prohibited substance or appendix C substance for human use only if—

(a) the dealing is authorised by a licence for the purposes of research at a recognised research institution; and

(b) the research is approved by a human research ethics committee that is constituted in accordance with, and acting in compliance with, the NHMRC *National Statement on Ethical Conduct in Research Involving Humans* (1999), as in force from time to time.

*Note* **Administration-related dealing**, **NHMRC** and **recognised research institution**—see s (5).

(4) Also, for this Act, a person is **authorised** to supply a regulated substance by wholesale if—

(a) the person is authorised (however described) under a corresponding law to supply the substance by wholesale; and

- (b) the person does not have a place of business in the ACT; and
- (c) if a condition or restriction applies to the person under the corresponding law or is prescribed by regulation—the person complies with each condition or restriction; and
- (d) the chief health officer has not, under part 8.1 (Authorisations—disciplinary action), prohibited the person from supplying the substance by wholesale in the ACT.

*Note* **Wholesale**—see the dictionary.

- (5) In this section:

***administration-related dealing***, in relation to a dangerous poison, prohibited substance or appendix C substance for human use, means—

- (a) giving a written or oral direction to administer the poison or substance, or supply the poison or substance for administration, to a person; or
- (b) supplying the poison or substance for administration to a person; or
- (c) administering the poison or substance to a person.

***NHMRC*** means the National Health and Medical Research Council under the *National Health and Medical Research Council Act 1992* (Cwlth).

***recognised research institution*** means any of the following:

- (a) the Australian Catholic University;
- (b) the Australian National University;
- (c) the Canberra Hospital;
- (d) the Canberra Institute of Technology;

- (e) the Commonwealth Scientific and Industrial Research Organisation;
- (f) the University College within the Australian Defence Force Academy;
- (g) the University of Canberra;
- (h) any other entity prescribed by regulation.

**21 Meaning of *deals* with a regulated therapeutic good—Act**

For this Act, a person *deals* with a regulated therapeutic good if the person supplies the good.

**22 When *authorised* to deal with regulated therapeutic goods**

- (1) For this Act, a person is *authorised* to deal with a regulated therapeutic good if—
- (a) the person has a licence or permit under a Commonwealth Act, this Act or another territory law that authorises the dealing; or
  - (b) the person may or must deal with the good under a Commonwealth Act, this Act or another territory law; or
- Note* A reference to an Act includes a reference to statutory instruments made or in force under the Act, including any regulation and any law or instrument applied, adopted or incorporated by the Act (see Legislation Act, s 104).
- (c) the chief health officer approves the dealing under a regulation; or
  - (d) the dealing is otherwise authorised by regulation.

- (2) Also, for this Act, a person is **authorised** to supply a regulated therapeutic good by wholesale if—
- (a) the person is authorised (however described) under a corresponding law to supply the good by wholesale; and
  - (b) the person does not have a place of business in the ACT; and
  - (c) if a condition or restriction applies to the person under the corresponding law or is prescribed by regulation—the person complies with each condition or restriction; and
  - (d) the chief health officer has not, under part 8.1 (Authorisations—disciplinary action), prohibited the person from supplying the good by wholesale in the ACT.

*Note* **Wholesale**—see the dictionary.

## 23 **Meaning of *supply authority*—Act**

In this Act:

***supply authority***—each of the following is a ***supply authority***:

- (a) a written prescription;
- (b) a written requisition;
- (c) a purchase order;
- (d) a standing order;
- (e) a document that purports to be a document mentioned in paragraph (a), (b), (c) or (d).

*Note* A purchase order and standing order must be in writing (see the definitions of these terms in the dictionary).



## 24 Meaning of *possess*, *sell* and *supply*—Act

In this Act:

*possess*, for a regulated substance, includes the following:

- (a) receive or obtain possession of the substance;
- (b) have control over the disposition of the substance (whether with or without custody of the substance);
- (c) have joint possession of the substance.

*sell* includes the following:

- (a) offer or expose for sale;
- (b) dispose of by any method for value (or offer or expose for disposal by any method for value);
- (c) possess for sale or disposal for value.

*supply*—

- (a) includes the following:
  - (i) sell (or offer or expose for sale);
  - (ii) dispense;  
*Note* *Dispense* means supply on prescription (see dict).
  - (iii) supply under a requisition or standing order;
  - (iv) dispose of by any method for free (other than by discarding); but
- (b) does not include administer.

## Chapter 4 Offences relating to regulated substances

### Part 4.1 Dealings with regulated substances—offences

#### Division 4.1.1 Preliminary

##### 25 Meaning of *declared substance*—pt 4.1

In this part:

*declared substance* means—

- (a) a medicine; or
- (b) a dangerous poison; or
- (c) a prohibited substance; or
- (d) an appendix C substance; or
- (e) a low harm poison, or moderate harm poison, prescribed by regulation.

#### Division 4.1.2 Declared substances—supply

##### 26 Supplying declared substances

- (1) A person commits an offence if—
  - (a) the person supplies a declared substance to someone else; and
  - (b) the person is not authorised to supply the substance to the other person.

Maximum penalty: 500 penalty units, imprisonment for 5 years or both.

*Note* **Supply** includes sell or offer to sell (see s 24).

- (2) A person commits an offence if—
- (a) the person supplies a declared substance to himself or herself;  
and
  - (b) the person is not authorised to supply the substance to himself or herself.

Maximum penalty: 500 penalty units, imprisonment for 5 years or both.

**27 Supplying declared substances on invalid supply authorities—strict liability offences**

- (1) A person commits an offence if—
- (a) the person is authorised to supply a declared substance on a supply authority; and
  - (b) the person supplies the declared substance on a supply authority; and
  - (c) 1 or more of the following apply in relation to the supply authority:
    - (i) all or part of the authority is illegible;
    - (ii) the authority has been changed;
    - (iii) the authority has been marked ‘cancelled’;
    - (iv) for a supply authority for a declared substance that is a controlled medicine—the authority is issued more than 6 months before the date the substance medicine is supplied;
    - (v) for a supply authority for a declared substance other than a controlled medicine—the authority is issued more than 1 year before the date the substance is supplied.

Maximum penalty: 50 penalty units.

- (2) Subsection (1) (c) (i) and (ii) do not apply in relation to the supply of a declared substance by a person if, before the supply, the person checks the content of the supply authority with the person who issued the authority (the *issuer*) and—
- (a) the supply is in accordance with the authority as confirmed by the issuer; or
  - (b) if the authority is a prescription—
    - (i) the authority is changed by a pharmacist at the oral direction of the issuer; and
    - (ii) the pharmacist notes the change on the authority as prescribed by regulation; and
    - (iii) the supply is in accordance with the authority as changed.
- (3) Subsection (1) does not apply to an employee or agent of a person (the *principal*) if the employee or agent supplies the declared substance at the direction of the principal.
- (4) To remove any doubt, subsection (3) does not affect the principal's liability for the offence under section 171 (Acts and omissions of representatives of individuals).
- (5) An offence against subsection (1) is a strict liability offence.

**28 Supplying declared substances on invalid supply authorities—recklessness**

A person (the *supplier*) commits an offence if—

- (a) a supply authority is issued by a person who is not authorised to issue the authority; and
- (b) the supplier supplies a declared substance on the supply authority; and

- (c) the supplier is reckless about whether the supply authority is issued by someone who is not authorised to issue it.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

**29 Supplying declared substances on invalid supply authorities—other offences**

- (1) A person commits an offence if—
- (a) the person supplies a declared substance on a supply authority; and
  - (b) 1 or more of the following apply in relation to the supply authority:
    - (i) the person knows the authority was obtained because of false information given to the person (the *issuer*) who issued the authority;
    - (ii) the person could reasonably believe that the authority has been changed by someone other than the issuer;
    - (iii) the person could reasonably believe that the authority is false in a material particular.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (2) However, subsection (1) (b) (ii) does not apply to the supply of a declared substance by a person if—
- (a) before supplying the substance, the person checks whether the change to the supply authority was made by the issuer; and
  - (b) the issuer confirms the change.
- (3) Further, subsection (1) (b) (ii) does not apply to the supply of a declared substance on a prescription or requisition if—

- (a) before the substance is supplied by the person, the prescription or requisition is changed at the oral direction of the issuer; and
- (b) the person notes the change on the prescription or requisition as prescribed by regulation.

### 30 Cancellation etc of invalid supply authorities for declared substances

- (1) In this section:

*relevant circumstance*, in relation to a supply authority given to a person to supply a declared substance, means—

- (a) all or part of the authority is illegible; or
- (b) all or part of the authority has been obliterated; or
- (c) 1 or more of the following apply in relation to the supply authority:
  - (i) the supply authority was issued by someone who was not authorised to issue it;
  - (ii) the person knows the authority was obtained because of false information given to the person (the *issuer*) who issued the authority;
  - (iii) the person could reasonably believe that the authority has been changed by someone other than the issuer;
  - (iv) the person could reasonably believe that the authority is false in a material particular;
  - (v) the person could reasonably believe that the supply authority is a forgery.

- (2) A person commits an offence if—

- (a) the person is authorised to supply a declared substance on a supply authority; and

- (b) the person is given a supply authority for the supply of the substance; and
- (c) a relevant circumstance applies in relation to the authority; and
- (d) the person does not cancel the authority as prescribed by regulation.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

*Note* For how long a cancelled supply authority must be kept, see s 47.

**31 Supply of certain declared substances—information for chief health officer**

- (1) A person commits an offence if—
  - (a) the person supplies any of the following on a supply authority:
    - (i) a controlled medicine;
    - (ii) a declared substance (other than a controlled medicine) prescribed by regulation; and
  - (b) the person does not give the chief health officer the required information as prescribed by regulation.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (2) A person commits an offence if—
  - (a) the person supplies any of the following otherwise than on a supply authority:
    - (i) a controlled medicine;
    - (ii) a declared substance (other than a controlled medicine) prescribed by regulation; and

(b) the person does not give the chief health officer the required information as prescribed by regulation.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

(3) Strict liability applies to subsection (1) (b) and subsection (2) (b).

(4) In this section:

*required information* means the information prescribed by regulation.

### **32 Information about invalid supply authorities for chief health officer**

(1) A person commits an offence if—

(a) the person cancels a supply authority for a declared substance prescribed by regulation for section 30 (Cancellation etc of invalid supply authorities for declared substances); and

(b) the declared substance is—

(i) a prescription only medicine; or

(ii) a controlled medicine; or

(iii) a dangerous poison; or

(iv) another declared substance prescribed by regulation; and

(c) either—

(i) the person fails to tell the chief health officer and a police officer about the authority and the reason for cancelling the authority immediately after cancelling it; or

(ii) not later than 24 hours after the relevant circumstance under section 30 happens, the person fails to—

(A) tell the chief health officer, in writing, about the reason; and



(B) give the chief health officer a copy of the cancelled authority.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (2) A person commits an offence if—
- (a) the person supplies a declared substance on a supply authority; and
  - (b) the declared substance is—
    - (i) a prescription only medicine; or
    - (ii) a controlled medicine; or
    - (iii) a dangerous poison; or
    - (iv) another declared substance prescribed by regulation; and
  - (c) after the person supplies the substance the person becomes aware of any of the following (the *designated circumstance*):
    - (i) the supply authority was issued by someone who was not authorised to issue it;
    - (ii) the supply contravened a provision of—
      - (A) section 27 (1) (c) (Supplying declared substances on invalid supply authorities—strict liability offences); or
      - (B) section 29 (1) (b) (Supplying declared substances on invalid supply authorities—other offences); and
  - (d) either—
    - (i) the person fails to tell the chief health officer and a police officer about the supply authority immediately after the person becomes aware of the designated circumstance; or

(ii) not later than 24 hours after the person becomes aware of the designated circumstance, the person fails to—

(A) tell the chief health officer, in writing, about the supply authority; and

(B) give the chief health officer a copy of the authority.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

(3) A person must not be prosecuted for an offence under subsection (2) involving a contravention of section 27 (1) (c) or section 29 (1) (b) if—

(a) at the time the person supplied the declared substance on the supply authority the person believed on reasonable grounds that no designated circumstance applied in relation to the supply authority; and

(b) the person does not contravene subsection (2).

### **Division 4.1.3 Regulated substances—other dealings**

#### **33 Manufacturing regulated substances**

A person commits an offence if—

(a) the person manufactures a regulated substance; and

(b) the person is not authorised to manufacture the substance.

Maximum penalty: 500 penalty units, imprisonment for 5 years or both.

#### **34 Discarding declared etc substances**

(1) A person commits an offence if—

- (a) a regulation prescribes how a declared substance must be discarded; and
- (b) the person discards the substance; and
- (c) the person does not discard the substance as prescribed.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (2) A person commits an offence if—

- (a) the person possesses a declared substance; and
- (b) the chief health officer gives the person a direction under section 191 (Directions about dealings with regulated substances and therapeutic goods) in relation to the discarding of the substance; and
- (c) the person does not discard the substance as directed.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (3) A person commits an offence if the person discards a declared substance in a way that—

- (a) puts the health or safety of people at risk; or
- (b) is likely to cause damage to property or the environment.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

*Note* The *Dangerous Substances Act 2004* and *Environment Protection Act 1997* may also apply to the discarding of a regulated substance.

- (4) However, subsection (3) does not apply if the declared substance is discarded in accordance with—

- (a) a regulation about how the substance must be discarded; or
- (b) a direction by the chief health officer under section 191.

- (5) A person commits an offence if—
- (a) the person discards a low harm poison or moderate harm poison; and
  - (b) the poison is not a declared substance; and
  - (c) the discarding—
    - (i) puts the health or safety of people at risk; or
    - (ii) causes damage to property or the environment.

Maximum penalty: 50 penalty units, imprisonment for 6 months or both.

*Note* The *Dangerous Substances Act 2004* and *Environment Protection Act 1997* may also apply to the discarding of regulated substances.

### **35 Obtaining certain declared substances**

- (1) A person commits an offence if—
- (a) the person obtains a declared substance that is—
    - (i) a pharmacy medicine, or pharmacist only medicine, prescribed by regulation; or
    - (ii) a prescription only medicine; or
    - (iii) a controlled medicine; or
    - (iv) a dangerous poison; or
    - (v) a prohibited substance; and
  - (b) the person is not authorised to obtain the substance.

Maximum penalty: 200 penalty units, imprisonment for 2 years or both.

- (2) A person commits an offence if—
- (a) the person obtains a prescription only medicine; and

(b) the person is not authorised to obtain the medicine.

Maximum penalty: 50 penalty units.

(3) An offence against subsection (2) is a strict liability offence.

### **36 Possessing certain declared substances**

A person commits an offence if—

- (a) the person possesses a declared substance that is—
- (i) a pharmacy medicine, or pharmacist only medicine, prescribed by regulation; or
  - (ii) a prescription only medicine; or
  - (iii) a controlled medicine; or
  - (iv) a dangerous poison; or
  - (v) a prohibited substance; and

(b) the person is not authorised to possess the substance.

Maximum penalty: 200 penalty units, imprisonment for 2 years or both.

### **37 Administering certain declared substances**

(1) A person commits an offence if—

- (a) the person administers a declared substance (other than a pharmacy medicine or pharmacist only medicine) to someone else; and
- (b) the person is not authorised to administer the substance to the other person.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

(2) A person commits an offence if—

- (a) the person administers a declared substance (other than a pharmacy medicine or pharmacist only medicine) to himself or herself; and
- (b) the person is not authorised to administer the substance to himself or herself.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (3) A person commits an offence if—
  - (a) the person administers a declared substance (other than a pharmacy medicine or pharmacist only medicine) to an animal; and
  - (b) the person is not authorised to administer the substance to the animal.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

### **38 Issuing purchase orders for declared substances**

- (1) A person commits an offence if—
  - (a) the person issues a purchase order for a declared substance; and
  - (b) the person is not authorised to issue the purchase order for the substance.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (2) A person commits an offence if—
  - (a) the person is authorised to issue a purchase order for a declared substance; and
  - (b) the person issues a purchase order for the substance; and

- (c) the purchase order does not comply with the requirements prescribed by regulation.

Maximum penalty: 50 penalty units.

- (3) An offence against subsection (2) is a strict liability offence.

### **39 Reporting loss and theft of certain regulated substances**

- (1) In this section:

*reportable substance* means—

- (a) a controlled medicine; or
- (b) a dangerous poison; or
- (c) a prohibited substance; or
- (d) an appendix C substance; or
- (e) another regulated substance prescribed by regulation.

- (2) A person commits an offence if—

- (a) the person is authorised to possess a reportable substance; and
- (b) the person possesses the substance; and
- (c) the substance is lost or the person suspects that the substance has been lost; and
- (d) the person fails to tell the chief health officer, in writing, about the loss or suspected loss and how it happened as soon as practicable (but not later than 7 days) after the day the person becomes aware of the loss or suspected loss.

Maximum penalty: 50 penalty units, imprisonment for 6 months or both.

- (3) A person commits an offence if—

- (a) the person is authorised to possess a reportable substance; and

- (b) the person possesses the substance; and
- (c) the substance is stolen or the person suspects that the substance has been stolen; and
- (d) the person fails to tell the chief health officer and a police officer about the theft or suspected theft—
  - (i) orally immediately after the person becomes aware of the theft or suspected theft; and
  - (ii) in writing not later than 24 hours after the person becomes aware of the theft or suspected theft.

Maximum penalty: 50 penalty units, imprisonment for 6 months or both.

#### **40 Prescribing medicines**

- (1) A person commits an offence if—
  - (a) the person prescribes a medicine (whether orally or in writing) for someone else; and
  - (b) the person is not authorised to prescribe the medicine for the other person.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (2) A person commits an offence if—
  - (a) the person prescribes a medicine (whether orally or in writing) for himself or herself; and
  - (b) the person is not authorised to prescribe the medicine for himself or herself.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.



- (3) A person commits an offence if—
- (a) the person prescribes a medicine (whether orally or in writing) for an animal; and
  - (b) the person is not authorised to prescribe the medicine for the animal.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

**41 Issuing requisitions for medicines**

A person commits an offence if—

- (a) the person issues a requisition for a medicine (whether orally or in writing); and
- (b) the person is not authorised to issue the requisition.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

**42 Issuing standing orders for medicines**

A person commits an offence if—

- (a) the person issues a standing order for a medicine; and
- (b) the person is not authorised to issue the standing order.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

**43 Medicines for animals not to be prescribed etc for human use**

- (1) A person commits an offence if—
- (a) the person prescribes a medicine for human use; and

- (b) the medicine is manufactured, packed, labelled or prepared for use for animal treatment; and
- (c) the person is not authorised to prescribe the medicine for human use.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (2) A person commits an offence if—
  - (a) the person supplies a medicine for human use; and
  - (b) the medicine is manufactured, packed, labelled or prepared for use for animal treatment; and
  - (c) the person is not authorised to supply the medicine for human use.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

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

- (3) A person commits an offence if—
  - (a) the person administers a medicine to himself, herself or someone else; and
  - (b) the medicine is manufactured, packed, labelled or prepared for use for animal treatment; and
  - (c) the person is not authorised to administer the medicine for human use.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

## **Division 4.1.4 Dealings—other offences**

### **44 Contravening authorisation conditions for regulated substances**

- (1) A person commits an offence if—
- (a) the person is authorised to deal with a regulated substance; and
  - (b) the authorisation is subject to a condition; and
  - (c) the person is reckless about whether the dealing contravenes the condition.

Maximum penalty: 200 penalty units, imprisonment for 2 years or both.

- (2) A person commits an offence if—
- (a) the person is authorised to deal with a regulated substance; and
  - (b) the authorisation is subject to a condition; and
  - (c) the person contravenes the condition.

Maximum penalty: 50 penalty units.

*Note 1* For examples of conditions that might be prescribed by regulation, see s 186.

*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).

- (3) An offence against subsection (2) is a strict liability offence.

**45 Pretending to be authorised to deal with regulated substance**

- (1) A person commits an offence if the person pretends to be authorised to deal with a regulated substance.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (2) A person commits an offence if the person pretends to be authorised to deal with a regulated substance.

Maximum penalty: 50 penalty units.

- (3) An offence against subsection (2) is a strict liability offence.

## **Part 4.2**                      **Records for regulated substances—offences**

### **Division 4.2.1**            **Record-keeping generally**

#### **46**                      **Accessibility of records**

- (1) A person commits an offence if—
- (a) the person is required under this Act to record something in relation to a regulated substance; and
  - (b) the person does not record the thing—
    - (i) in writing; and
    - (ii) in English; and
    - (iii) in a way that is easily retrievable.

Maximum penalty: 50 penalty units.

*Note 1*    **Written** includes in electronic form (see dict).

*Note 2*    A reference to an Act includes a reference to statutory instruments made or in force under the Act, including any regulation and any law or instrument applied, adopted or incorporated by the Act (see Legislation Act, s 104).

- (2) An offence against this section is a strict liability offence.

#### **47**                      **Keeping cancelled invalid supply authorities**

- (1) A person commits an offence if—
- (a) the person cancels a supply authority under section 30 (Cancellation etc of invalid supply authorities for declared substances); and

- (b) the person fails to ensure that the cancelled supply authority is kept for at least 2 years after the day the person cancels the supply authority.

Maximum penalty: 50 penalty units.

- (2) Subsection (1) does not apply to a person if—
- (a) the person is required under this Act to give the supply authority to the chief health officer or a police officer; or
- (b) either the chief health officer or a police officer requires the person to give the supply authority to the chief health officer or police officer.
- (3) An offence against subsection (1) is a strict liability offence.

## Division 4.2.2 Registers for regulated substances

### 48 Meaning of *must keep* register—div 4.2.2

For this division, a person *must keep* a register for a regulated substance—

- (a) if the person is prescribed by regulation for the substance; or
- (b) if—
- (i) the person is a pharmacist who is responsible for the management of a community pharmacy; and
- (ii) controlled medicines are kept at the pharmacy.

*Note* **Community pharmacy**—see the dictionary.

### 49 Registers—not keeping

- (1) A person commits an offence if—
- (a) the person must keep a register for a regulated substance; and

(b) the person does not keep the register as prescribed by regulation.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

(2) A person commits an offence if—

(a) the person must keep a register for a regulated substance; and

(b) the person does not keep the register as prescribed by regulation.

Maximum penalty: 50 penalty units.

(3) An offence against subsection (2) is a strict liability offence.

## **50 Registers—where to be kept**

(1) A person commits an offence if—

(a) the person must keep a register for a regulated substance; and

(b) a regulation prescribes a place to keep the register; and

(c) the person fails to keep the register at the place prescribed.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

(2) A person commits an offence if—

(a) the person must keep a register for a regulated substance; and

(b) a regulation prescribes a place to keep the register; and

(c) the person fails to keep the register at the place prescribed.

Maximum penalty: 50 penalty units.

(3) An offence against subsection (2) is a strict liability offence.

## 51 Registers—duty to ensure entries made

- (1) A person (the *principal*) who must keep a register for a regulated substance commits an offence if—
- (a) the principal, or an employee or agent of the principal, deals with the regulated substance; and
  - (b) the principal fails to ensure that the details prescribed by regulation for the dealing are entered in the register prescribed by regulation as soon as practicable (but not later than 24 hours) after the dealing happens.

Maximum penalty: 50 penalty units.

- (2) An offence against subsection (1) is a strict liability offence.

## 52 Registers—signing entries

- (1) A person commits an offence if—
- (a) the person makes an entry in a register for a regulated substance; and
  - (b) the person fails to sign the entry as soon as practicable (but not later than 24 hours) after the entry is made.

Maximum penalty: 50 penalty units.

*Note* *Signs*—see the dictionary.

- (2) An offence against this section is a strict liability offence.

## 53 Registers—witnessing administration of medicines

A person commits an offence if—

- (a) a regulated substance is prescribed by regulation; and
- (b) the person is prescribed by regulation as a witness in relation to the administration of the substance; and



- (c) the person witnesses the administration of the medicine; and
- (d) the administration of the medicine is entered in a register for the medicine; and
- (e) the person fails to sign the entry in the register as witness as soon as practicable (but not later than 24 hours) after the entry is made.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

*Note* **Signs**—see the dictionary.

#### **54 Registers—witnessing discarding**

A person commits an offence if—

- (a) a regulated substance is prescribed by regulation; and
- (b) the person is prescribed by regulation as a witness in relation to the discarding of the substance; and
- (c) the person witnesses the discarding of the substance; and
- (d) the discarding of the substance is entered in the register for the substance; and
- (e) the person fails to sign the entry in the register as witness as soon as practicable (but not later than 24 hours) after the entry is made.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

*Note* **Signs**—see the dictionary.

## **55 Registers—changes etc to entries**

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

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (2) However, subsection (1) does not apply to a person if the person—
- (a) made the entry in the register; and
  - (b) amends the entry as prescribed by regulation.

*Note* It is an offence to produce a document in compliance with a territory law if the document is false or misleading in a material particular (see Criminal Code, s 339).

## **56 Registers—period to be kept**

- (1) A person commits an offence if—
- (a) the person must keep a register for a regulated substance; and
  - (b) the person fails to ensure that the register is kept for at least 2 years after the day when the last entry is made in the register.

Maximum penalty: 50 penalty units.

*Note* For how long a register for a regulated substance kept electronically must be kept, see the *Electronic Transactions Act 2001*, s 11 and this Act, s 187.

- (2) An offence against this section is a strict liability offence.

## **57 Registers—damage or loss**

- (1) A person commits an offence if—
- (a) the person must keep a register for a regulated substance; and
  - (b) the register is damaged in a material respect, stolen, lost or destroyed; and

- (c) the person fails to tell the chief health officer, in writing, about the damage, theft, loss or destruction as soon as practicable (but not later than 7 days) after the day it happens.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (2) A person commits an offence if—
- (a) the person must keep a register for a regulated substance; and
  - (b) the register is damaged in a material respect, stolen, lost or destroyed; and
  - (c) the person does not take an inventory as prescribed by regulation of each regulated substance in the person's possession to which the register related.

*Note* **Possess** includes have control over disposition (see s 24).

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (3) This section does not apply to a register for a regulated substance if the most recent entry in the register is made more than 2 years before the day the register is damaged, stolen, lost or destroyed.
- (4) In this section:

**material respect**—a register for a regulated substance is damaged in a **material respect** if anything required to be entered in the register is missing or cannot be easily read.

**58 Transferring responsibility for community pharmacies—  
stocktake etc of controlled medicines**

- (1) A pharmacist (the *responsible pharmacist*) who is responsible for the management of a community pharmacy commits an offence if—
- (a) the pharmacist proposes to stop being responsible for the pharmacy for a continuous period of longer than 14 days; and
  - (b) before the pharmacist stops being responsible for the pharmacy, the pharmacist fails to—
    - (i) take a written inventory of each quantity of each form and strength of a controlled medicine held in the pharmacy; and
    - (ii) enter each of the quantities in the controlled medicines register for the pharmacy; and
    - (iii) sign and date each entry in the register.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

*Note* **Community pharmacy** and **signs**—see the dictionary.

- (2) A pharmacist commits an offence if—
- (a) the pharmacist intends to take responsibility for a community pharmacy for a continuous period of more than 14 days; and
  - (b) before taking responsibility for the pharmacy, the pharmacist fails to—
    - (i) check the entries made in the controlled medicines register for the pharmacy under subsection (1) (b) (ii); and

- (ii) for each of the entries in the register, indicate in writing whether the pharmacist agrees that the entry is a correct record of the quantity of the form and strength of the controlled medicine held in the pharmacy; and
- (iii) sign and date each of the entries in the register.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (3) The responsible pharmacist for a community pharmacy commits an offence if—
  - (a) the pharmacist takes an inventory of controlled medicines held in the pharmacy; and
  - (b) the quantity of a form and strength of a controlled medicine held at the pharmacy is not the quantity shown for the form and strength of the medicine in the controlled medicines register for the pharmacy; and
  - (c) the pharmacist fails to take reasonable steps to resolve the discrepancy between—
    - (i) the quantity of the form and strength of the controlled medicine held at the pharmacy; and
    - (ii) the quantity shown in the register.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (4) The responsible pharmacist for a community pharmacy commits an offence if—
  - (a) the pharmacist takes an inventory of controlled medicines held in the pharmacy; and

- (b) the quantity of a form and strength of a controlled medicine held at the pharmacy is not the quantity shown for the form and strength of the medicine in the controlled medicines register for the pharmacy; and
- (c) the pharmacist does not tell the chief health officer about the discrepancy—
  - (i) orally immediately after checking the entries in the controlled medicines register; and
  - (ii) in writing not later than 24 hours after finishing the check.

Maximum penalty: 50 penalty units, imprisonment for 6 months or both.

- (5) In this section:

***controlled medicines register***, for a community pharmacy, means a register for controlled medicines that a pharmacist must keep for the pharmacy under section 48 (Meaning of *must keep* register—div 4.2.2).

## **Part 4.3                      Regulated substances—other offences**

### **Division 4.3.1              Packaging and labelling—offences**

#### **59                      Packaging of supplied regulated substances**

- (1) A person commits an offence if—
- (a) the person is authorised to supply a regulated substance; and
  - (b) the person supplies the substance to someone else; and
  - (c) the substance is not packaged—
    - (i) as prescribed by regulation; or
    - (ii) in accordance with an approval under section 193 (Approval of non-standard packaging and labelling).

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (2) A person commits an offence if—
- (a) the person is authorised to supply a regulated substance; and
  - (b) the person supplies the substance to someone else; and
  - (c) the substance is not packaged—
    - (i) as prescribed by regulation; or
    - (ii) in accordance with an approval under section 193.

Maximum penalty: 50 penalty units.

- (3) This section does not apply to a regulated substance that is supplied for immediate administration to a person.
- (4) An offence against subsection (2) is a strict liability offence.

## **60 Labelling of supplied regulated substances**

- (1) A person commits an offence if—
- (a) the person is authorised to supply a regulated substance; and
  - (b) the person supplies a regulated substance to someone else; and
  - (c) the substance is not labelled—
    - (i) as prescribed by regulation; or
    - (ii) in accordance with an approval under section 193 (Approval of non-standard packaging and labelling).

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (2) A person commits an offence if—
- (a) the person is authorised to supply a regulated substance; and
  - (b) the person supplies a regulated substance to someone else; and
  - (c) the substance is not labelled—
    - (i) as prescribed by regulation; or
    - (ii) in accordance with an approval under section 193.

Maximum penalty: 50 penalty units.

- (3) This section does not apply to a regulated substance that is supplied for immediate administration to a person.
- (4) An offence against subsection (2) is a strict liability offence.



## **Division 4.3.2 Storage—offence**

### **61 Storing declared substances**

A person commits an offence if—

- (a) the person is authorised to possess a declared substance; and
- (b) the person is prescribed by regulation in relation to the substance; and
- (c) the person fails to store the substance as prescribed by regulation.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

## **Division 4.3.3 Containers—offences**

### **62 Permanently named containers—use for other regulated substances**

A person commits an offence if—

- (a) the person uses a container for a regulated substance; and
- (b) the container is permanently marked with the name of a different regulated substance.

Maximum penalty: 50 penalty units, imprisonment for 6 months or both.

### **63 Certain containers not to be used for human-use substances**

(1) A person commits an offence if—

- (a) the person supplies a human-use substance in a container; and

(b) the container is of a kind prescribed by regulation.

Maximum penalty: 50 penalty units, imprisonment for 6 months or both.

(2) For this section, each of the following substances is a *human-use substance*:

- (a) food;
- (b) a drink;
- (c) a condiment.

#### Division 4.3.4 Representations and advertisements—offences

##### 64 False statements to obtain certain regulated substances etc

(1) In this section:

*reportable substance*—see section 39.

(2) A person commits an offence if—

(a) the person makes a statement to a person (the *authorised person*) who is authorised to administer or supply a reportable substance; and

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

(b) the statement is false or misleading; and

(c) the person knows the statement—

- (i) is false or misleading; or
- (ii) omits anything without which the statement is false or misleading; and

- (d) the person makes the statement for the purpose of obtaining the substance from the authorised person.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (3) A person commits an offence if—
- (a) the person makes a statement to a person (the *authorised person*) who is authorised to issue a prescription or purchase order for a reportable substance; and
  - (b) the statement is false or misleading; and
  - (c) the person is reckless about whether the statement—
    - (i) is false or misleading; or
    - (ii) omits anything without which the statement is false or misleading; and
  - (d) the person makes the statement for the purpose of obtaining the prescription or purchase order from the authorised person.

Maximum penalty: 50 penalty units, imprisonment for 6 months or both.

- (4) A person commits an offence if—
- (a) the person states a name or home address to—
    - (i) a person (the *authorised person*) authorised to dispense a reportable substance; or
    - (ii) an employee or agent of an authorised person in the course of the employee's or agent's employment or agency; and
  - (b) the statement—
    - (i) is false or misleading; or

- (ii) omits anything without which the statement is false or misleading.

Maximum penalty: 50 penalty units.

- (5) An offence against subsection (4) is a strict liability offence.
- (6) Subsections (2), (3) and (4) do not apply to the making of a statement if the statement is not false or misleading in a material particular.
- (7) Subsections (2), (3) and (4) do not apply to the omission of something from a statement if the omission does not make the statement not false or misleading in a material particular.

## **65 Falsely representing substance is regulated**

- (1) A person (the *supplier*) commits an offence if—
- (a) the supplier supplies a substance as a particular regulated substance (the *purported substance*); and
- (b) the supplier knows that the substance is not the purported substance.

Maximum penalty: 200 penalty units, imprisonment for 2 years or both.

- (2) A person (the *supplier*) commits an offence if—
- (a) the supplier supplies a substance as a particular regulated substance (the *purported substance*); and
- (b) the supplier is reckless about whether the substance is the purported substance.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

**66 Advertising controlled medicines and prohibited substances**

- (1) A person commits an offence if—
- (a) the person publishes an advertisement; and
  - (b) the advertisement promotes or encourages the use of a controlled medicine or prohibited substance.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (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 controlled medicine or prohibited substance.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (3) This section does not apply to—
- (a) an advertisement for a controlled medicine in a publication published primarily for dentists, doctors, pharmacists or veterinary surgeons; or
  - (b) an advertisement by a pharmacist prescribed by regulation; or
  - (c) an advertisement prescribed by regulation.

- (4) In this section:

***advertisement*** means writing, sound or a picture, symbol, light or other visible device, object or sign (or a combination of 2 or more of these) that a reasonable person would consider publicises, or otherwise promotes, the purchase or use of a controlled medicine or prohibited substance.

## Division 4.3.5 Vending machines—offences

### 67 Meaning of *vending machine*—div 4.3.5

In this division:

*vending machine* means a machine or device from which regulated substances can be obtained, including by 1 or more of the following:

- (a) electronic funds transfer;
- (b) inserting money, a token or another object.

#### Example of other objects—par (b)

- 1 credit card
- 2 debit card
- 3 key

*Note* An example is part of the Act, 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).

### 68 Vending machines—use for supply of regulated substances

- (1) A person commits an offence if—
  - (a) the person is the occupier of premises; and
  - (b) a vending machine is installed on the premises; and
  - (c) the vending machine is used, or available for use, for the supply of a regulated substance by a person other than the occupier or an employee or agent of the occupier.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (2) Subsection (1) does not apply if the vending machine was placed on the premises without the occupier's consent.

**69 Vending machines—use for supply of unscheduled medicines**

- (1) In this section:

***manufacturer's pack***, of an unscheduled medicine, means a primary pack of the medicine that has been packaged and labelled by the medicine's manufacturer as prescribed by regulation.

*Note* ***Primary pack*** means the pack in which medicine and its immediate container or immediate wrapper or measure pack are presented for sale or supply (see the medicines and poisons standard).

***unscheduled medicine*** means a substance mentioned in the medicines and poisons standard, schedules 2, 3, 4 or 8 if none of the schedules apply to the substance because of an exception in the standard.

**Example**

Aspirin is mentioned in several schedules but in small packages is an unscheduled medicine.

*Note* An example is part of the Act, 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) A person commits an offence if—
- (a) the person is the occupier of premises; and
  - (b) a vending machine is installed on the premises; and
  - (c) the vending machine is used, or available for use, for the supply of an unscheduled medicine.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (3) Subsection (2) does not apply if the vending machine was placed on the premises without the occupier's consent.

- (4) Also, subsection (2) does not apply if—
- (a) the unscheduled medicine is supplied in a manufacturer's pack containing not more than 2 adult doses of the medicine; and
  - (b) the medicine was packed in the manufacturer's pack by the manufacturer of the medicine; and
  - (c) the vending machine is presented and located in a way that makes unsupervised access by children unlikely.

### **Division 4.3.6 Paints—offences**

*Note to div 4.3.6*

*Paint*—see the medicines and poisons standard, pt 1, par 1 (1) (see s 16).

#### **70 Manufacture, supply and use of paints containing white lead**

- (1) A person commits an offence if—
- (a) the person manufactures a paint containing basic lead carbonate (white lead); and
  - (b) the paint is not manufactured as prescribed by regulation.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

- (2) A person commits an offence if—
- (a) the person supplies a paint containing basic lead carbonate (white lead); and
  - (b) the paint is not supplied as prescribed by regulation.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.



- (3) A person commits an offence if—
- (a) the person uses a paint containing basic lead carbonate (white lead); and
  - (b) the paint is not used as prescribed by regulation.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

## **71 Manufacture, supply and use of paints for certain purposes**

- (1) A person commits an offence if the person manufactures, supplies or uses a first schedule paint as prescribed by regulation.

Maximum penalty: 40 penalty units.

*Note* **First schedule paint**—see the medicines and poisons standard, pt 1, par 1 (1).

- (2) A person commits an offence if the person manufactures, supplies or uses a second schedule paint as prescribed by regulation.

Maximum penalty: 50 penalty units, imprisonment for 6 months or both.

*Note* **Second schedule paint**—see the medicines and poisons standard, pt 1, par 1 (1).

- (3) A person commits an offence if the person manufactures, supplies or uses a third schedule paint as prescribed by regulation.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

*Note* **Third schedule paint**—see the medicines and poisons standard, pt 1, par 1 (1).

**72 Manufacture, supply and use of paints for toys**

A person commits an offence if—

- (a) the person manufactures, supplies or uses a paint for application to toys; and
- (b) the paint is not prescribed by regulation.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

**73 Manufacture, supply and use of paints containing pesticides**

A person commits an offence if—

- (a) the person manufactures, supplies or uses a paint containing a pesticide; and
- (b) the pesticide is not prescribed by regulation.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

*Note* **Pesticide**—see the medicines and poisons standard, pt 1, par 1 (1).

## Chapter 5                      Offences relating to regulated therapeutic goods

### 74                      Supplying regulated therapeutic goods

- (1) A person commits an offence if—
- (a) the person supplies a regulated therapeutic good to someone else; and
  - (b) the person is not authorised to supply the good to the other person.

Maximum penalty: 500 penalty units, imprisonment for 5 years or both.

*Note 1*    **Supply** includes sell or offer to sell (see s 24).

*Note 2*    **Regulated therapeutic good**—see s 14.

- (2) A person commits an offence if—
- (a) the person supplies a regulated therapeutic good to himself or herself; and
  - (b) the person is not authorised to supply the good to himself or herself.

Maximum penalty: 500 penalty units, imprisonment for 5 years or both.

### 75                      Contravening authorisation conditions for regulated therapeutic goods

- (1) A person commits an offence if—
- (a) the person is authorised to deal with a regulated therapeutic good; and
  - (b) the authorisation is subject to a condition; and

(c) the person contravenes the condition.

Maximum penalty: 50 penalty units.

*Note* 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).

(2) An offence against this section is a strict liability offence.

## **76 Pretending to be authorised to deal with regulated therapeutic goods**

A person commits an offence if the person pretends to be authorised to deal with a regulated therapeutic good.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

## **77 Falsely representing thing is regulated**

(1) A person (the *supplier*) commits an offence if—

- (a) the supplier supplies a thing as a particular regulated therapeutic good (the *purported therapeutic good*); and
- (b) the supplier knows that the thing is not the purported therapeutic good.

Maximum penalty: 200 penalty units, imprisonment for 2 years or both.

(2) A person (the *supplier*) commits an offence if—

- (a) the supplier supplies a thing as a particular regulated therapeutic good (the *purported therapeutic good*); and
- (b) the supplier is reckless about whether the thing is the purported therapeutic good.

Maximum penalty: 100 penalty units, imprisonment for 1 year or both.

## Chapter 6 Licences for regulated substances and regulated therapeutic goods

### Part 6.1 Licences generally

#### 78 Meaning of *licence* etc—ch 6

- (1) In this chapter:

*licence* means a licence that authorises the licence-holder to deal with a regulated substance or regulated therapeutic good.

- (2) A regulation may prescribe the licences that may be issued under this Act.
- (3) To remove any doubt, the chief health officer may issue a licence to a person to deal with a regulated substance or regulated therapeutic good even if the licence is not prescribed by regulation for subsection (2).

#### 79 Meaning of *close associate*—ch 6

- (1) In this chapter:

*close associate*—a person is a *close associate* of someone (the *related person*) if—

- (a) the person holds or will hold an executive position (however described) in the related person's business; or
- (b) the chief health officer is satisfied that the person is or will be able to exercise a significant influence in relation to the conduct of the related person's business because the person holds or will hold a financial interest, or is entitled to exercise a relevant power, in the business.

*Note* **Business**—see the dictionary.

(2) In this section:

***executive position***—a position (however described) in the related person's business is an ***executive position*** if the holder of the position is concerned with, or takes part in, the management of the business.

***exercise*** a power includes exercise the power on behalf of someone else.

***financial interest***, in a business, means—

- (a) a share in the capital of the business; or
- (b) an entitlement to receive income derived from the business, however the entitlement arises.

***hold*** a position includes hold the position on behalf of someone else.

***power*** means a power exercisable—

- (a) by voting or otherwise; and
- (b) alone or with others.

***relevant power***, in a business, means a power—

- (a) to take part in a directorial, managerial or executive decision for the business; or
- (b) to elect or appoint a person as an executive officer in the business.

## **80 Meaning of *influential person* for corporation—ch 6**

(1) In this chapter:

***influential person***, for a corporation, means any of the following:

- (a) an executive officer of the corporation;
- (b) a person who may exercise a relevant power in relation to the corporation;

- (c) a related corporation;
  - (d) an executive officer of a related corporation.
- (2) In this section:

***related corporation*** means a related body corporate under the Corporations Act.

***relevant power***, for a corporation, means a power—

- (a) to take part in a directorial, managerial or executive decision for the corporation; or
- (b) to elect or appoint a person as an executive officer in the corporation; or
- (c) to exercise a significant influence in relation to the conduct of the corporation.

## **81 Suitability of individuals for licences**

- (1) In deciding whether an individual is a ***suitable person*** to hold a licence, the chief health officer must have regard to the following:
- (a) the knowledge, experience and training of the individual in relation to the regulated substances or regulated therapeutic goods to which the licence relates;
  - (b) the dealings with regulated substances or regulated therapeutic goods to which the licence relates;
  - (c) whether the individual or a close associate of the individual, or a corporation of which the individual was at the relevant time an executive officer, has—
    - (i) supplied information or a document in relation to this Act that is false or misleading in a material particular; or
    - (ii) contravened this Act or a corresponding law, whether or not the individual, associate or corporation has been

convicted or found guilty of an offence for the contravention; or

- (iii) failed to comply with a condition of a licence under this Act or a licence (however described) under a corresponding law, whether or not the individual, associate or corporation has been convicted or found guilty of an offence for the failure;

- (d) anything prescribed by regulation.

*Note* A reference to an Act includes a reference to statutory instruments made or in force under the Act, including any regulation and any law or instrument applied, adopted or incorporated by the Act (see Legislation Act, s 104).

- (2) However, an individual is not a *suitable person* to hold a licence if—

- (a) the individual, a close associate of the individual, or a corporation of which the individual was at the relevant time an executive officer, has been convicted or found guilty of any of the following in the 5-year period before the day the application for the licence is made:

- (i) an offence against this Act;
- (ii) an offence in Australia or elsewhere in relation to a regulated substance or regulated therapeutic good; or

- (b) the individual, or a close associate of the individual, is, or was at any time in the 5-year period before the day the application for the licence is made, bankrupt or personally insolvent; or

*Note* **Bankrupt or personally insolvent**—see the Legislation Act, dictionary, pt 1.

- (c) at any time in the 5-year period before the day the application for the licence is made, the individual, or a close associate of the individual, was involved in the management of a corporation when—



- (i) the corporation became the subject of a winding-up order;  
or
  - (ii) an administrator was appointed for the corporation; or
  - (d) a circumstance prescribed by regulation applies in relation to the individual or a close associate of the individual.
- (3) Despite subsection (2), the chief health officer may decide that an individual is a *suitable person* to hold a licence if satisfied that—
- (a) the individual's dealings with regulated substances or regulated therapeutic goods authorised, or to be authorised, by the licence would not be inconsistent with the objects of this Act if the chief health officer decided that the individual is a suitable person; and
  - (b) it is otherwise in the public interest that the individual be treated as a suitable person.

## 82 Suitability of corporations for licences

- (1) For this Act, a corporation is a *suitable person* for a licence if—
- (a) each influential person of the corporation is a suitable person to hold a licence; and
  - (b) the corporation is not the subject of a winding-up order, and has not been the subject of a winding-up order in the 5-year period before the day the application for the licence is made; and
  - (c) an administrator has not been appointed for the corporation in the 5-year period before the day the application for the licence is made.
- (2) However, if a corporation is not a suitable person for a licence under subsection (1), the chief health officer may decide that the corporation is a *suitable person* to hold a licence if satisfied that—

- (a) the corporation's dealings with regulated substances or regulated therapeutic goods authorised, or to be authorised, by the licence would not be inconsistent with the objects of this Act if the chief health officer decided that the corporation is a suitable person; and
- (b) it is otherwise in the public interest that the corporation be treated as a suitable person.

**83 Power to ask for information etc from applicants and others**

- (1) In this section:

*application* means—

- (a) an application for a licence; or
- (b) an application to amend a licence.

*designated person*, in relation to an applicant or licence means—

- (a) the applicant or licence-holder; or
- (b) a close associate of, or influential person for, the applicant or licence-holder.

- (2) The chief health officer may, in writing, ask a designated person in relation to an application or licence to do 1 or more of the following:
- (a) give the chief health officer stated information relevant to the application or licence;
  - (b) produce for the chief health officer's inspection a stated document relevant to the application or licence;
  - (c) allow the chief health officer to examine, copy or take extracts from a stated document relevant to the application or licence (including a document produced for the chief health officer's inspection under paragraph (b));

- (d) verify, by statutory declaration or otherwise, information given or a document produced to the chief health officer;
- (e) authorise a stated person to do anything mentioned in paragraphs (a) to (d);
- (f) give the chief health officer the authorities and consents that the chief health officer asks for to allow the chief health officer to obtain from other people information (including financial and other confidential information) that is—
  - (i) about the designated person; and
  - (ii) relevant to—
    - (A) the consideration of the application; or
    - (B) a consideration of whether the licence-holder continues to be a suitable person for a licence.

**Examples—par (a)**

- 1 The notice may ask the designated person to give information by preparing a document in a stated way (including as a statutory declaration) or by completing a document provided by the chief health officer.
- 2 The notice may ask the designated person to give the chief health officer information about a close associate because of a change of the kind to which section 93 (Licensee to keep chief health officer informed) applies.

**Example—par (b)**

a statement supplied by a police officer about the applicant's criminal history (if any)

**Example—par (c)**

The notice may ask the applicant to authorise the applicant's accountant, or a former close associate, to give the chief health officer stated information or documents about the applicant.

*Note 1* The *Statutory Declarations Act 1959* (Cwlth) applies to the making of statutory declarations under ACT laws.

*Note 2* An example is part of the Act, 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 request under subsection (2) must state a reasonable time within which the request must be complied with.

## Part 6.2 Licences—issue and amendment

### 84 Applications for licences

- (1) A person may apply to the chief health officer for a licence.

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

*Note 2* A fee may be determined under s 197 for this section.

- (2) The applicant must give the chief health officer a written statement (a **change statement**) if, before the application is decided, a change happens in relation to—

- (a) something mentioned in the application; or
- (b) a document, or something mentioned in a document, that accompanied the application.

- (3) A change statement must—

- (a) set out the details of the change; and
- (b) ask the chief health officer to amend the application to include the change; and
- (c) be signed by the applicant.

### 85 Decision on applications for licences

- (1) On application under section 84, the chief health officer must issue the licence to the applicant if satisfied that—

- (a) no restriction on the issue of the licence prescribed by regulation applies in relation to the applicant; and
- (b) the applicant is a suitable person to hold the licence; and
- (c) the applicant can comply with this Act in relation to the regulated substances or regulated therapeutic goods to which the application relates.

- (2) The chief health officer must refuse to issue the licence if not satisfied about the matters mentioned in subsection (1).
- (3) However, the chief health officer need not decide the application if—
  - (a) if a form is approved under section 198 for an application under section 84 (1)—the application does not include the information and any documents required by the application form; or
  - (b) the chief health officer has asked for something under section 83 (Power to ask for information etc from applicants and others) and the request has not been complied with.

**86 Term of licences**

- (1) A licence is issued for the period stated in the licence.
- (2) A licence must not be issued for longer than 3 years, or any shorter period prescribed by regulation.

**87 Licences not transferable**

A licence is not transferable.

**88 Form of licences**

- (1) A licence must be in writing and include the following information:
  - (a) what licence it is or the dealings with regulated substances or regulated therapeutic goods authorised by the licence;
  - (b) the regulated substances or regulated therapeutic goods to which the licence relates;
  - (c) the full name of the licence-holder;
  - (d) the licence-holder's ABN (if any);

- (e) if the licence-holder is a corporation—the corporation's ACN;
- (f) if applicable, the location of the premises where the licence-holder is authorised to deal with a regulated substance or regulated therapeutic good under the licence;
- (g) if applicable, the name of each individual who is to supervise the dealings authorised under the licence;
- (h) any conditions included in the licence by the chief health officer;

*Note* See s 90 to s 92 for conditions included in a licence by the chief health officer.

- (i) a unique identifying number;
  - (j) when the term of the licence ends;
  - (k) any other information prescribed by regulation.
- (2) For this Act, the conditions mentioned in subsection (1) (h) may be included in a separate document and, if they are, the separate document forms part of the licence.

## **89 Statutory licence conditions**

A licence is subject to the following conditions:

- (a) the licence-holder must comply with any written request by the chief health officer under section 83 (Power to ask for information etc from applicants and others) in relation to the amendment of the licence;
- (b) if section 93 (Licensee to keep chief health officer informed) applies in relation to the licence-holder, the licence-holder must comply with the section;
- (c) a condition prescribed by regulation.

## 90 Other licence conditions

- (1) A licence is subject to any condition the chief health officer includes in the licence when giving the licence or at any other time.
- (2) For subsection (1), the chief health officer may include a condition in a licence to ensure that regulated substances and regulated therapeutic goods are properly dealt with under the licence, including, for example—
  - (a) a condition about—
    - (i) the supervision of the dealings; and
    - (ii) the security of regulated substances and regulated therapeutic goods and of premises where regulated substances and regulated therapeutic goods are stored; and
    - (iii) the keeping of records about the dealings; and
  - (b) for a regulated substance—a condition recommended by the medicines and poisons standard for dealing with the regulated substance.

*Note* An example is part of the Act, 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).

## 91 Amending licence on chief health officer's initiative

- (1) The chief health officer may, by written notice (an *amendment notice*) given to a licence-holder, amend the licence to change a licence condition.
- (2) However, the chief health officer may amend the licence to change a licence condition only if—
  - (a) the chief health officer has given the licence-holder written notice (a *proposal notice*) of the proposed amendment; and



- (b) the notice states that written comments on the proposal may be made to the chief health officer before the end of a stated period of at least 14 days after the day the proposal notice is given to the licence-holder; and
  - (c) after the end of the stated period, the chief health officer has considered any comments made in accordance with the notice.
- (3) The amendment takes effect on the day the amendment notice is given to the licence-holder or any later day stated in the notice.
- (4) In this section:
- change*, for a licence condition, means—
    - (a) amend an existing licence condition; or
    - (b) impose a new licence condition; or
    - (c) remove an existing licence condition.

*condition* does not include a condition mentioned in section 89 (Statutory licence conditions).

## 92 Amending licence on application by licence-holder

- (1) A licence-holder may apply to the chief health officer to amend the licence (including by changing a licence condition).
- Note 1* If a form is approved under s 198 for this provision, the form must be used.
- Note 2* A fee may be determined under s 197 for this section.
- (2) In deciding whether to amend the licence, the chief health officer may consider anything that may be considered under section 85 (Decision on applications for licences) in relation to an application for a licence.

- (3) If the chief health officer receives an application under subsection (1), the chief health officer must—
- (a) amend the licence in accordance with the application; or
  - (b) amend the licence in terms different to the application; or
  - (c) refuse to amend the licence.
- (4) However, the chief health officer need not decide the application if the chief health officer has asked for something under section 83 (Power to ask for information etc from applicants and others) and the request has not been complied with.
- (5) In this section:
- change*, for a licence condition—see section 91 (4).
- condition*—see section 91 (4).

### **93 Licensee to keep chief health officer informed**

- (1) This section applies if a licence-holder believes that there will be a change (the *anticipated change*) to anything stated in—
- (a) the licence; or
  - (b) the application for the licence; or
  - (c) an application to amend the licence.

*Note* Failure to comply with this section contravenes a condition of the licence (see s 89 (b)).

- (2) The licence-holder must—
- (a) give the chief health officer written notice of the anticipated change not later than 7 days before the day the change is expected to happen; and

- (b) if the change affects the information shown on the licence—  
apply under section 92 to amend the licence to take account of  
the change.

**Examples of changes**

- 1 a change of the person who, under the licence that authorises the supply by wholesale of a controlled medicine, must supervise the supply of the medicine
- 2 a change in a close associate of, or influential person for, the licence-holder
- 3 a structural change in premises relevant to dealing with a regulated substance

*Note* An example is part of the Act, 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).

**94 Returning licences for amendment**

- (1) A licence-holder commits an offence if—
- (a) the licence-holder's licence is amended under section 91 (Amending licence on chief health officer's initiative) or section 92 (Amending licence on application by licence-holder); and
  - (b) the licence-holder fails to return the licence to the chief health officer as soon as practicable (but not later than 7 days) after the day the licence-holder is told about the chief health officer's action or decision.

Maximum penalty: 20 penalty units.

- (2) An offence against this section is a strict liability offence.

**95 Replacing licences**

- (1) The chief health officer may issue a replacement licence to a licence-holder if satisfied that the licence-holder's original licence has been lost, stolen or destroyed.

- (2) For subsection (1), the chief health officer may require the licence-holder to give the chief health officer a statutory declaration signed by the licence-holder, stating that the original licence has been lost, stolen or destroyed.

*Note 1* A fee may be determined under s 197 for this section.

*Note 2* The *Statutory Declarations Act 1959* (Cwlth) applies to the making of statutory declarations under ACT laws.

## Part 6.3 Licences—other provisions

### 96 Contravening licence conditions

- (1) A person commits an offence if—
  - (a) the person is a licence-holder; and
  - (b) the licence is subject to a condition; and
  - (c) the person is reckless about whether an act or omission by the person contravenes the condition.

Maximum penalty: 200 penalty units, imprisonment for 2 years or both.

- (2) A licence-holder commits an offence if the licence-holder contravenes a condition of the licence.

Maximum penalty: 50 penalty units.

- (3) An offence against subsection (2) is a strict liability offence.

### 97 Surrendering licences

- (1) A licence-holder may surrender the licence by giving written notice of the surrender to the chief health officer.
- (2) The licence-holder must, with the notice—
  - (a) return the licence to the chief health officer; or
  - (b) if the licence has been lost, stolen or destroyed—give the chief health officer a statutory declaration signed by the licence-holder stating that the licence has been lost, stolen or destroyed.

*Note* The *Statutory Declarations Act 1959* (Cwlth) applies to the making of statutory declarations under ACT laws.

## Chapter 7      Enforcement

### Part 7.1      Inspection and seizure powers

#### Division 7.1.1      Preliminary

#### 98      Definitions—pt 7.1

In this part:

*connected*—a thing is *connected* with an offence if—

- (a) the offence has been committed in relation to it; or
- (b) it will provide evidence of the commission of the offence; or
- (c) it was used, is being used, or is intended to be used, to commit the offence.

*occupier*, of premises, includes—

- (a) a person believed on reasonable grounds to be an occupier of the premises; and
- (b) a person apparently in charge of the premises.

*offence* includes an offence that there are reasonable grounds for believing has been, is being, or will be, committed.

#### 99      Meaning of *medicines and poisons inspector*—Act

In this Act:

*medicines and poisons inspector* means—

- (a) a police officer; or
- (b) a person appointed under section 100.

## **Division 7.1.2 Medicines and poisons inspectors**

### **100 Appointment of medicines and poisons inspectors**

The chief health officer may appoint a public servant to be a medicines and poisons inspector for this Act.

*Note 1* For the making of appointments (including acting appointments), see the Legislation Act, pt 19.3.

*Note 2* In particular, a person may be appointed for a particular provision of a law (see Legislation Act, s 7 (3)) and an appointment may be made by naming a person or nominating the occupant of a position (see Legislation Act, s 207).

### **101 Identity cards**

- (1) The chief health officer must give a medicines and poisons inspector (other than a police officer) an identity card stating the person's name and that the person is a medicines and poisons inspector.
- (2) The identity card must show—
  - (a) a recent photograph of the person; and
  - (b) the card's date of issue and expiry; and
  - (c) anything else prescribed by regulation.
- (3) A person commits an offence if—
  - (a) the person stops being a medicines and poisons inspector; and
  - (b) the person does not return the person's identity card to the chief health officer as soon as practicable (but not later than 7 days) after the day the person stops being a medicines and poisons inspector.

Maximum penalty: 1 penalty unit.

- (4) An offence against this section is a strict liability offence.

## Division 7.1.3 Powers of medicines and poisons inspectors

### 102 Power to enter premises

- (1) For this Act, a medicines and poisons inspector may—
  - (a) at any reasonable time, enter premises that the public is entitled to use or that are open to the public (whether or not on payment); or
  - (b) at any time, enter premises with the occupier's consent; or
  - (c) enter premises in accordance with a search warrant; or
  - (d) at any time, enter premises if the inspector believes on reasonable grounds that the circumstances are so serious and urgent that immediate entry to the premises without the authority of a search warrant is necessary.
- (2) However, subsection (1) (a) does not authorise entry into a part of premises that is being used only for residential purposes.
- (3) A medicines and poisons inspector may, without the consent of the occupier of premises, enter land around the premises to ask for consent to enter the premises.
- (4) To remove any doubt, a medicines and poisons inspector may enter premises under subsection (1) without payment of an entry fee or other charge.
- (5) In this section:  
*at any reasonable time* includes at any time when the public is entitled to use the premises, or when the premises are open to or used by the public (whether or not on payment).



**103 Production of identity card**

A medicines and poisons inspector must not remain at premises entered under this part if the inspector does not produce his or her identity card when asked by the occupier.

**104 Consent to entry**

- (1) When seeking the consent of an occupier of premises to enter the premises under section 102 (1) (b), a medicines and poisons inspector must—
  - (a) produce his or her identity card; and
  - (b) tell the occupier—
    - (i) the purpose of the entry; and
    - (ii) that anything found and seized under this part may be used in evidence in court; and
    - (iii) that consent may be refused.
- (2) If the occupier consents, the medicines and poisons inspector must ask the occupier to sign a written acknowledgment (an *acknowledgement of consent*)—
  - (a) that the occupier was told—
    - (i) the purpose of the entry; and
    - (ii) that anything found and seized under this part may be used in evidence in court; and
    - (iii) that consent may be refused; and
  - (b) that the occupier consented to the entry; and
  - (c) stating the time and date when consent was given.
- (3) If the occupier signs an acknowledgment of consent, the medicines and poisons inspector must immediately give a copy to the occupier.

- (4) A court must find that the occupier did not consent to entry to the premises by the medicines and poisons inspector under this division if—
- (a) the question arises in a proceeding in the court whether the occupier consented to the entry; and
  - (b) an acknowledgment of consent is not produced in evidence; and
  - (c) it is not proved that the occupier consented to the entry.

**105 General powers on entry to premises**

- (1) A medicines and poisons inspector who enters premises under this part may, for this Act, do 1 or more of the following in relation to the premises or anything on the premises:
- (a) inspect or examine;
  - (b) examine and copy, or take extracts from, documents relating to a regulated substance or regulated therapeutic good;
  - (c) examine and copy, or take extracts from, any packaging, labelling or advertising material;
  - (d) take measurements or conduct tests;
  - (e) take samples;
  - (f) subject to part 7.2 (Taking and analysis of samples of substances), take for analysis samples of anything else (including any substance) at the premises;
  - (g) open (or require to be opened) any container or package that the inspector believes on reasonable grounds contains a regulated substance or regulated therapeutic good;
  - (h) take photographs, films, or audio, video or other recordings;

- (i) require the occupier, or anyone at the premises, to give information, answer questions, or produce documents or anything else, reasonably needed to exercise the inspector's functions under this Act.

*Note* The Legislation Act, s 170 and s 171 deal with the application of the privilege against self-incrimination and client legal privilege.

- (2) A person must take all reasonable steps to comply with a requirement made of the person under subsection (1) (g) or (i).

Maximum penalty: 50 penalty units, imprisonment for 6 months or both.

## **106 Power to seize things**

- (1) A medicines and poisons inspector who enters premises under this part with the occupier's consent may seize anything at the premises if—
  - (a) the inspector is satisfied on reasonable grounds that the thing is connected with an offence against this Act; and
  - (b) seizure of the thing is consistent with the purpose of the entry told to the occupier when seeking the occupier's consent.
- (2) A medicines and poisons inspector who enters premises under a warrant under this part may seize anything at the premises that the inspector is authorised to seize under the warrant.
- (3) A medicines and poisons inspector who enters premises under this part (whether with the occupier's consent, under a warrant or otherwise) may seize anything at the premises if satisfied on reasonable grounds that—
  - (a) the thing is connected with an offence against this Act; and

- (b) the seizure is necessary to prevent the thing from being—
  - (i) concealed, lost or destroyed; or
  - (ii) used to commit, continue or repeat the offence.
- (4) Also, a medicines and poisons inspector who enters premises under this part (whether with the occupier's consent or otherwise) may seize anything at the premises if satisfied on reasonable grounds that the thing—
  - (a) puts the health or safety of people at risk; or
  - (b) may cause damage to property or the environment.
- (5) The powers of a medicines and poisons inspector under subsections (3) and (4) are additional to any powers of the inspector under subsection (1) or any other territory law.
- (6) Having seized a thing, a medicines and poisons inspector may—
  - (a) remove the thing from the premises where it was seized (the *place of seizure*) to another place; or
  - (b) leave the thing at the place of seizure but restrict access to it.
- (7) A person commits an offence if—
  - (a) the person interferes with a seized thing, or anything containing a seized thing, to which access has been restricted under subsection (6); and
  - (b) the person does not have a medicines and poisons inspector's approval to interfere with the thing.

Maximum penalty: 50 penalty units.

- (8) An offence against this section is a strict liability offence.

**107 Power to destroy unsafe things**

- (1) This section applies to anything inspected or seized under this part by a medicines and poisons inspector if the inspector is satisfied on reasonable grounds that the thing—
  - (a) puts the health or safety of people at risk; or
  - (b) is likely to cause damage to property or the environment.
- (2) The medicines and poisons inspector may direct an occupier of the premises where the thing is to destroy or otherwise dispose of the thing.
- (3) The direction may state 1 or more of the following:
  - (a) how the thing must be destroyed or otherwise disposed of;
  - (b) how the thing must be kept until it is destroyed or otherwise disposed of;
  - (c) the period within which the thing must be destroyed or otherwise disposed of.
- (4) A person given a direction under subsection (2) commits an offence if the person contravenes a direction given to the person under subsection (2).

Maximum penalty: 100 penalty units.
- (5) Alternatively, if the thing has been seized under this part, the medicines and poisons inspector may destroy or otherwise dispose of the thing.

- (6) Costs incurred by the Territory in relation to the disposal of a thing under subsection (5) are a debt owing to the Territory by, and are recoverable together and separately from, the following people:
- (a) the person who owned the thing;
  - (b) each person in charge of the premises where the thing was.
- (7) An offence against this section is a strict liability offence.

### **108 Power to require name and address**

- (1) A medicines and poisons inspector may require a person to state the person's name and home address if the inspector believes on reasonable grounds that the person is committing or has just committed an offence against this Act.

*Note* 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).

- (2) The medicines and poisons inspector must tell the person the reason for the requirement and, as soon as practicable, record the reason.
- (3) The person may ask the medicines and poisons inspector to produce the inspector's identity card for inspection by the person.
- (4) A person must comply with a requirement made of the medicines and poisons inspector under subsection (1) if the inspector—
- (a) tells the person the reason for the requirement; and
  - (b) complies with any request made by the person under subsection (3).

Maximum penalty: 10 penalty units.

## **Division 7.1.4 Search warrants**

### **109 Warrants generally**

- (1) A medicines and poisons inspector may apply to a magistrate for a warrant to enter premises.
- (2) The application must be sworn and state the grounds on which the warrant is sought.
- (3) The magistrate may refuse to consider the application until the medicines and poisons inspector gives the magistrate all the information the magistrate requires about the application in the way the magistrate requires.
- (4) The magistrate may issue a warrant only if satisfied there are reasonable grounds for suspecting—
  - (a) there is a particular thing or activity connected with an offence against this Act; and
  - (b) the thing or activity is, or is being engaged in, at the premises, or may be, or may be engaged in, at the premises within the next 14 days.

*Note* At premises includes in or on the premises (see dict).

- (5) The warrant must state—
  - (a) that a medicines and poisons inspector may, with any necessary assistance and force, enter the premises and exercise the inspector's powers under this part; and
  - (b) the offence for which the warrant is issued; and
  - (c) the things that may be seized under the warrant; and
  - (d) the hours when the premises may be entered; and
  - (e) the date, within 14 days after the day of the warrant's issue, that the warrant ends.

(6) In this section:

*connected*—an activity is *connected* with an offence if—

- (a) the offence has been committed by engaging or not engaging in it; or
- (b) it will provide evidence of the commission of the offence.

### **110 Warrants—application made other than in person**

- (1) A medicines and poisons inspector may apply for a warrant by phone, fax, radio or other form of communication if the inspector considers it necessary because of—
  - (a) urgent circumstances; or
  - (b) other special circumstances.
- (2) Before applying for the warrant, the medicines and poisons inspector must prepare an application stating the grounds on which the warrant is sought.
- (3) The medicines and poisons inspector may apply for the warrant before the application is sworn.
- (4) After issuing the warrant, the magistrate must immediately fax a copy to the medicines and poisons inspector if it is practicable to do so.
- (5) If it is not practicable to fax a copy to the medicines and poisons inspector—
  - (a) the magistrate must—
    - (i) tell the inspector what the terms of the warrant are; and
    - (ii) tell the inspector the date and time the warrant was issued; and



- (b) the inspector must complete a form of warrant (the *warrant form*) and write on it—
  - (i) the magistrate's name; and
  - (ii) the date and time the magistrate issued the warrant; and
  - (iii) the warrant's terms.
- (6) The faxed copy of the warrant, or the warrant form properly completed by the medicines and poisons inspector, authorises the entry and exercise of the inspector's powers under this part.
- (7) The medicines and poisons inspector must, at the first reasonable opportunity, send to the magistrate—
  - (a) the sworn application; and
  - (b) if the inspector completed a warrant form—the completed warrant form.
- (8) On receiving the documents, the magistrate must attach them to the warrant.
- (9) A court must find that a power exercised by a medicines and poisons inspector was not authorised by a warrant under this section if—
  - (a) the question arises in a proceeding before the court whether the exercise of power was authorised by a warrant; and
  - (b) the warrant is not produced in evidence; and
  - (c) it is not proved that the exercise of power was authorised by a warrant under this section.

**111 Search warrants—announcement before entry**

- (1) A medicines and poisons inspector must, before anyone enters premises under a search warrant—
  - (a) announce that the inspector is authorised to enter the premises; and
  - (b) give anyone at the premises an opportunity to allow entry to the premises; and
  - (c) if an occupier of the premises, or someone else who apparently represents the occupier, is present at the premises—identify himself or herself to the person.
- (2) The medicines and poisons inspector is not required to comply with subsection (1) if the inspector believes on reasonable grounds that immediate entry to the premises is required to ensure—
  - (a) the safety of anyone (including the inspector or any person assisting); or
  - (b) that the effective execution of the warrant is not frustrated.

**112 Details of search warrant to be given to occupier etc**

If an occupier of premises, or someone else who apparently represents the occupier, is present at the premises while a search warrant is being executed, the medicines and poisons inspector or a person assisting must make available to the person—

- (a) a copy of the warrant; and
- (b) a document setting out the rights and obligations of the person.

**113 Occupier entitled to be present during search etc**

- (1) If an occupier of premises, or someone else who apparently represents the occupier, is present at the premises while a search warrant is being executed, the occupier or the other person is entitled to observe the search being conducted.
- (2) However, the person is not entitled to observe the search if—
  - (a) to do so would impede the search; or
  - (b) the person is under arrest, and allowing the person to observe the search being conducted would interfere with the objectives of the search.
- (3) This section does not prevent 2 or more areas of the premises being searched at the same time.

**114 Moving things to another place for examination or processing**

- (1) A thing found at premises entered under a search warrant may be moved to another place for examination or processing to decide whether it may be seized under the warrant if—
  - (a) both of the following apply:
    - (i) there are reasonable grounds for believing that the thing is or contains something to which the warrant relates;
    - (ii) it is significantly more practicable to do so having regard to the timeliness and cost of examining or processing the thing at another place and the availability of expert assistance; or
  - (b) the occupier of the premises agrees in writing.
- (2) The thing may be moved to another place for examination or processing for not longer than 72 hours.

- (3) A medicines and poisons inspector may apply to a magistrate for an extension of time if the inspector believes on reasonable grounds that the thing cannot be examined or processed within 72 hours.
- (4) The medicines and poisons inspector must give notice of the application to the occupier of the premises, and the occupier is entitled to be heard on the application.
- (5) If a thing is moved to another place under this section, the medicines and poisons inspector must, if practicable—
  - (a) tell the occupier of the premises the address of the place where, and time when, the examination or processing will be carried out; and
  - (b) allow the occupier or the occupier's representative to be present during the examination or processing.
- (6) The provisions of this part relating to the issue of search warrants apply, with any necessary changes, to the giving of an extension under this section.

## **115 Use of electronic equipment at premises**

- (1) A medicines and poisons inspector or a person assisting may operate electronic equipment at premises entered under a search warrant to access data (including data not held at the premises) if the inspector or person believes on reasonable grounds that—
  - (a) the data might be something to which the warrant relates; and
  - (b) the equipment can be operated without damaging the data.
- (2) If the medicines and poisons inspector or person assisting believes on reasonable grounds that any data accessed by operating the electronic equipment might be something to which the warrant relates, the inspector or person may—
  - (a) copy the data to a data storage device brought to the premises;  
or

- (b) if the occupier of the premises agrees in writing—copy the data to a data storage device at the premises.
- (3) The medicines and poisons inspector or person assisting may take the device from the premises.
- (4) The medicines and poisons inspector or person assisting may do the following things if the inspector or person finds that anything (the *material*) to which the warrant relates is accessible using the equipment:
  - (a) seize the equipment and any data storage device;
  - (b) if the material can, by using facilities at the premises, be put in documentary form—operate the facilities to put the material in documentary form and seize the documents produced.
- (5) A medicines and poisons inspector may seize equipment under subsection (4) (a) only if—
  - (a) it is not practicable to copy the data as mentioned in subsection (2) or to put the material in documentary form as mentioned in subsection (4) (b); or
  - (b) possession of the equipment by the occupier of the premises or someone else could be an offence.

## **116 Person with knowledge of computer to assist access etc**

- (1) A medicines and poisons inspector may apply to a magistrate for an order requiring a stated person to provide any information or assistance that is reasonably necessary to allow the inspector or a person assisting to do 1 or more of the following:
  - (a) access data held in or accessible from a computer that is at the premises;
  - (b) copy the data to a data storage device;
  - (c) convert the data into documentary form.

- (2) The magistrate may make an order if satisfied that—
- (a) there are reasonable grounds for suspecting that something to which the warrant relates is accessible from the computer; and
  - (b) the stated person is—
    - (i) reasonably suspected of possessing, or having under the person's control, something to which the warrant relates; or
    - (ii) the owner or lessee of the computer; or
    - (iii) an employee or agent of the owner or lessee of the computer; and
  - (c) the stated person has knowledge of—
    - (i) the computer or a computer network of which the computer forms a part; or
    - (ii) measures applied to protect data held in or accessible from the computer.
- (3) A person commits an offence if the person contravenes an order under this section.
- Maximum penalty: 50 penalty units, imprisonment for 6 months or both.
- (4) The provisions of this part relating to the issue of search warrants apply, with any necessary changes, to the making of an order under this section.

## **117 Securing electronic equipment**

- (1) This section applies if the medicines and poisons inspector or a person assisting believes on reasonable grounds that—
  - (a) something (the *material*) to which the warrant relates may be accessible by operating electronic equipment at the premises; and
  - (b) expert assistance is required to operate the equipment; and
  - (c) the material may be destroyed, altered or otherwise interfered with if the inspector or person does not take action.
- (2) The medicines and poisons inspector or person assisting may do whatever is necessary to secure the equipment, whether by locking it up, placing a guard or otherwise.
- (3) The medicines and poisons inspector or a person assisting must give written notice to an occupier of the premises of—
  - (a) the inspector's or person's intention to secure the equipment; and
  - (b) the fact that the equipment may be secured for up to 24 hours.
- (4) The equipment may be secured until the earlier of the following events happens:
  - (a) the end of the 24-hour period;
  - (b) the equipment is operated by the expert.
- (5) If the medicines and poisons inspector or a person assisting believes on reasonable grounds that the expert assistance will not be available within the 24-hour period, the inspector or person may apply to a magistrate to extend the period.
- (6) The medicines and poisons inspector or a person assisting must tell an occupier of the premises of the intention to apply for an extension, and the occupier is entitled to be heard on the application.

- (7) The provisions of this part relating to the issue of search warrants apply, with any necessary changes, to the giving of an extension under this section.

## **118 Copies of seized things to be provided**

- (1) This section applies if—
- (a) an occupier of premises, or someone else who apparently represents the occupier, is present at the premises while a search warrant is executed; and
  - (b) the medicines and poisons inspector seizes—
    - (i) a document, film, computer file or something else that can be readily copied; or
    - (ii) a data storage device containing information that can be readily copied.
- (2) The occupier or other person may ask the medicines and poisons inspector to give the person a copy of the thing or information.
- (3) The medicines and poisons inspector must give the person the copy as soon as practicable after the seizure.
- (4) However, the medicines and poisons inspector is not required to give the copy if—
- (a) the thing was seized under section 115 (Use of electronic equipment at premises); or
  - (b) possession of the thing or information by an occupier of the premises or someone else would be an offence.



## **Division 7.1.5      Return and forfeiture of things seized**

### **119      Receipt for things seized**

- (1) As soon as practicable after a medicines and poisons inspector seizes a thing under this part, the inspector must give a receipt for it to the person from whom it was seized.
- (2) If, for any reason, it is not practicable to comply with subsection (1), the medicines and poisons inspector must leave the receipt, secured conspicuously, at the place of seizure under section 106 (Power to seize things).
- (3) A receipt under this section must include the following:
  - (a) a description of the thing seized;
  - (b) an explanation of why the thing was seized;
  - (c) the medicines and poisons inspector's name, and how to contact the inspector;
  - (d) if the thing is moved from the premises where it is seized—where the thing is to be taken.

### **120      Access to things seized**

- (1) A person who would, apart from the seizure, be entitled to inspect a thing seized under this part may—
  - (a) inspect it; and
  - (b) if it is a document—take extracts from it or make copies of it.
- (2) This section does not apply to—
  - (a) a thing seized under section 106 (4) (which is about the seizure of a thing that poses a risk to the health or safety of people or of damage to property or the environment); or

- (b) a thing or information if possession of it by the person otherwise entitled to inspect it would be an offence.

## **121 Return of things seized**

- (1) A thing seized under this part must be returned to its owner, or reasonable compensation must be paid by the Territory to the owner for the loss of the thing, if—
  - (a) an infringement notice for an offence relating to the thing is not served on the owner within 90 days after the day of seizure and a prosecution for an offence relating to the thing—
    - (i) is not started within the 90-day period; or
    - (ii) is started within the 90-day period but the court does not find the offence proved; or
  - (b) an infringement notice for an offence relating to the thing is served on the owner within 90 days after the day of seizure, the infringement notice is withdrawn and a prosecution for an offence relating to the thing—
    - (i) is not started within the 90-day period; or
    - (ii) is started within the 90-day period but the court does not find the offence proved; or
  - (c) an infringement notice for an offence relating to the thing is served on the owner and not withdrawn within 90 days after the day of seizure, liability for the offence is disputed in accordance with the *Magistrates Court Act 1930*, section 132 (Disputing liability for infringement notice offence) and an information—
    - (i) is not laid in the Magistrates Court against the person for the offence within 60 days after the day notice is given under section 132 that liability is disputed; or

- (ii) is laid in the Magistrates Court against the person for the offence within the 60-day period, but the Magistrates Court does not find the offence proved.
- (2) However, this section does not apply—
- (a) to a thing seized under section 106 (4) (which is about the seizure of things that pose a risk to the health or safety of people or of damage to property or the environment); or
  - (b) to a thing if the chief health officer believes on reasonable grounds that the only practical use of the thing in relation to the premises where it was seized would be an offence against this Act or another territory law; or
  - (c) to a thing if possession of it by its owner would be an offence.

*Note* See also section 125 (Forfeiture of seized things).

## **122 Application for order disallowing seizure**

- (1) A person claiming to be entitled to anything seized under this part may apply to the Magistrates Court within 10 days after the day of the seizure for an order disallowing the seizure.
- (2) However, this section does not apply to a thing seized under section 106 (4) (which is about the seizure of things that pose a risk to the health or safety of people or of damage to property or the environment).
- (3) The application may be heard only if the applicant has served a copy of the application on the chief health officer.
- (4) The chief health officer is entitled to appear as respondent at the hearing of the application.

### **123 Order for return of seized thing**

- (1) This section applies if a person claiming to be entitled to anything seized under this part applies to the Magistrates Court under section 122 for an order disallowing the seizure.
- (2) The Magistrates Court must make an order disallowing the seizure if satisfied that—
  - (a) the applicant would, apart from the seizure, be entitled to the return of the seized thing; and
  - (b) the thing is not connected with an offence against this Act; and
  - (c) possession of the thing by the person would not be an offence.
- (3) The Magistrates Court may also make an order disallowing the seizure if satisfied there are exceptional circumstances justifying the making of the order.
- (4) If the Magistrates Court makes an order disallowing the seizure, the court may make 1 or more of the following ancillary orders:
  - (a) an order directing the chief health officer to return the thing to the applicant or someone else that appears to be entitled to it;
  - (b) if the thing cannot be returned or has depreciated in value because of the seizure—an order directing the Territory to pay reasonable compensation;
  - (c) an order about the payment of costs in relation to the application.

### **124 Adjournment pending hearing of other proceedings**

- (1) This section applies to the hearing of an application under section 122 (Application for order disallowing seizure).

- (2) If it appears to the Magistrates Court that the seized thing is required to be produced in evidence in a pending proceeding in relation to an offence against a territory law, the court may, on the application of the chief health officer or its own initiative, adjourn the hearing until the end of the pending proceeding.

## **125 Forfeiture of seized things**

- (1) This section applies if—
- (a) anything seized under this part has not been returned under section 121 (Return of things seized); and
  - (b) an application for disallowance of the seizure under section 122 (Application for order disallowing seizure)—
    - (i) has not been made within 10 days after the day of seizure; or
    - (ii) has been made within the 10-day period, but the application has been refused or has been withdrawn before a decision in relation to the application had been made.
- (2) If this section applies to the seized thing—
- (a) it is forfeited to the Territory; and
  - (b) it may be sold, destroyed or otherwise disposed of as the chief health officer directs.

## **126 Return of forfeited things**

- (1) This section applies to something forfeited under section 125 that has not been disposed of in a way that would prevent its return.

- (2) If the chief health officer becomes satisfied that there has been no offence against this Act with which the thing is connected, the chief health officer must, as soon as practicable, return the thing to the person from whom it was seized or someone else who appears to the chief health officer to be entitled to it.
- (3) On its return, any proprietary and other interests in the thing that existed immediately before its forfeiture are restored.

## **127 Cost of disposal of forfeited things**

- (1) This section applies if—
  - (a) a person is convicted, or found guilty, of an offence against this Act in relation to something forfeited to the Territory under this part; and
  - (b) the thing is connected with an offence against this Act; and
  - (c) the person was the owner of the thing immediately before its forfeiture.

*Note* **Found guilty**—see the Legislation Act, dict, pt 1.

- (2) If this section applies, costs incurred by or on behalf of the Territory in relation to the lawful disposal of the thing (including storage costs) are a debt owing to the Territory by the person.

## **Division 7.1.6 Medicines and poisons inspectors— other provisions**

### **128 Disposal etc of things obtained otherwise than under pt 7.1**

- (1) This section applies if the chief health officer comes into possession of a regulated substance or regulated therapeutic good otherwise than under this part.

- (2) The chief health officer may dispose of the regulated substance or regulated therapeutic good as prescribed by regulation.

### **129      Damage etc to be minimised**

- (1) In the exercise, or purported exercise, of a function under this part, a medicines and poisons inspector must take all reasonable steps to ensure that the inspector, and any person assisting the inspector, causes as little inconvenience, detriment and damage as practicable.
- (2) If a medicines and poisons inspector, or a person assisting a medicines and poisons inspector, damages anything in the exercise or purported exercise of a function under this part, the inspector must give written notice of the particulars of the damage to the person the inspector believes on reasonable grounds is the owner of the thing.
- (3) If the damage happens at premises entered under this part in the absence of the occupier, the notice may be given by leaving it, secured conspicuously, at the premises.

### **130      Compensation for exercise of enforcement powers**

- (1) A person may claim compensation from the Territory if the person suffers loss or expense because of the exercise, or purported exercise, of a function under this part by a medicines and poisons inspector or a person assisting the inspector.
- (2) Compensation may be claimed and ordered in a proceeding for—
  - (a) compensation brought in a court of competent jurisdiction; or
  - (b) an offence against this Act brought against the person making the claim for compensation.
- (3) A court may order the payment of reasonable compensation for the loss or expense only if satisfied it is just to make the order in the circumstances of the particular case.

- (4) A regulation may prescribe matters that may, must or must not be taken into account by the court in considering whether it is just to make the order.
- (5) To remove any doubt, this section does not authorise a court to order the payment of compensation for regulated substances or regulated therapeutic goods seized by a medicines and poisons inspector if the substance or good was recalled under the *Therapeutic Goods Act 1989* (Cwlth).



## Part 7.2                      Taking and analysis of samples of substances

### 131                      **Inspector may buy samples without complying with pt 7.2**

This part does not stop a medicines and poisons inspector from buying a sample of a substance for analysis for the routine monitoring of compliance with this Act without complying with the requirements of this part.

*Note*                      For the admissibility of the analysis of a sample of a substance taken by a medicines and poisons inspector, see s 181.

### 132                      **Person in charge etc to be told sample to be analysed**

- (1) This section applies if a medicines and poisons inspector proposes to take, or takes, a sample of a substance for analysis from premises where a regulated substance is dealt with.
- (2) Before or as soon as practicable after taking the sample, the medicines and poisons inspector must tell a person in charge of the premises of the inspector's intention to have the sample analysed.
- (3) If a person in charge is not present or readily available, the medicines and poisons inspector must instead tell the person from whom the sample was obtained of the inspector's intention to have the sample analysed.

### 133                      **Payment for samples**

- (1) This section applies if a medicines and poisons inspector takes a sample of a substance for analysis from premises where a regulated substance is dealt with.
- (2) The medicines and poisons inspector must pay, or offer to pay, the person from whom the sample is taken—
  - (a) the amount (if any) prescribed by regulation as the amount payable for the sample; or

- (b) if no amount is prescribed—the current market value of the sample.

**134 Samples from packaged substances**

If a package of a substance contains 2 or more smaller packages of the same substance, the medicines and poisons inspector may take 1 of the smaller packages for analysis.

**135 Procedures for dividing samples**

- (1) This section—
  - (a) applies to a sample of a substance being taken by a medicines and poisons inspector for analysis; and
  - (b) is subject to section 136.
- (2) The medicines and poisons inspector must—
  - (a) divide the sample into 3 parts, and mark and either seal or fasten each part; and
  - (b) leave 1 part with the person told under section 132 (Person in charge etc to be told sample to be analysed) of the inspector's intention to have the sample analysed; and
  - (c) keep 1 part for analysis; and
  - (d) keep 1 part for future comparison with the other parts.
- (3) If a sample of a substance taken by a medicines and poisons inspector is in the form of separate or severable objects, the inspector—
  - (a) may take a number of the objects; and
  - (b) if the inspector takes a number of the objects, must—
    - (i) divide them into 3 parts each consisting of 1 or more of the objects, or of the severable parts of the objects, and mark and either seal or fasten each part; and

(ii) deal with the sample under subsection (2) (b) to (d).

**136 Exception to usual procedures for dividing samples**

- (1) This section applies to a sample of a substance being taken by a medicines and poisons inspector for analysis if dividing the substance into 3 parts would, in the inspector's opinion—
  - (a) so affect or impair the composition or quality of the sample as to make the parts unsuitable for accurate analysis; or
  - (b) result in the parts being too small for accurate analysis; or
  - (c) otherwise make the sample unsuitable for analysis (including a method of analysis prescribed by regulation for the substance in relation to which the sample is taken).
- (2) The medicines and poisons inspector may take as many samples as the inspector considers necessary to allow an accurate analysis to be made, and may deal with each sample in any way that is appropriate in the circumstances, instead of complying with section 135.

**137 Certificates of analysis by authorised analysts**

- (1) The analysis of a sample of a substance for the chief health officer must be carried out by, or under the supervision of, an authorised analyst.
- (2) An authorised analyst who analyses the sample must give to the chief health officer a certificate of analysis that—
  - (a) is signed and dated by the analyst; and
  - (b) contains a written report of the analysis that sets out the findings; and

(c) identifies the method of analysis.

*Note 1* If a form is approved under s 198 for the certificate, the form must be used.

*Note 2* For evidentiary certificates by authorised analysts, see the *Public Health Act 1997*, s 135A.

(3) In this section:

***authorised analyst*** means an analyst appointed under the *Public Health Act 1997*, section 15 who is authorised under that Act to exercise a function under this Act.

## Chapter 8                      Restrictions on dealing with regulated substances and regulated therapeutic goods

### Part 8.1                      Authorisations—disciplinary action

#### 138                      Application—pt 8.1

- (1) This part does not apply in relation to a dealing by a person with a regulated substance or regulated therapeutic good if the dealing is—
- (a) authorised by a licence or permit under a Commonwealth Act; or
  - (b) the dealing is otherwise in accordance with a Commonwealth Act.

*Note*                      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).

- (2) To remove any doubt, this part does not limit the power of anyone exercising a function under this Act to—
- (a) make a notification under the *Health Practitioner Regulation National Law (ACT)* about a health practitioner; or
  - (b) make a report under the *Health Professionals Act 2004*, part 9.2 about a health professional.

*Note*                      **Function** includes authority, duty and power (see Legislation Act, dict, pt 1).

**139 Definitions—pt 8.1**

In this part:

*authorisation holder* means a person who is, or has been, authorised to deal with a regulated substance or regulated therapeutic good.

*disciplinary action*—see section 141.

*disciplinary notice*—see section 142.

*ground for disciplinary action*, against an authorisation holder—see section 140.

*interstate wholesaler* means a person who is or has been authorised under—

- (a) section 20 (4) (When *authorised* to deal with regulated substances) to supply a regulated substance by wholesale; or
- (b) section 22 (2) (When *authorised* to deal with regulated therapeutic goods) to supply a regulated therapeutic good by wholesale.

**140 Grounds for disciplinary action against authorisation holders**

- (1) Each of the following is a *ground for disciplinary action* against an authorisation holder:
  - (a) the authorisation holder has given information to the chief health officer that was false or misleading in a material particular;
  - (b) the authorisation holder has failed to give information required to be given under this Act;
  - (c) the authorisation holder has contravened a condition of the authorisation;
  - (d) the authorisation holder, or an agent or employee of the authorisation holder, has contravened this Act (whether or not

the authorisation holder or employee is convicted, or found guilty, of the offence);

*Note* 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).

- (e) if the authorisation holder is or has been a licence-holder—
- (i) when the chief health officer issued the licence, grounds existed to refuse the application for the licence but the chief health officer was not aware of them; or
  - (ii) the licence-holder is not, or is no longer, a suitable person for a licence; or
  - (iii) the licence-holder no longer carries out the dealing to which the licence relates; or
  - (iv) a ground mentioned in paragraph (a), (b), (c) or (d) applies in relation to a close associate of, or influential person for, the licence-holder; or
  - (v) a close associate of, or influential person for, the licence-holder is not, or is no longer, a suitable person for the licence;
- (f) if the person is or was an interstate wholesaler—
- (i) the person, or an agent or employee of the person, supplied a regulated substance or regulated therapeutic good to someone not authorised to obtain it; or
  - (ii) the person, or an agent or employee of the person, contravened a condition or restriction that applies or applied to the person under a corresponding law or a regulation.

- (2) In subsection (1) (d), a reference to a contravention of this Act includes a reference to the following:
- (a) a contravention of the Criminal Code in relation to a document completed, kept or given, or required to be completed, kept or given, under this Act;
  - (b) a contravention of the Criminal Code in relation to anything else done, or not done, under this Act.

*Note* See also the Criminal Code, pt 2.4 (Extensions of criminal responsibility) and pt 2.5 (Corporate criminal responsibility).

- (3) In this section:

*close associate*—see section 79.

*influential person*—see section 80.

## **141 Disciplinary action against authorisation holders**

- (1) Each of the following is *disciplinary action* when taken against an authorisation holder (other than a former authorisation holder):
- (a) reprimanding the authorisation holder;
  - (b) requiring the authorisation holder, or an employee of the authorisation holder, to complete a stated course of training to the satisfaction of the chief health officer or another stated person;
  - (c) imposing a condition on the authorisation holder's authority to deal with a regulated substance or regulated therapeutic good;
  - (d) varying the authorisation holder's authority to deal with a regulated substance or regulated therapeutic good;



- (e) suspending the authorisation holder's authority to deal with a regulated substance or regulated therapeutic good, or a particular authorised dealing under the authorisation—
    - (i) for a stated period; or
    - (ii) until the authorisation holder, or an employee of the authorisation holder, completes a stated course of training to the satisfaction of the chief health officer or someone else; or
    - (iii) until a stated event happens;
  - (f) cancelling the authorisation holder's authority to deal with a regulated substance or regulated therapeutic good;
  - (g) if the authorisation holder is an interstate wholesaler—prohibiting the authorisation holder from supplying a regulated substance or regulated therapeutic good by wholesale in the ACT.
- (2) Each of the following is *disciplinary action* when taken against a former authorisation holder:
- (a) reprimanding the former authorisation holder;
  - (b) disqualifying the former authorisation holder from being authorised, or authorised in a particular way, to deal with a regulated substance or regulated therapeutic good—
    - (i) for a stated period; or
    - (ii) until the former authorisation holder, or an employee of the former authorisation holder, completes a stated course of training to the satisfaction of the chief health officer or someone else; or
    - (iii) until a stated event happens;

- (c) if the former authorisation holder was an interstate wholesaler—prohibiting the former authorisation holder from supplying a regulated substance or regulated therapeutic good by wholesale in the ACT.

## **142 Taking disciplinary action against authorisation holders**

- (1) If the chief health officer is satisfied that a ground for disciplinary action exists, or may exist, in relation to an authorisation holder, the chief health officer may give the authorisation holder a notice (a *disciplinary notice*).
- (2) The disciplinary notice must—
  - (a) state the ground for disciplinary action; and
  - (b) tell the authorisation holder that he or she may, not later than 3 weeks after the day the authorisation holder is given the notice, give a written response to the chief health officer about the notice.
- (3) If, after considering any response given not later than the end of the 3-week period, the chief health officer is satisfied that a ground for disciplinary action exists in relation to the authorisation holder, the chief health officer may take disciplinary action against the authorisation holder.
- (4) To remove any doubt, the disciplinary action may consist of 2 or more of the actions mentioned in section 141.
- (5) The disciplinary action takes effect when the authorisation holder receives written notice of the action or, if the notice states a later time of effect, at the stated time.

### 143 Immediate suspension of authorisations

- (1) This section applies if the chief health officer has given, or is considering whether to give, a disciplinary notice to an authorisation holder.
- (2) The chief health officer may give the authorisation holder a written notice (an *immediate suspension notice*) suspending—
  - (a) the authorisation holder's authority to deal with a regulated substance or regulated therapeutic good; or
  - (b) a particular authorised dealing under the authorisation.
- (3) However, the chief health officer may suspend the authorisation under subsection (2) only if—
  - (a) the chief health officer has taken into account the circumstances leading to the decision to give or consider giving the disciplinary notice and the grounds stated, or that may be stated, in the disciplinary notice; and
  - (b) the chief health officer believes on reasonable grounds that it is in the public interest that the authorisation be suspended before a decision is made whether or not to take action against the authorisation holder under section 142.
- (4) If an immediate suspension notice is given to the authorisation holder, the authorisation holder's authority to deal with the regulated substance or regulated therapeutic good to which the authorisation relates is suspended when the notice is given to the authorisation holder.

*Note* If the authorisation is a licence or approval, the licence or approval must be returned to the chief health officer, see s 145.

- (5) If the authorisation holder is given an immediate suspension notice because the chief health officer is considering whether to give a disciplinary notice to the authorisation holder, the chief health officer must, as soon as practicable—
- (a) give a disciplinary notice to the authorisation holder; or
  - (b) tell the authorisation holder in writing that a disciplinary notice will not be given to the authorisation holder.
- (6) An immediate suspension notice ends—
- (a) if the chief health officer decides not to give a disciplinary notice to the authorisation holder—when the chief health officer tells the authorisation holder about the decision under subsection (5) (b); or
  - (b) if a disciplinary notice is given to the authorisation holder—
    - (i) when any disciplinary action takes effect; or
    - (ii) the authorisation holder is given written notice by the chief health officer that no disciplinary action will be taken.

#### **144 Effect of suspension of authorisations**

- (1) If an authorisation to deal with a regulated substance or regulated therapeutic good is suspended, the authorisation does not authorise the authorisation holder to carry on any dealing with the regulated substance or regulated therapeutic good under the authorisation during the suspension.
- (2) If an authorised dealing with a regulated substance or regulated therapeutic good under an authorisation is suspended, the authorisation—
- (a) does not authorise the authorisation holder to carry out the dealing under the authorisation during the suspension; and

- (b) is taken to be varied under this part to the extent necessary to give effect to the suspension.

#### **145 Return of certain licences and approvals**

- (1) A person commits an offence if—
- (a) the person is the holder of—
    - (i) a licence; or
    - (ii) an approval under section 20 (1) (c) (When *authorised* to deal with regulated substances) or section 22 (1) (c) (When *authorised* to deal with regulated therapeutic goods); and
  - (b) the person's authorisation to deal with a regulated substance or regulated therapeutic good is varied, suspended or cancelled under this part; and
  - (c) the person fails to return the licence or approval to the chief health officer as soon as practicable (but not later than 7 days) after the day the person is told about the variation, suspension or cancellation.

Maximum penalty: 20 penalty units.

- (2) An offence against this section is a strict liability offence.

#### **146 Action by chief health officer in relation to certain licences and approvals**

- (1) If a licence or approval varied under this part is returned to the chief health officer, the chief health officer must—
- (a) vary the licence or approval and return it to the authorisation holder; or

- (b) give the authorisation holder a replacement licence or approval that includes the variation.

*Note* A licence or approval is taken to be varied if an authorised dealing under the licence or approval is suspended (see s 144 (2)).

- (2) If a licence or approval is suspended under this part and the suspension ends before the end of the term of the licence or approval, the chief health officer must—
  - (a) return the licence or approval to the authorisation holder; or
  - (b) give the authorisation holder a replacement licence or approval for the remainder of the term of the licence or approval.
- (3) In this section:

***approval*** means an approval under section 20 (1) (c) (When *authorised* to deal with regulated substances) or section 22 (1) (c) (When *authorised* to deal with regulated therapeutic goods).

## Part 8.2                      **Controlled medicines and prohibited substances—disqualification by courts**

### 147            **Definitions—pt 8.2**

In this part:

*drug offence* means an offence against—

- (a) chapter 4 (Offences relating to regulated substances) in relation to a controlled medicine or prohibited substance; or
- (b) the Criminal Code, chapter 6 (Serious drug offences); or
- (c) the *Drugs of Dependence Act 1989*, part 10 (Offences).

*relevant person* means—

- (a) a person who is authorised to deal with a regulated substance; or
- (b) a person who is authorised under this Act or another territory law to possess a controlled medicine or prohibited substance.

### 148            **Drug offences—disqualification from dealing**

- (1) This section applies if a relevant person is convicted, or found guilty, of a drug offence.
- (2) The convicting court may direct that the relevant person must not, during a stated period, deal with a controlled medicine or prohibited substance (or both) in the ways stated in the direction.
- (3) However, the court must not give the direction unless satisfied that giving the direction is in the interests of the person or the public.

- (4) The *Magistrates Court Act 1930*, section 208 (which is about appeals in criminal matters) applies in relation to the direction as if the direction were a penalty imposed by the court in relation to the conviction of a person of an offence.

#### **149 Notice of disqualification from dealing**

- (1) If a court gives a direction under section 148 (2), the court's registrar must give a copy of the direction to—
- (a) the relevant person; and
  - (b) the chief health officer.
- (2) The chief health officer must give a copy of the direction to—
- (a) the relevant person's employer (if any); and
  - (b) if the relevant person is a health professional—the relevant health profession board for the person under the *Health Professionals Act 2004*; and
  - (c) if the relevant person is a health practitioner—the relevant national board for the person under the *Health Practitioner Regulation National Law (ACT)*.

#### **150 Effect of disqualification from dealing**

- (1) This section applies if a direction is given under section 148 (2) (Drug offences—disqualification from dealing) in relation to a relevant person.
- (2) The relevant person's authorisation to deal with a controlled medicine or prohibited substance is taken, to the extent necessary to give effect to the court's direction, not to be in force for the period stated in the direction.



## Part 8.3 Surrender of prescribed authorisations

### 151 Application—pt 8.3

This part applies to a person who is authorised under a regulation to deal with a regulated substance or regulated therapeutic good, other than—

- (a) a licence-holder; or

*Note* For the surrender of a licence, see s 97.

- (b) a person who is dealing with a medicine or poison in accordance with an approval by the chief health officer under a regulation; or

*Note* The approval may be revoked by the chief health officer (see Legislation Act, s 46 (1)).

- (c) a medicines and poisons inspector; or

- (d) a person prescribed by regulation.

### 152 Surrender of authorisation under regulation

- (1) A person to whom this part applies may, by written notice (a *surrender notice*) given to the chief health officer, declare that the person does not wish to be authorised under a regulation—

- (a) to deal with a stated regulated substance or regulated therapeutic good; or

- (b) for stated dealings with a stated regulated substance or regulated therapeutic good.

- (2) A surrender notice—
  - (a) may state a period during which the declaration is to apply or an event on which the declaration ends; and
  - (b) may be revoked by giving the chief health officer written notice of the revocation at least 7 days before the revocation takes effect.
- (3) If the chief health officer receives from a person a surrender notice or notice revoking a surrender notice, the chief health officer must give a copy of the notice to—
  - (a) the person's employer (if any); and
  - (b) if the relevant person is a health professional—the relevant health profession board for the person under the *Health Professions Act 2004*; and
  - (c) if the relevant person is a health practitioner—the relevant national board for the person under the *Health Practitioner Regulation National Law (ACT)*.

### **153 Effect of surrender of authorisation under regulation**

- (1) This section applies while a surrender notice under section 152 relating to a regulated substance or regulated therapeutic good is in force in relation to a person.
- (2) The person's authorisation to deal with the regulated substance or regulated therapeutic good is taken, to the extent necessary to give effect to the surrender notice, not to be in force while the notice is in force.

## Chapter 9 Notification and review of decisions

### 154 Meaning of *reviewable decision*—ch 9

In this chapter:

*reviewable decision* means a decision mentioned in schedule 1, column 3 under a provision of this Act mentioned in column 2 in relation to the decision.

### 155 Reviewable decision notices

If a person makes a reviewable decision, the person must give a reviewable decision notice to each entity mentioned in schedule 1, 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*.

### 155A Applications for review

The following may apply to the ACAT for a review of a reviewable decision:

- (a) an entity mentioned in schedule 1, 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.

## Chapter 10      Incorporation of Commonwealth therapeutic goods laws

### Part 10.1      Preliminary

#### 156      Definitions—ch 10

In this chapter:

*applied provisions* means the Commonwealth therapeutic goods laws that apply as a law of the Territory under section 157.

*Commonwealth administrative laws* means—

- (a) the *Administrative Appeals Tribunal Act 1975* (Cwlth); and
- (b) the *Freedom of Information Act 1982* (Cwlth); and
- (c) the *Ombudsman Act 1976* (Cwlth); and
- (d) the *Privacy Act 1988* (Cwlth).

*Note*      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).

*Commonwealth Minister* means the Minister responsible for administering the Commonwealth therapeutic goods laws.

*Commonwealth Secretary* means the Secretary of the Commonwealth department that is—

- (a) administered by the Commonwealth Minister; and
- (b) responsible for the Commonwealth therapeutic goods laws.

***Commonwealth therapeutic goods laws*** means the *Therapeutic Goods Act 1989* (Cwlth) (including the statutory instruments under the Act) as modified by this Act.

*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* A reference to a law includes a reference to the law as originally made and as in force from time to time (see Legislation Act, s 102).

*Note 3* Commonwealth legislation is available at [www.comlaw.gov.au](http://www.comlaw.gov.au).

## **Part 10.2**                    **Application in ACT of Commonwealth therapeutic goods laws**

### **Division 10.2.1**        **The applied provisions**

#### **157**            **Application of Commonwealth therapeutic goods laws to ACT**

- (1) The Commonwealth therapeutic goods laws apply as a law of the Territory.

*Note*        *Commonwealth therapeutic goods laws*—see s 156.

- (2) This Act may modify the applied provisions.

*Note*        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).

#### **158**            **Interpretation of Commonwealth therapeutic goods laws**

- (1) The *Acts Interpretation Act 1901* (Cwlth) applies as a law of the Territory in relation to the interpretation of the applied provisions as if the applied provisions were Commonwealth laws.

*Note 1*        The *Acts Interpretation Act 1901* (Cwlth) is available at [www.comlaw.gov.au](http://www.comlaw.gov.au).

*Note 2*        A reference to a law includes a reference to the law as originally made and as in force from time to time (see Legislation Act, s 102).

- (2) The Legislation Act does not apply to the applied provisions.

## **Division 10.2.2      Functions under applied provisions**

### **159      Functions of Commonwealth Minister**

The Commonwealth Minister has the same functions under the applied provisions as the Commonwealth Minister has under the Commonwealth therapeutic goods laws as those laws apply to the Commonwealth.

*Note*      *Function* includes power and duty (see Legislation Act, dict, pt 1).

### **160      Functions of Commonwealth Secretary**

The Commonwealth Secretary has the same functions under the applied provisions as the Commonwealth Secretary has under the Commonwealth therapeutic goods laws as those laws apply to the Commonwealth.

### **161      Functions of other people**

A medicines and poisons inspector or Commonwealth officer under the Commonwealth therapeutic goods laws has the same functions under the applied provisions as the inspector or officer has under the Commonwealth therapeutic goods laws as the laws apply to the Commonwealth.

### **162      Delegations by Commonwealth Minister or Secretary**

A delegation by the Commonwealth Minister or the Commonwealth Secretary under the *Therapeutic Goods Act 1989* (Cwlth), section 57 is taken to extend to, and have effect for the purposes of, the corresponding provision of the applied provisions.

**163 Appointments under Commonwealth therapeutic goods laws**

The appointment of a person to a position under a provision of the Commonwealth therapeutic goods laws is taken to extend to, and have effect for the purposes of, the applied provisions.

**Division 10.2.3 Applied provisions—administrative law matters**

**164 Application of Commonwealth administrative laws to applied provisions**

- (1) The Commonwealth administrative laws apply as laws of the Territory to any matter arising in relation to the applied provisions as if those provisions were a law of the Commonwealth and not a territory law.

*Note* Subsection (4) contains an exception to s (1).

- (2) For the purposes of a territory law, a matter arising in relation to the applied provisions—
  - (a) is taken to be a matter arising in relation to the laws of the Commonwealth in the same way as it would if the applied provisions were a law of the Commonwealth; and
  - (b) is taken not to be a matter arising in relation to the laws of the Territory.
- (3) However, a regulation may modify the operation of subsection (2).
- (4) A provision of a Commonwealth administrative law applied under subsection (1) that purports to give jurisdiction to a federal court is taken not to have that effect.



**165 Functions given to Commonwealth officers and authorities**

- (1) A Commonwealth administrative law applying as a territory law under section 164 that gives a Commonwealth officer or Commonwealth authority a function also gives the officer or authority the same function in relation to a matter arising in relation to the applied provisions.

*Note* **Function** includes power and duty (see Legislation Act, dict, pt 1).

- (2) In exercising a function given by this section, the Commonwealth officer or Commonwealth authority must act as nearly as practicable as the officer or authority would act in exercising the same function under the Commonwealth administrative law.
- (3) A function given to a Commonwealth officer or Commonwealth authority because of this section cannot be exercised by a territory officer or territory authority.

**Division 10.2.4 Applied provisions—offences**

**166 Object—div 10.2.4**

- (1) The object of this division is to further the object of this chapter by providing for an offence against the applied provisions to be treated as if it were an offence against a law of the Commonwealth.
- (2) For subsection (1), the purposes for which an offence is to be treated as if it were an offence against a law of the Commonwealth include, for example—
  - (a) the investigation and prosecution of offences; and
  - (b) the arrest, custody, bail, trial and conviction of offenders or people charged with offences; and

- (c) proceedings relating to matters mentioned in paragraph (a) or (b); and
- (d) appeals and review relating to criminal proceedings and to proceedings of the kind mentioned in paragraph (c); and
- (e) the sentencing, punishment and release of people convicted of offences; and
- (f) fines, penalties and forfeitures; and
- (g) liability to make reparation in connection with offences; and
- (h) proceeds of crime; and
- (i) spent convictions.

*Note* An example is part of the Act, 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).

## **167 Application of Commonwealth criminal laws to offences against applied provisions**

- (1) The relevant Commonwealth laws apply as laws of the Territory in relation to an offence against the applied provisions as if the applied provisions were a law of the Commonwealth and not a law of the Territory.
- (2) For the purposes of a territory law, an offence against the applied provisions—
  - (a) is taken to be an offence against the laws of the Commonwealth in the same way as it would be if the applied provisions were a law of the Commonwealth; and
  - (b) is taken not to be an offence against the laws of the Territory.
- (3) However, a regulation may modify the operation of subsection (2).

(4) In this section:

*relevant Commonwealth laws* means—

- (a) the Commonwealth laws that would apply in relation to an offence against the applied provisions if it were an offence against a law of the Commonwealth; and
- (b) includes any Commonwealth law in relation to a matter mentioned in section 166 (2) (a) to (i).

**168 Functions of Commonwealth officers and authorities relating to offences**

- (1) A provision of a Commonwealth law applying under section 167 that gives a Commonwealth officer or Commonwealth authority a function in relation to an offence against the Commonwealth therapeutic goods laws also gives the officer or authority the same function in relation to an offence against the corresponding provision of the applied provisions.

*Note* **Function** includes power and duty (see Legislation Act, dict, pt 1).

- (2) In exercising a function given by subsection (1), the Commonwealth officer or Commonwealth authority must act as nearly as practicable as the officer or authority would act in exercising the same function in relation to an offence against the corresponding provision of the Commonwealth therapeutic goods laws.

**169 No double jeopardy for offences against applied provisions**

- (1) This section applies if—
  - (a) an act or omission is an offence against both the applied provisions and the Commonwealth therapeutic goods laws; and
  - (b) the offender has been punished for the offence under the Commonwealth laws.

- (2) The offender is not liable to be punished for the offence under the applied provisions.

## **Division 10.2.5 Applied provisions—other provisions**

### **170 Commonwealth may keep fees paid to Commonwealth Secretary**

The Commonwealth may keep fees paid to, or recovered by, the Commonwealth Secretary in relation to the exercise of functions given to the Secretary by the applied provisions.

## Chapter 11      Procedural and evidentiary provisions

### Part 11.1      General provisions about offences against Act

#### 171      Acts and omissions of representatives of individuals

(1) In this section:

*fault element* includes intention, knowledge, recklessness, opinion, belief or purpose but does not include negligence.

*offence against this Act* includes an offence against the Criminal Code in relation to—

- (a) a document completed, kept or given, or required to be completed, kept or given, under this Act; and
- (b) anything else done, or not done, under this Act.

*person* means an individual.

*Note*      See the Criminal Code, pt 2.5 for provisions about corporate criminal responsibility.

*representative*, of a person, means an employee or agent of the person.

(2) This section applies to a prosecution for an offence against—

- (a) a provision of—
  - (i) chapter 4 (Offences relating to regulated substances); or
  - (ii) chapter 5 (Offences relating to regulated therapeutic goods); or
- (b) section 96 (Contravening licence conditions).

- (3) Conduct engaged in by a representative of a person within the scope of the representative's actual or apparent authority is also taken to have been engaged in by the person.
- (4) However, subsection (3) does not apply if the person establishes that the person took all reasonable steps to prevent the conduct.
- (5) In deciding whether the person took all reasonable steps to prevent the conduct, a court must consider—
  - (a) any action the person took to ensure that the representative had a reasonable knowledge and understanding of the requirement to comply with the contravened provision; and
  - (b) the level of management, control or supervision that was appropriate for the person to exercise over the representative.
- (6) Subsection (5) does not limit the matters that the court may consider.
- (7) If it is relevant to prove that a person had a fault element or was negligent in relation to a physical element of an offence, it is enough to show that—
  - (a) the conduct relevant to the physical element was engaged in by a representative of the person within the scope of the representative's actual or apparent authority; and
  - (b) the representative had the fault element or was negligent in relation to the physical element.
- (8) A person may rely on the Criminal Code, section 36 (Mistake of fact—strict liability) in relation to conduct by a representative that would be an offence by the person only if—
  - (a) the representative was under a mistaken but reasonable belief about the facts that, had they existed, would have meant that the conduct would not have been an offence; and
  - (b) the person proves that the person exercised appropriate diligence to prevent the conduct.

- (9) A person may not rely on the Criminal Code, section 39 (Intervening conduct or event) in relation to a physical element of an offence brought about by someone else if the other person is a representative of the person.
- (10) A person who is convicted of an offence cannot be punished by imprisonment for the offence if the person would not have been convicted of the offence without subsection (3) or subsection (7).

## **172 Criminal liability of corporation officers**

- (1) This section applies to the following provisions:
  - (a) a provision of—
    - (i) chapter 4 (Offences relating to regulated substances); or
    - (ii) chapter 5 (Offences relating to regulated therapeutic goods);
  - (b) section 94 (Returning licences for amendment);
  - (c) section 96 (Contravening licence conditions);
  - (d) section 145 (Return of certain licences and approvals).
- (2) An executive officer of a corporation commits an offence if—
  - (a) the corporation contravenes a provision to which this section applies; and
  - (b) the contravention is an offence against this Act (the *relevant offence*); and
  - (c) the officer was reckless about whether the contravention would happen; and
  - (d) the officer was in a position to influence the conduct of the corporation in relation to the contravention; and

(e) the officer failed to take all reasonable steps to prevent the contravention.

**Maximum penalty:** The maximum penalty that may be imposed for the commission of the relevant offence by an individual.

- (3) This section applies whether or not the corporation is prosecuted for, or convicted of, the relevant offence.
- (4) In deciding whether the executive officer took (or failed to take) reasonable steps to prevent the contravention, a court must have regard to the following:
- (a) any action the officer took directed towards ensuring the following (to the extent that the action is relevant to the act or omission):
    - (i) that the corporation arranged regular professional assessments of the corporation's compliance with the contravened provision;
    - (ii) that the corporation implemented any appropriate recommendation arising from such an assessment;
    - (iii) that the corporation's employees, agents and contractors had a reasonable knowledge and understanding of the requirement to comply with the contravened provision;
  - (b) any action the officer took when the officer became aware that the contravention was, or could be, about to happen.
- (5) Subsection (4) does not limit the matters to which the court may have regard.
- (6) This section does not apply if the corporation would have a defence to a prosecution for the relevant offence.

### **173 No defence to claim deterioration of sample**

It is not a defence in a proceeding for an offence against this Act for a defendant to claim that any part of a sample kept for future



comparison with a sample that has been analysed has, from natural causes, deteriorated, perished or undergone material change.

#### **174 Remedial orders by court for offences**

- (1) This section applies if—
  - (a) a person is convicted, or found guilty, of an offence against this Act; and
  - (b) the prosecutor asks the court to make an order under this section; and
  - (c) it appears to the court that the person could partly or completely rectify a state of affairs that arose as a direct or indirect result of the conduct that was the subject of the offence.

*Note* **Found guilty**—see the Legislation Act, dict, pt 1.

- (2) The court may order the person to take any steps that it considers are necessary and appropriate to rectify the state of affairs and that are within the person's power to take.
- (3) If a court makes an order under this section, it may also make any other consequential orders (including orders about costs) that it considers appropriate.

#### **175 Court may order costs and expenses**

- (1) A court that hears a proceeding for an offence against this Act may make any order it considers appropriate in relation to costs and expenses in relation to the examination, seizure, detention, storage, analysis (including further analysis), destruction or other disposition of anything the subject of the proceeding.
- (2) This section does not affect any other power of the court to award costs.

## 176 Court may order forfeiture

A court that convicts a person, or finds a person guilty, of an offence against this Act may order the forfeiture to the Territory of anything that was used in the commission of the offence.

## 177 Notices of noncompliance by territory entities

- (1) This section applies if a territory entity (other than a territory-owned corporation) commits an offence against this Act and the offence is an infringement notice offence.

*Note 1* **Territory-owned corporation**—see the Legislation Act, dict, pt 1.

*Note 2* A reference to an Act includes a reference to statutory instruments made or in force under the Act, including any regulation and any law or instrument applied, adopted or incorporated by the Act (see Legislation Act, s 104).

- (2) An authorised person for the infringement notice offence may serve a notice of noncompliance on the responsible director-general for the territory entity.

*Note* For how documents may be served, see the Legislation Act, pt 19.5.

- (3) The responsible director-general must include in the director-general's annual report a statement of the number of notices of noncompliance serviced on the director-general and matter to which each notice related.

- (4) In this section:

**annual report** means a report under the *Annual Reports (Government Agencies) Act 2004*.

**authorised person**, for an infringement notice offence, means an authorised person for the infringement notice offence under the *Magistrates Court Act 1930*, section 134A.

**responsible director-general**—see the *Auditor-General Act 1996*, dictionary.

*territory entity* means—

- (a) an administrative unit; or
- (b) a territory entity under the *Auditor-General Act 1996*.

## Part 11.2 Evidentiary provisions

### 178 Evidence—authorisations under Commonwealth and State laws

- (1) This section applies to the prosecution of a person for an offence against chapter 4 (Offences relating to regulated substances) or chapter 5 (Offences relating to regulated therapeutic goods) if, to prove the offence, it is necessary to prove that at a particular time the person was not authorised to deal with a regulated substance or therapeutic good in a particular way.
- (2) Without evidence to the contrary, the person is taken not to have been authorised under a Commonwealth or State law to deal with the regulated substance or regulated therapeutic good in that way at the particular time.
- (3) To remove any doubt, a reference in subsection (2) to a State law does not include a territory law.

### 179 Presumptions

In a proceeding for an offence against this Act, it is presumed until the contrary is proved on the balance of probabilities, that—

- (a) a regulated substance or regulated therapeutic good that is part of a batch, lot or consignment of the substance of the same kind or description is representative of all the substance or good in the batch, lot or consignment; and
- (b) each part of a sample of a regulated substance divided for analysis for this Act is of uniform composition with every other part of the sample; and
- (c) a person manufactured, packed or supplied a regulated substance or regulated therapeutic good if the person appears to have done so from any marking or label on an article, container or package containing the substance or therapeutic good for sale; and

- (d) a thing that is labelled with the name of—
  - (i) a regulated substance is the regulated substance; and
  - (ii) a regulated therapeutic good is the regulated therapeutic good.

**180 Certificate evidence etc**

- (1) This section applies in relation to a proceeding for an offence against this Act.
- (2) A document that appears to be a copy of a licence, authorisation or approval under this Act is evidence of the issue or giving of a licence, authorisation or approval.
- (3) A certificate that appears to be signed by or on behalf of the chief health officer, and that states any of the following matters, is evidence of the matters:
  - (a) that there was, or was not, in force a licence, authorisation or approval in relation to a stated person or premises;
  - (b) that a licence, authorisation or approval authorised or required or did not authorise or require a stated dealing at a particular time and place;
  - (c) that a licence, authorisation or approval was or was not subject to stated conditions;
  - (d) that a substance is or is not a regulated substance;
  - (e) that a regulated substance belongs to or does not belong to a particular kind of regulated substances;
  - (f) a thing is or is not a regulated therapeutic good;
  - (g) the receipt or otherwise of a notice, application or payment;

- (h) that an amount of fees or another amount is or was payable under this Act by a stated person.

*Note*      For evidentiary certificates by authorised analysts, see the *Public Health Act 1997*, s 135A.

- (4) A certificate that appears to be signed by or on behalf of the chief health officer, and states anything prescribed by regulation, is evidence of the thing.
- (5) A certificate mentioned in subsection (3) or subsection (4) may state anything by reference to a date or period.
- (6) A court must accept a certificate or other document mentioned in this section as proof of the matters stated in it if there is no evidence to the contrary.

### **181      Admissibility of analysis of samples taken by inspectors**

The analysis of a sample of a substance taken by a medicines and poisons inspector is admissible in evidence in a proceeding for an offence against this Act only if the sample was taken as required or allowed under part 7.2 (Taking and analysis of samples of substances).

### **182      Power of court to order further analysis**

- (1) This section applies if the court before which a person is being prosecuted for an offence against this Act is satisfied that there is a disagreement between the evidence of the analysts for the parties to the proceeding.
- (2) The court may order that the part of a sample kept for comparison under section 135 (Procedures for dividing samples) be sent by the chief health officer to an independent analyst.
- (3) For subsection (2), the order may require the sample to be sent to a particular analyst or to an analyst agreed to by the parties.

- (4) An analysis of a sample under this section is for the information of the court.
- (5) Subject to section 175 (Court may order costs and expenses), the cost of an analysis under this section is payable by the Territory.

## Chapter 12 Regulations about regulated substances and regulated therapeutic goods

### 183 Meaning of *regulated thing*—ch 12

In this chapter:

*regulated thing* means a regulated substance or regulated therapeutic good.

### 184 Regulation-making power

- (1) The Executive may make regulations for this Act.

*Note* Regulations must be notified, and presented to the Legislative Assembly, under the Legislation Act.

- (2) A regulation may create offences and fix maximum penalties of not more than 30 penalty units for the offences.

### 185 Regulations—regulated things

- (1) A regulation may make provision in relation to regulated things, including, for example—
  - (a) the methods and equipment for examining and testing things to decide whether they are regulated things; and
  - (b) the methods and equipment for classifying regulated things; and
  - (c) the storage and display, including requirements about security and accessibility, of regulated things; and
  - (d) the advertising and supply of regulated things; and
  - (e) the safe dealing with regulated things; and
  - (f) the use of regulated things; and



- (g) the authorisation, control, notification and prohibition of dealings with regulated things; and
- (h) the plant, premises and systems for dealing with regulated things; and
- (i) the security requirements for premises used to deal with regulated things; and
- (j) the packing, marking, labelling and packaging of regulated things, including the maximum sizes and packages of regulated things; and
- (k) the making and keeping of records in relation to regulated things (including plant and premises for dealing with regulated things) and their inspection and auditing.

*Note* An example is part of the Act, 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) A regulation may also make provision in relation to regulated things, and other things, that can be used to manufacture regulated things.

## **186 Regulations—authorisations**

- (1) A regulation may make provision in relation to authorisations for dealing with regulated things, including, for example—
  - (a) the circumstances in which an authorisation is required for dealing with, or doing something else in relation to, regulated things, including the kind of regulated thing, the kind of dealings, the circumstances of the dealings and the amount that may be dealt with; and
  - (b) the requirements for an application for an authorisation; and
  - (c) the suitability of people to hold an authorisation to deal with regulated things, including—

- (i) the knowledge, experience and training of people; and
- (ii) the testing or examination of people to decide whether they are, or continue to be, suitable people to hold an authorisation; and
- (d) the circumstances in which authorisations may or must not be given; and
- (e) the suitability of premises (including vehicles) in relation to dealings with regulated things; and
- (f) the supervision of dealings with regulated things; and
- (g) the authorisations that may be issued and the authority given to people by particular authorisations; and
- (h) the conditions of authorisations; and
- (i) the creation and publication of registers in relation to authorisations; and
- (j) authorising people to deal with regulated things for research, education or any other purpose.

**Examples of conditions—par (h)**

- 1 how dispensed medicines are to be labelled
- 2 the recording of the supply of regulated things
- 3 the packaging of dangerous poisons
- 4 how long documents relating to dealings with regulated things must be kept

*Note* An example is part of the Act, 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) A regulation may also make provision in relation to the recognition of authorisations (however described) under corresponding laws and the circumstances in which an authorisation to deal with a regulated thing under a corresponding law authorises people to deal with the regulated thing in the ACT.

**187 Regulations—records kept electronically**

- (1) If a document that is required to be kept under this Act is kept in electronic form, a regulation may require that the electronic form of the document be recorded or retained on a particular kind of data storage device.
- (2) Subsection (1) applies despite the *Electronic Transactions Act 2001*, section 11 (1) (c) and (2) (d) (Retention of information and documents).

*Note* Section 11 (1) (c) and (2) (d) provide for regulations under the *Electronic Transactions Act 2001* to prescribe data storage devices.

- (3) For the *Electronic Transactions Act 2001*, a regulation under subsection (1) is taken to be a regulation under that Act.
- (4) In this section:

*data storage device*—see the *Electronic Transactions Act 2001*, dictionary.

**188 Regulations—medicines advisory committee**

A regulation may make provision in relation to the appointment of members to, and the procedures of, the medicines advisory committee.

*Note* The committee is established under s 194.

**189 Regulations—application etc of instruments**

- (1) A regulation may apply, adopt or incorporate a law of another jurisdiction or an instrument, or a provision of a law of another jurisdiction or instrument, as in force from time to time.

*Note 1* The text of an applied, adopted or incorporated law or instrument, whether applied as in force from time to time or at a particular time, is taken to be a notifiable instrument if the operation of the Legislation Act, s 47 (5) or (6) is not disappplied (see s 47 (7)).

*Note 2* A notifiable instrument must be notified under the Legislation Act.

- (2) In this section:

*law of another jurisdiction*—see the Legislation Act, section 47 (10).

### **190 Regulations—exemption of people, dealings etc**

- (1) A regulation may—

- (a) exempt a person, regulated thing, premises or dealing with a regulated thing, or anything else, prescribed by regulation from this Act; or
- (b) authorise the Minister to exempt a person, regulated thing, premises or dealing with a regulated thing, or anything else, prescribed by regulation from this Act.

*Note* A reference to an Act includes a reference to a provision of an Act (see Legislation Act, s 7 (3)).

- (2) An exemption under subsection (1) may be conditional.
- (3) A regulation may provide for the Minister to suspend the operation of—
- (a) a regulation mentioned in subsection (1) (a) in the way and circumstances prescribed by regulation; or
  - (b) an exemption given under subsection (1) (a) in the way and circumstances prescribed by regulation.
- (4) An exemption under subsection (1) (a) is a disallowable instrument.

*Note* A disallowable instrument must be notified, and presented to the Legislative Assembly, under the Legislation Act.

## Chapter 13      Miscellaneous

### **191      Directions about dealings with regulated substances and therapeutic goods**

- (1) For this Act, the chief health officer may give a direction about dealing with a regulated substance or regulated therapeutic good to a person who is authorised to deal with the substance or good.
- (2) Without limiting subsection (1), the chief health officer may give a direction that the chief health officer considers necessary for any of the following:
  - (a) discarding a regulated substance or regulated therapeutic good;
  - (b) safe dealing with a regulated substance or regulated therapeutic good;
  - (c) ensuring compliance with any requirement under this Act or any other territory law in relation to a regulated substance or regulated therapeutic good.
- (3) A direction may be given orally or in writing.
- (4) A direction under subsection (2) (a)—
  - (a) must state a reasonable period within which the regulated substance or regulated therapeutic good must be discarded; and
  - (b) may include requirements for the storage of the substance or good until discarded.

### **192      Guidelines about dealings with regulated substances and therapeutic goods**

- (1) The chief health officer may issue guidelines about dealings with regulated substances and regulated therapeutic goods.

(2) Without limiting subsection (1), a guideline may make provision about the circumstances in which a regulated substance or regulated therapeutic good may be dealt with.

(3) A guideline is a notifiable instrument.

*Note*      A notifiable instrument must be notified under the Legislation Act.

### **193      Approval of non-standard packaging and labelling**

(1) The chief health officer may approve the packaging or labelling of a regulated substance that does not comply with the medicines and poisons standard if satisfied that the use of the packaging or labelling is as safe as using the packaging or labelling allowed under the standard for the substance.

(2) The chief health officer may approve a form of packaging or labelling for a regulated therapeutic good if satisfied that the use of the packaging or labelling is safe.

(3) An approval may be conditional.

(4) An approval is a notifiable instrument.

*Note*      A notifiable instrument must be notified under the Legislation Act.

### **194      Establishment of medicines advisory committee**

The Medicines Advisory Committee is established.

### **195      Secrecy**

(1) In this section:

*court* includes any tribunal or other entity having power to require the production of documents or the answering of questions.

*produce* includes permit access to.

***protected information*** means information about a person that is disclosed to, or obtained by, a person to whom this section applies because of the exercise of a function under this Act.

- (2) This section applies to—
- (a) a person who is or has been a member of the medicines advisory committee; or
  - (b) anyone else who has exercised, or purported to exercise, a function under this Act.
- (3) A person to whom this section applies commits an offence if the person—
- (a) makes a record of protected information; or
  - (b) directly or indirectly discloses or communicates to a person protected information about someone else.

Maximum penalty: 50 penalty units, imprisonment for 6 months or both.

- (4) Subsection (3) does not apply if the record is made, or the information is disclosed or communicated—
- (a) under this or any other Act; or
  - (b) in relation to the exercise of a function of the person to whom this section applies under this or any other Act; or
  - (c) about a person if the giving of the information is necessary to remove a threat to the life or health of the person; or
  - (d) to a person administering or enforcing a corresponding law; or
  - (e) to a law enforcement authority; or
  - (f) to a national board under the *Health Practitioner Regulation National Law (ACT)* or a health profession board under the *Health Professionals Act 2004*; or

(g) to a court under a summons or subpoena.

- (5) Subsection (3) does not prevent a person to whom this section applies from communicating protected information to a person about someone else with the consent of the other person.

### **196      Protection of officials from liability**

- (1) In this section:

*official* means—

- (a) a member of the medicines advisory committee; or
- (b) anyone else who exercises a function under this Act.
- (2) An official, or anyone engaging in conduct under the direction of an official, is not personally liable for anything done or omitted to be done honestly and without recklessness—
- (a) in the exercise of a function under this Act; or
- (b) in the reasonable belief that the conduct was in the exercise of a function under this Act.
- (3) Any civil liability that would, apart from subsection (2), attach to an official attaches instead to the Territory.

### **197      Determination of fees**

- (1) The Minister may determine fees for this Act.

*Note*      The Legislation Act contains provisions about the making of determinations and regulations relating to fees (see pt 6.3).

- (2) A determination is a disallowable instrument.

*Note*      A disallowable instrument must be notified, and presented to the Legislative Assembly, under the Legislation Act.



**198 Approved forms**

- (1) The Minister may approve forms for this Act.
- (2) If the Minister approves a form for a particular purpose, the approved form must be used for that purpose.

*Note* For other provisions about forms, see the Legislation Act, s 255.

- (3) An approved form is a notifiable instrument.

*Note* A notifiable instrument must be notified under the Legislation Act.

## Schedule 1      Reviewable decisions

(see ch 9)

column 1 item	column 2 section	column 3 decision	column 4 entity
1	85	issue licence for less than maximum period	applicant for licence
2	85 (2)	refuse to issue licence	applicant for licence
3	90 (1)	issue licence subject to condition included by chief health officer	applicant for licence
4	91	amend licence	licence-holder
5	92	amend licence in terms different from application or refuse to amend licence	licence-holder
6	142 (3)	<ul style="list-style-type: none"> <li>• reprimand authorisation holder</li> <li>• require authorisation holder or employee to complete training</li> <li>• impose condition on authorisation holder's authority to deal with regulated substance/regulated therapeutic good</li> <li>• vary authorisation holder's authority to deal with regulated</li> </ul>	authorisation holder

column 1 item	column 2 section	column 3 decision	column 4 entity
		substance/regulated therapeutic good <ul style="list-style-type: none"> <li>• suspend authorisation holder's authority to deal with regulated substance/regulated therapeutic good or deal with regulated substance/regulated therapeutic good in particular way</li> <li>• period of suspension/course of training/stated event</li> <li>• cancel authorisation holder's authority to deal with regulated substance/regulated therapeutic good</li> <li>• prohibit interstate wholesaler from supplying regulated substance/regulated therapeutic good by wholesale in ACT</li> </ul>	
7	142 (3)	<ul style="list-style-type: none"> <li>• reprimand former authorisation holder</li> <li>• disqualify former authorisation holder from being authorised to deal with regulated</li> </ul>	former authorisation holder

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column 1 item	column 2 section	column 3 decision	column 4 entity
		substance/regulated therapeutic good or deal with regulated substance/regulated therapeutic good in particular way <ul style="list-style-type: none"> <li>• period of disqualification/course of training/stated event</li> <li>• prohibit former interstate wholesaler from supplying regulated substance/regulated therapeutic good by wholesale in ACT</li> </ul>	
8	191	give direction	person to whom direction is given

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## Dictionary

(see s 3)

*Note 1* The Legislation Act contains definitions and other provisions relevant to this Act.

*Note 2* For example, the Legislation Act, dict, pt 1, defines the following terms:

- ACAT
- bankrupt or personally insolvent
- contravene
- corporation
- dentist
- doctor
- function
- health practitioner
- home address
- midwife
- Minister (see s 162)
- nurse
- nurse practitioner
- optometrist
- pharmacist
- reviewable decision notice
- under.

***appendix C substance***—see section 13.

***applied provisions***, for chapter 10 (Incorporation of Commonwealth therapeutic goods laws)—see section 156.

***applies***, in relation to a substance for a schedule or appendix of the medicines and poisons standard—see section 17.

***at premises*** includes in or on the premises.

***authorisation holder***, for part 8.1 (Authorisations—disciplinary action)—see section 139.

***authorised***—

- (a) to deal with a regulated substance—see section 20; and
- (b) to deal with a regulated therapeutic good—see section 22.

***business*** includes—

- (a) a business not carried on for profit; and
- (b) a trade or profession.

***chief pharmacist***, for an institution with a pharmacy, means the pharmacist having the supervision of all other pharmacists employed at the institution.

***close associate***, of someone, for chapter 6 (Licences for regulated substances and regulated therapeutic goods)—see section 79.

***Commonwealth administrative laws***, for chapter 10 (Incorporation of Commonwealth therapeutic goods laws)—see section 156.

***Commonwealth Minister***, for chapter 10 (Incorporation of Commonwealth therapeutic goods laws)—see section 156.

***Commonwealth Secretary***, for chapter 10 (Incorporation of Commonwealth therapeutic goods laws)—see section 156.

***Commonwealth therapeutic goods laws***, for chapter 10 (Incorporation of Commonwealth therapeutic goods laws)—see section 156.

***community pharmacy*** means a pharmacy at a place other than an institution.

***connected***, with an offence, for part 7.1 (Inspection and seizure powers)—see section 98.

***controlled medicine***—see section 11.

***corresponding law*** means—

- (a) a law of a State corresponding, or substantially corresponding, to this Act; or

- (b) a law of the Commonwealth, a State or New Zealand that is declared by regulation to be a corresponding law, whether or not the law corresponds, or substantially corresponds, to this Act.

*Note* *State* includes a territory (see Legislation Act, dict, pt 1).

***dangerous poison***—see section 12.

***day hospital*** means a facility where a person is admitted for surgical or medical treatment and discharged on the same day.

***deals***—

- (a) with a regulated substance—see section 19; and  
(b) with a regulated therapeutic good—see section 21.

***declared substance***, for part 4.1 (Supply of certain regulated substances—offences)—see section 25.

***disciplinary action***, for part 8.1 (Authorisations—disciplinary action)—see section 141.

***disciplinary notice***, for part 8.1 (Authorisations—disciplinary action)—see section 142 (1).

***dispense*** means supply on prescription.

***dosage unit*** means an individual dose of a medicine or poison for therapeutic use and includes a tablet, capsule, cachet, single-dose powders or single-dose sachet or powders or granules.

***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

(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.

**drug offence**, for part 8.2 (Controlled medicines and prohibited substances—disqualification by courts)—see section 147.

**executive officer**, of a corporation, means a person, however described and whether or not the person is a director of the corporation, who is concerned with, or takes part in, the corporation's management.

**ground for disciplinary action**, against an authorisation holder, for part 8.1 (Authorisations—disciplinary action)—see section 140 (1).

**health professional**—see the *Health Professionals Act 2004*, section 14.

**hospital**—

(a) means a public hospital, private hospital or day hospital; and

*Note* A hospice is a hospital (see *The Macquarie Dictionary*, 3rd ed, def *hospice*).

(b) includes a body prescribed by regulation as a hospital.

**influential person**, for a corporation, for chapter 6 (Licences for regulated substances and regulated therapeutic goods)—see section 80.



***institution***—

- (a) means a hospital, residential aged care facility, residential disability care facility or other institution used for the accommodation, treatment and care of people suffering from mental or physical conditions; and

*Note* ***Hospital, residential aged care facility*** and ***residential disability care facility*** are defined in this dictionary.

- (b) includes a body prescribed by regulation as an institution.

***interstate wholesaler***, for part 8.1 (Authorisations—disciplinary action)—see section 139.

***licence***, for chapter 6 (Licences for regulated substances and regulated therapeutic goods)—see section 78.

***low harm poison***—see section 12.

***manufacture***, for a regulated substance, means do 1 or more of the following in relation to the substance:

- (a) carry out a process to produce the substance;
- (b) refine the substance;
- (c) convert the substance into another regulated substance;
- (d) make or prepare an ampoule, capsule, tablet, vial or other dosage form that consists of, or contains, the substance;
- (e) mix, compound or formulate the substance with another regulated substance or any other substance;
- (f) pack or repack the substance for sale by wholesale or for use in connection with a business, industry, profession or trade.

***medicine***—see section 11.

***medicines advisory committee*** means the Medicines Advisory Committee established by section 194.

***medicines and poisons inspector***—see section 99.

***medicines and poisons standard***—see section 15.

***moderate harm poison***—see section 12.

***must keep***, a register for a regulated substance, for division 4.2.2 (Registers for regulated substances)—see section 48.

***occupier***, of premises, for part 7.1 (Inspection and seizure powers)—see section 98.

***offence***, for part 7.1 (Inspection and seizure powers)—see section 98.

***opioid dependency treatment centre*** means a facility—

- (a) licensed under this Act to treat opioid dependency; or
- (b) operated by the Territory where treatment, including the supply and administration of controlled medicines, is provided to drug-dependent people for their drug dependency.

***pharmacist only medicine***—see section 11.

***pharmacy medicine***—see section 11.

***poison***—see section 12.

***possess***, for a regulated substance—see section 24.

***premises*** includes land or a structure or vehicle and any part of an area of land or a structure or vehicle.

***prescribe*** means issue a prescription.

***prescription***, in relation to a medicine, means an oral or written direction (other than a purchase order, requisition or standing order) to a person—

- (a) who is authorised to administer the medicine to administer the medicine; or
- (b) who is authorised to dispense the medicine to dispense the medicine.

***prescription only medicine***—see section 11.

***prohibited substance***—see section 13.

***purchase order*** means a written order for the supply of a regulated substance.

***register***, for a regulated substance, means a register that a person is required to keep under section 48 for the substance.

***regulated substance***—see section 10.

***regulated therapeutic good***—see section 14.

***regulated thing***, for chapter 12 (Regulations about regulated substances and regulated therapeutic goods)—see section 183.

***relevant person***, for part 8.2 (Controlled medicines and prohibited substances—disqualification by courts)—see section 147.

***requisition*** means an oral or written request for the supply of a medicine—

- (a) from a pharmacy in an institution to a ward or another pharmacy in the institution; or
- (b) to a pharmacy in an institution from a ward in the institution; or
- (c) to a ward in an institution from another ward in the institution; or
- (d) from a pharmacy in an institution to a pharmacy in another institution.

***residential aged care facility*** means a residential facility that provides residential care within the meaning of the *Aged Care Act 1997* (Cwlth), section 41-3 (Meaning of *residential care*) to residents at the facility.

***residential disability care facility***—

- (a) means a residential facility that provides disability care to people with disabilities; but
- (b) does not include a residential aged care facility.

**reviewable decision**, for chapter 9 (Notification and review of decisions)—see section 154.

**sell**—see section 24.

**signs**—a person **signs** something if the person signs with the person's usual signature, whether electronically or otherwise.

**standing order** means a written order authorising the supply or administration of medicines as stated in the order, in stated clinical circumstances.

**suitable person**—

(a) for an individual—see section 81; and

(b) for a corporation—see section 82.

**supply**—see section 24.

**supply authority**—see section 23.

**vending machine**, for division 4.3.5 (Other offences—vending machines)—see section 67.

**ward** means an area of an institution used to accommodate or treat people, including an operating theatre and an opioid dependency treatment centre.

**wholesale** means supply—

(a) for retail sale; or

(b) for use in connection with a business, industry, profession or trade.

**written** includes in electronic form.

## 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	NI = Notifiable instrument
AF = Approved form	o = order
am = amended	om = omitted/repealed
amdt = amendment	ord = ordinance
AR = Assembly resolution	orig = original
ch = chapter	par = paragraph/subparagraph
CN = Commencement notice	pres = present
def = definition	prev = previous
DI = Disallowable instrument	(prev...) = previously
dict = dictionary	pt = part
disallowed = disallowed by the Legislative Assembly	r = rule/subrule
div = division	reloc = relocated
exp = expires/expired	renum = renumbered
Gaz = gazette	R[X] = Republication No
hdg = heading	RI = reissue
IA = Interpretation Act 1967	s = section/subsection
ins = inserted/added	sch = schedule
LA = Legislation Act 2001	sdiv = subdivision
LR = legislation register	SL = Subordinate law
LRA = Legislation (Republication) Act 1996	sub = substituted
mod = modified/modification	<u>underlining</u> = whole or part not commenced or to be expired

## Endnotes

3 Legislation history

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### 3 Legislation history

#### **Medicines, Poisons and Therapeutic Goods Act 2008 A2008-26**

notified LR 14 August 2008

s 1, s 2 commenced 14 August 2008 (LA s 75 (1))

remainder commenced 14 February 2009 (s 2 and LA s 79)

as amended by

#### **ACT Civil and Administrative Tribunal Legislation Amendment Act 2008 A2008-36 sch 1 pt 1.37**

notified LR 4 September 2008

s 1, s 2 commenced 4 September 2008 (LA s 75 (1))

sch 1 pt 1.37 commenced 14 February 2009 (s 2 (5) and see A2008-26 s 2 and LA s 79)

as modified by

#### **Medicines, Poisons and Therapeutic Goods Regulation 2008 SL2008-42 (as am by SL2009-27 s 6)**

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)

#### **Medicines, Poisons and Therapeutic Goods Amendment Regulation 2009 (No 1) SL2009-27 s 6**

notified LR 5 June 2009

s 1, s 2 commenced 5 June 2009 (LA s 75 (1))

s 6 commenced 6 June 2009 (s 2)

*Note* This regulation only amends the Medicines, Poisons and Therapeutic Goods Regulation 2008 SL2008-42.

#### **Statute Law Amendment Act 2009 A2009-20 sch 3 pt 3.52**

notified LR 1 September 2009

s 1, s 2 commenced 1 September 2009 (LA s 75 (1))

sch 3 pt 3.52 commenced 22 September 2009 (s 2)

**Statute Law Amendment Act 2009 (No 2) A2009-49 sch 1 pt 1.8, sch 3 pt 3.50**

notified LR 26 November 2009  
s 1, s 2 commenced 26 November 2009 (LA s 75 (1))  
sch 1 pt 1.8, sch 3 pt 3.50 commenced 17 December 2009 (s 2)

**Health Practitioner Regulation National Law (ACT) Act 2010 A2010-10 sch 2 pt 2.14**

notified LR 31 March 2010  
s 1, s 2 commenced 31 March 2010 (LA s 75 (1))  
sch 2 pt 2.14 commenced 1 July 2010 (s 2 (1) (a))

**Administrative (One ACT Public Service Miscellaneous Amendments) Act 2011 A2011-22 sch 1 pt 1.113**

notified LR 30 June 2011  
s 1, s 2 commenced 30 June 2011 (LA s 75 (1))  
sch 1 pt 1.113 commenced 1 July 2011 (s 2 (1))

**Statute Law Amendment Act 2011 (No 3) A2011-52 sch 1 pt 1.4**

notified LR 28 November 2011  
s 1, s 2 commenced 28 November 2011 (LA s 75 (1))  
sch 1 pt 1.4 commenced 12 December 2011 (s 2)

## Endnotes

4 Amendment history

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### 4 Amendment history

#### Commencement

s 2 om LA s 89 (4)

#### Objects

s 6 am A2010-10 amdt 2.79

#### Appropriate prescription and supply of medicines

s 7 am A2010-10 amdt 2.80

#### Meaning of *possess, sell and supply*—Act

s 24 am A2009-49 amdt 3.118

#### False statements to obtain certain regulated substances etc

s 64 am A2009-49 amdt 3.119

#### Suitability of individuals for licences

s 81 am A2009-20 amdt 3.132; A2011-52 amdt 1.6

#### Power to ask for information etc from applicants and others

s 83 am A2009-20 amdt 3.133

#### Decision on applications for licences

s 85 am A2009-20 amdt 3.134

#### Form of licences

s 88 am A2009-20 amdt 3.135; A2009-49 amdt 1.21

#### Statutory licence conditions

s 89 am A2009-20 amdt 3.136

#### Other licence conditions

s 90 am A2009-20 amdt 3.137

#### Licensee to keep chief health officer informed

s 93 hdg sub A2009-49 amdt 1.22

s 93 am A2009-49 amdt 1.22

#### Power to enter premises

s 102 am A2009-20 amdt 3.138; pars renum R3 LA

#### Procedures for dividing samples

s 135 am A2009-20 amdt 3.139

#### Application—pt 8.1

s 138 am A2010-10 amdt 2.81

#### Notice of disqualification from dealing

s 149 am A2010-10 amdt 2.82

#### Surrender of authorisation under regulation

s 152 am A2010-10 amdt 2.82



**Notification and review of decisions**

ch 9 hdg sub A2008-36 amdt 1.491

**Meaning of *reviewable decision*—ch 9**

s 154 sub A2008-36 amdt 1.491

**Reviewable decision notices**

s 155 sub A2008-36 amdt 1.491

**Applications for review**

s 155A ins A2008-36 amdt 1.491

**Notices of noncompliance by territory entities**

s 177 am A2011-22 amdts 1.331-1.333

**Regulations—authorisations**

s 186 am A2009-20 amdt 3.140

**Secrecy**

s 195 am A2010-10 amdt 2.83

**Transitional**

ch 14 hdg exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional—general**

pt 14.1 hdg exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Definitions—ch 14**

s 500 exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional regulations**

s 501 exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional effect—Legislation Act, s 88**

s 502 exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Expiry—ch 14**

s 503 exp 14 February 2011 (s 503)

**Consequential and other amendments and repeals**

pt 14.2 hdg om LA s 89 (3)

**Legislation amended—sch 2**

s 510 om LA s 89 (3)

**Legislation repealed**

s 511 om LA s 89 (3)

**Transitional—licences and authorisations**

pt 14.3 hdg exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional—existing licences**

s 520 am A2009-20 amdt 3.141  
exp 14 February 2011 (s 503 (LA s 88 declaration applies))

## Endnotes

4 Amendment history

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**Transitional—uncompleted licence applications**

s 521 exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional—existing authorisations**

s 522 am A2009-20 amdt 3.141  
exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional—uncompleted authorisation applications**

s 523 exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional—uncompleted applications for ACAT review**

s 524 sub A2008-36 amdt 1.492  
exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional—approvals to prescribe drugs of dependence**

pt 14.4 hdg exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional—meaning of *drugs advisory committee*—pt 14.4**

s 530 exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional—existing approvals to prescribe drugs of dependence**

s 531 exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional—uncompleted applications to prescribe drugs of dependence**

s 532 exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional—uncompleted applications for drugs advisory committee review**

s 533 exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional—supply authorities**

pt 14.5 hdg exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional—prescriptions generally**

s 540 exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional—requisitions generally**

s 541 exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional—purchase orders generally**

s 542 exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional—standing orders**

s 543 exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional—other**

pt 14.6 hdg exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional—registers**

s 550 exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Transitional—drugs advisory committee members**

s 551 exp 14 February 2011 (s 503 (LA s 88 declaration applies))

**Modification—Crimes Act 1900**

s 552 ins as mod SL2008-42 s 1100 (as ins by SL2009-27 s 6)  
mod lapsed 21 December 2010 (SL2008-42 s 1100 om by  
A2010-50 amdt 1.13)

**Reviewable decisions**

sch 1 sub A2008-36 amdt 1.493

**Consequential and other amendments**

sch 2 om LA s 89 (3)

**Dictionary**

dict am A2008-36 amdt 1.494; A2009-49 amdt 3.120; A2010-10  
amdt 2.84; A2011-52 amdt 1.7  
def **reviewable decision** ins A2008-36 amdt 1.495

## Endnotes

### 5 Earlier republications

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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.

<b>Republication No and date</b>	<b>Effective</b>	<b>Last amendment made by</b>	<b>Republication for</b>
R1 14 Feb 2009	14 Feb 2009– 5 June 2009	A2008-36	new Act and amendments by A2008-36
R2 6 June 2009	6 June 2009– 21 Sept 2009	SL2009-27	modifications by SL2008-42 as amended by SL2009-27
R3 22 Sept 2009	22 Sept 2009– 16 Dec 2009	A2009-20	amendments by A2009-20
R4 17 Dec 2009	17 Dec 2009– 30 June 2010	A2009-49	amendments by A2009-49
R5 1 July 2010	1 July 2010– 20 Dec 2010	A2010-10	amendments by A2010-10
R6 21 Dec 2010	21 Dec 2010– 14 Feb 2011	A2010-10	lapsed modification (s 552)
R7 15 Feb 2011	15 Feb 2011– 30 June 2011	A2010-10	expiry of transitional provisions (ch 14)
R8 1 July 2011	1 July 2011– 11 Dec 2011	A2011-22	amendments by A2011-22

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