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Volume 2: sections 41B-69
Endnotes

Each volume has its own contents

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About this compilation

This compilation

This is a compilation of the *Therapeutic Goods Act 1989* that shows the text of the law as amended and in force on 5 September 2025 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. Any uncommenced amendments affecting the law are accessible on the Register (www.legislation.gov.au).

Application, saving and transitional provisions

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

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The *Legislation Act 2003* provides for First Parliamentary Counsel to make presentational changes to a compilation. Presentational changes are applied to give a more consistent look and feel to legislation published on the Register, and enable the user to more easily navigate those documents.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. Any modifications affecting the law are accessible on the Register.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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Chapter 4—Medical devices

Part 4-1—Introduction

Division 1—Overview of this Chapter

41B General

The purpose of this Chapter is to ensure the safety and satisfactory performance of medical devices. It does this by:

(a) setting out particular requirements for medical devices; and

(b) establishing administrative processes principally aimed at ensuring those requirements are met; and

(c) providing for enforcement through a series of offences and civil penalty provisions.

41BA Requirements for medical devices (Parts 4-2 and 4-3)

The requirements for medical devices are:

(a) essential principles (that are about the safety and performance characteristics of medical devices); and

(b) conformity assessment procedures (that are mainly about the application of quality management systems) or requirements comparable to conformity assessment procedures.

Note: Medical device standards may be made under Division 2 of Part 4-2, and conformity assessment standards may be made under Division 2 of Part 4-3, but they are not requirements.

41BB Administrative processes (Parts 4-4 to 4-10)

The administrative processes under this Chapter are:

(a) issuing conformity assessment certificates for some manufacturers of medical devices; and

(aa) making conformity assessment body determinations; and

(b) including medical devices in the Register; and

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(c) suspending or cancelling entries of medical devices from the Register; and

(ca) exempting medical devices from various provisions of this Chapter to deal with emergency situations; and

(d) exempting medical devices from the requirement to be included in the Register; and

(e) obtaining information about medical devices; and

(f) requiring public notification of problems with medical devices, and recall of such devices.

Note: Part 4-10 provides for assessment fees to be payable in some circumstances.

41BC Enforcement (Part 4-11)

Part 4-11 contains offences and civil penalty provisions that are aimed at ensuring that:

(a) the requirements for medical devices are complied with; and

(b) the administrative processes under this Chapter (particularly the inclusion of medical devices in the Register) are followed.

Note: There are some offences and civil penalty provisions in Parts 4-4 to 4-9. They generally relate to matters ancillary to administrative processes in those Parts (e.g. false or misleading statements in applications).

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Division 2—Interpretation

41BD What is a *medical device*

(1) A ***medical device*** is:

(a) any instrument, apparatus, appliance, software, implant, reagent, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

(i) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;

(iii) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;

(iv) control or support of conception;

(v) in vitro examination of a specimen derived from the human body for a specific medical purpose;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

(aa) any instrument, apparatus, appliance, software, implant, reagent, material or other article specified under subsection (2A); or

(ab) any instrument, apparatus, appliance, software, implant, reagent, material or other article that is included in a class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles specified under subsection (2B); or

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(b) an accessory to an instrument, apparatus, appliance, software, implant, reagent, material or other article covered by paragraph (a), (aa) or (ab); or

(c) a system or procedure pack.

Note: Declarations under subsection (3) exclude articles from the scope of this definition. Declarations under section 7 can also have this effect: see subsection 7(4).

(2) For the purposes of paragraph (1)(a), the purpose for which an instrument, apparatus, appliance, software, implant, reagent, material or other article (the ***main equipment***) is to be used is to be ascertained from the information supplied, by the person under whose name the main equipment is or is to be supplied, on or in any one or more of the following:

(a) the labelling on the main equipment;

(b) the instructions for using the main equipment;

(c) any advertising material relating to the main equipment;

(d) technical documentation describing the mechanism of action of the main equipment.

(2A) The Secretary may, by notice published in the *Gazette* or on the Department's website, specify a particular instrument, apparatus, appliance, software, implant, reagent, material or other article for the purposes of paragraph (1)(aa). The notice is not a legislative instrument. The notice takes effect on the day on which the notice is published in the Gazette or on the Department's website or on such later day as is specified in the notice.

(2B) The Secretary may, by legislative instrument, specify a particular class of instruments, apparatus, appliances, software, implants, reagents, materials or other articles for the purposes of paragraph (1)(ab).

(3) The Secretary may, by legislative instrument, declare that a particular instrument, apparatus, appliance, software, implant, reagent, material or other article, or that a particular class of instruments, apparatus, appliances, software, implants, reagents,

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materials or other articles, are not, for the purposes of this Act, medical devices.

Note: A declaration under this section does not stop articles from being therapeutic goods.

41BE Kinds of medical devices

General

(1) For the purposes of this Chapter, a medical device is taken to be of the same kind as another medical device if they:
  (a) have the same sponsor; and
  (b) have the same manufacturer; and
  (c) have the same device nomenclature system code (see subsection (3)); and
  (d) have the same medical device classification; and
  (e) are the same in relation to such other characteristics as the regulations prescribe, either generally or in relation to medical devices of the kind in question.

Unique medical devices

(2) If a medical device is not of the same kind as any other medical device:
  (a) this Chapter applies in relation to the device as if it were a kind of medical device; and
  (b) references in this Chapter to delivering a reasonable number of samples of the kind of device are taken to be references to delivering the device.

Device nomenclature codes

(3) The Minister may, by legislative instrument, determine device nomenclature codes for medical devices.

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41BEA Excluded purposes

The Secretary may, by legislative instrument, specify purposes for the purposes of paragraph 41FD(ia) and subsection 41FF(1A).

41BF System or procedure packs

Two or more goods (including at least one medical device) are a ***system or procedure pack*** if:

(a) all of the goods are to be interconnected or combined for use in a medical or surgical procedure; or

(b) all of the goods are packaged together for use in a medical or surgical procedure.

41BG Manufacturers of medical devices

(1) The ***manufacturer*** of a medical device is the person who is responsible for the design, production, packaging and labelling of the device before it is supplied under the person's name, whether or not it is the person, or another person acting on the person's behalf, who carries out those operations.

(2) If subsection (1) does not apply to a medical device, the ***manufacturer*** of the device is the person who, with a view to supplying the device under the person's name, does one or more of the following using ready-made products:

(a) assembles the device;

(b) packages the device;

(c) processes the device;

(d) fully refurbishes the device;

(e) labels the device;

(f) assigns to the device its purpose by means of information supplied, by the person, on or in any one or more of the following:

(i) the labelling on the device;

(ii) the instructions for using the device;

(iii) any advertising material relating to the device;

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(iv) technical documentation describing the mechanism of action of the device.

(3) However, a person is not the manufacturer of a medical device if:

(a) the person assembles or adapts the device for an individual patient; and

(b) the device has already been supplied by another person; and

(c) the assembly or adaptation does not change the purpose intended for the device by means of information supplied by that other person, on or in any one or more of the following:

(i) the labelling on the device;

(ii) the instructions for using the device;

(iii) any advertising material relating to the device;

(iv) technical documentation describing the mechanism of action of the device.

(4) A person is not the manufacturer of a medical device if the person is included in a class of persons prescribed by the regulations for the purposes of this subsection.

Note: This section applies in relation to vaping goods that are a medical device.

41BH Meaning of compliance with essential principles

(1) A medical device complies, for the purposes of this Chapter (including Part 4-11), with the essential principles if and only if it does not contravene any of the essential principles.

(2) However, a medical device is also taken, for the purposes of this Chapter (other than Part 4-11), to comply with the essential principles if:

(a) the medical device complies with one or more medical device standards that apply to it; and

(b) the medical device contravenes the essential principles only in respect of a part or parts of the essential principles to which that medical device standard, or one or more of those medical device standards, relate.

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(3) For the purposes of this section, a medical device standard relates to a part or parts of the essential principles only if the standard specifies that part or parts.

41BI Meaning of non-application of conformity assessment procedures

(1) A conformity assessment procedure is taken, for the purposes of this Chapter, not to have been applied to a medical device if:
  (a) there has been a contravention of the conformity assessment procedures; and
  (b) the contravention relates, wholly or partly, to that device or its manufacture.

(2) However, for the purposes of this Chapter (other than Part 4-11), subsection (1) does not apply if:
  (a) the quality management system applied in the manufacture of the medical device complies with one or more conformity assessment standards that apply to it; and
  (b) the contravention is only in respect of a part or parts of the conformity assessment procedures to which that conformity assessment standard, or one or more of those conformity assessment standards, relate.

(3) For the purposes of this section, a conformity assessment standard relates to a part or parts of the conformity assessment procedures only if the standard specifies that part or parts.

41BIA Meaning of non-application of overseas requirements comparable to conformity assessment procedures

(1) A requirement that is comparable to a conformity assessment procedure is taken, for the purposes of this Chapter, not to have been applied to a medical device by the manufacturer of the device if:
  (a) there has been a contravention of the requirement; and
  (b) the contravention relates, wholly or partly, to that device or its manufacture.

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(2) However, for the purposes of this Chapter (other than Part 4-11), subsection (1) does not apply if:

(a) the quality management system applied in the manufacture of the medical device complies with one or more conformity assessment standards that apply to it; and

(b) the contravention is only in respect of a part or parts of the requirement to which that conformity assessment standard, or one or more of those conformity assessment standards, relate.

41BIB Overseas regulators

(1) An ***overseas regulator*** is a body determined in an instrument under subsection (2).

(2) The Secretary may, by notifiable instrument, determine a body for the purposes of subsection (1). The Secretary must be satisfied that the body:

(a) is established outside Australia; and

(b) is empowered to issue certificates or other documents to the effect that the body is satisfied that requirements, comparable to the conformity assessment procedures, have been applied to medical devices by the manufacturers of the devices.

(3) Without limiting subsection (2), the Secretary may determine a body by reference to a designation, recognition, approval or authorisation (however described) of the body:

(a) by one or more countries; or

(b) by another body.

Note: For specification by class, see subsection 13(3) of the *Legislation Act 2003*.

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Division 3—Application provisions

41BJA Application of this Chapter to a biological

(1) Subject to this section, this Chapter does not apply to a biological on and after the commencement of this section.

Biologicals currently included in the Register

(2) If, immediately before the commencement of this section, therapeutic goods that are a biological were included in the Register under this Chapter, this Chapter continues to apply to the biological on and after that commencement until the time the biological is included in the Register under Part 3-2A.

Note: Section 32DN deals with including the biological under Part 3-2A.

Pending applications

(3) If:

(a) before the commencement of this section, an application was made under this Chapter for the inclusion in the Register of therapeutic goods that are a biological; and

(b) immediately before that commencement, the application was not finally determined; and

(c) the application had not been withdrawn before that commencement;

this Chapter continues to apply to the biological on and after that commencement until the earliest of the following:

(d) the time the biological is included in the Register under Part 3-2A;

(e) if the application is unsuccessful when it is finally determined—the time the application is finally determined;

(f) the time the application is withdrawn;

(g) the time the application lapses.

Note: Section 32DN deals with including the biological under Part 3-2A.

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(4) For the purposes of this section, an application is ***finally determined*** when the application, and any applications for review or appeals arising out of it, have been finally determined or otherwise disposed of.

Transitional

(5) This Chapter applies to a biological on and after the commencement of this section in relation to things done, or omitted to be done, in relation to the biological before the commencement of this section.

(6) If this Chapter continues to apply to a biological during a period described in subsection (2) or (3), then this Chapter also applies to the biological after the end of that period in relation to things done, or omitted to be done, in relation to the biological during that period.

41BK Application of the *Criminal Code*

Chapter 2 of the *Criminal Code* applies to all offences against this Chapter.

Note: Chapter 2 of the *Criminal Code* sets out the general principles of criminal responsibility.

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Part 4-2—Essential principles and medical device standards

41C What this Part is about

The essential principles set out the requirements relating to the safety and performance characteristics of medical devices. Compliance with applicable medical device standards is not required, but it is one way to establish compliance with essential principles. The regulations may make provision for and in relation to the Secretary causing a database of unique device identifiers of medical devices to be established and maintained.

Note: Dealing in medical devices that do not comply with the essential principles may be an offence or may contravene a civil penalty provision: see Division 1 of Part 4-11.

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Division 1—Essential principles

41CA Essential principles

(1) The regulations may set out requirements for medical devices.

(2) These requirements are to be known as the ***essential principles***.

(3) Regulations made for the purposes of subsection (1) may include requirements in relation to the inclusion in the database referred to in section 41CE of the following:

(a) unique device identifiers of medical devices;

(b) information relating to those unique device identifiers, those medical devices or the import, export, manufacture or supply of those medical devices.

(4) Subsection (3) has effect subject to subsection 41CE(2).

(5) Subsection (3) does not limit subsection (1).

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Division 2—Medical device standards

41CB Medical device standards

(1) The Minister may, by legislative instrument, make an order determining that:

(a) matters specified in the order constitute a medical device standard for kinds of medical devices identified in the order; and

(b) medical devices of those kinds that comply with the standard are to be treated as complying with those parts of the essential principles specified in the standard.

Note: Section 12 of the *Legislation Act 2003* deals with when a legislative instrument commences.

(2) The Minister may, by legislative instrument, vary or revoke an order made under subsection (1).

(3) Despite subsection 14(2) of the *Legislation Act 2003*, an order under subsection (1) of this section, or a variation of such an order, may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

41CC Content of medical device standards

(1) Without limiting the scope of section 41CB, an order establishing a medical device standard for kinds of medical devices may be specified by reference to:

(a) the safety or performance characteristics of the devices; or

(b) a monograph in the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopeia-National Formulary; or

(c) a monograph in a publication approved by the Minister for the purposes of this subsection; or

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(d) such a monograph as modified in a manner specified in the order; or
(e) a standard published by a standards organisation; or
(f) such other matters as the Minister thinks fit.

(2) For the purposes of paragraph (1)(e), these are standards organisations:
(a) Standards Australia;
(b) the International Organisation for Standardization;
(c) the International Electrotechnical Commission;
(d) the European Committee for Standardization;
(e) the European Committee for Electrotechnical Standardization;
(f) any other organisation declared by the Minister by notice published in the *Gazette* or on the Department's website.

41CD Inconsistencies between medical device standards

(1) A medical device standard that:
(a) applies to a kind of medical device; and
(b) is inconsistent with another medical device standard that applies only to some of the devices of that kind;
is, to the extent of the inconsistency, of no effect in relation to the devices referred to in paragraph (b).

(2) A medical device standard that applies to a kind of medical device that consists of a combination of component parts takes precedence over any medical device standard that applies to the component parts.

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Division 3—Database of unique device identifiers of medical devices

41CE Database of unique device identifiers of medical devices

(1) The regulations may make provision for and in relation to the Secretary causing a database to be established and maintained, to be known as:

(a) the Australian Unique Device Identification Database; or

(b) if another name is prescribed by the regulations—that other name.

Note: The essential principles may include requirements in relation to the inclusion in the database of unique device identifiers of medical devices and related information: see subsection 41CA(3).

Personal information

(2) The regulations must provide that the database must not include personal information, unless the personal information:

(a) is the name of a person in relation to whom a kind of medical device is included in the Register; or

(b) is about an authorised representative of the manufacturer of a kind of medical device; or

(c) is about an authorised representative of a person in relation to whom a kind of medical device is included in the Register.

Removal of information

(3) The regulations may provide for the removal of information from the database.

Corrections to information

(4) The regulations may provide for corrections to information in the database.

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Making the database available

(5) The regulations may provide for the whole or a part of the database to be made:

(a) available to specified persons, authorities or bodies; or

(b) publicly available.

(6) However, the regulations must provide that personal information covered by paragraph (2)(b) or (c) must not be made publicly available.

No limit on subsection (1)

(7) Subsections (2) to (6) do not limit subsection (1).

Database not a legislative instrument

(8) The database is not a legislative instrument.

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Part 4-3—Conformity assessment procedures

41D What this Part is about

The conformity assessment procedures set out the requirements relating to the application of quality management systems for medical devices, and other requirements imposed on manufacturers.

Compliance with applicable conformity assessment standards is not required, but it is one way to establish that one or more parts of the conformity assessment procedures have been applied to medical devices.

Note 1: Dealing in medical devices that have not had the conformity assessment procedures applied may be an offence or may contravene a civil penalty provision: see Division 2 of Part 4-11.

Note 2: See section 41BI on applying the conformity assessment procedures.

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Division 1—Conformity assessment procedures

41DA Conformity assessment procedures

(1) The regulations may set out requirements relating to the obligations of manufacturers of medical devices.

(2) These requirements are to be known as the ***conformity assessment procedures***.

(3) The conformity assessment procedures, or any part of the conformity assessment procedures, may:
  (a) be limited in their application to one or more medical device classifications; or
  (b) apply differently to different medical device classifications, different kinds of medical devices or different manufacturers.

(4) Without limiting subsection (1), the regulations may relate to all or any of the following:
  (a) application of quality management systems for the manufacture of medical devices;
  (b) certification of compliance with the essential principles, or the quality management systems for the manufacture of medical devices;
  (c) notification of, and assessment of, changes to a manufacturer's product range, product design or quality management systems;
  (d) declarations to be made by manufacturers of medical devices that conformity assessment procedures have been applied to the devices;
  (e) marks to be affixed to medical devices indicating the application of the conformity assessment procedures to the devices;
  (f) monitoring and inspecting the design of medical devices or the manufacturing processes for medical devices;
  (g) monitoring the performance of medical devices;

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(h) corrective action required in relation to the design, manufacture, packaging, labelling and supply of medical devices;

(i) keeping records of the manufacture of medical devices, the design of medical devices or the manufacturing processes for medical devices.

41DB Medical device classifications

The regulations may specify:

(a) classifications, to be known as ***medical device classifications***, applying to medical devices or kinds of medical devices; and

(b) matters in relation to the classification of medical devices or kinds of medical devices.

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Division 2—Conformity assessment standards

41DC Conformity assessment standards

(1) The Minister may, by legislative instrument, make an order determining that:

(a) matters specified in the order constitute a conformity assessment standard for quality management systems identified in the order; and

(b) a quality management system that complies with the standard is to be treated as having had applied to it those parts of the conformity assessment procedures specified in the standard.

Note: Section 12 of the *Legislation Act 2003* deals with when a legislative instrument commences.

(2) A conformity assessment standard may be limited to particular kinds of medical devices.

(3) The Minister may, by legislative instrument, vary or revoke an order made under subsection (1).

(4) Despite subsection 14(2) of the *Legislation Act 2003*, an order under subsection (1) of this section, or a variation of such an order, may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

41DD Content of conformity assessment standards

(1) Without limiting the scope of section 41DC, an order establishing a conformity assessment standard for a kind of medical device may be specified by reference to:

(a) procedures to be carried out under the quality management systems for the design, manufacture and final inspection of the devices; or

(b) a standard published by a standards organisation; or

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(c) such other matters as the Minister thinks fit.

(2) For the purposes of paragraph (1)(b), these are standards organisations:

(a) Standards Australia;

(b) the International Organisation for Standardization;

(c) the European Committee for Standardization;

(d) any other organisation declared by the Minister by notice published in the *Gazette* or on the Department's website.

41DE Inconsistencies between conformity assessment standards

A conformity assessment standard that:

(a) identifies quality management systems to which it applies; and

(b) is inconsistent with another conformity assessment standard that applies only to particular kinds of medical devices;

is, to the extent of the inconsistency, of no effect in relation to the devices referred to in paragraph (b).

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Part 4-4—Conformity assessment certificates

41E What this Part is about

The Secretary can issue a conformity assessment certificate (which may be limited to some medical devices) in respect of a manufacturer of medical devices, signifying one or more of these:

(a) that relevant quality management systems have been applied to the device;

(b) the essential principles for the device have been complied with;

(c) other certification requirements of the conformity assessment procedures have been met.

Note: A conformity assessment certificate may be required for an application to include a kind of medical device in the Register to pass preliminary assessment: see paragraph 41FDB(2)(e).

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Division 1—Issuing conformity assessment certificates

41EA When conformity assessment certificates are required

The regulations may prescribe:

(a) kinds of manufacturers in respect of whom a conformity assessment certificate must be issued before valid applications can be made for kinds of medical devices, manufactured by those manufacturers, to be included in the Register; or

(b) kinds of medical devices in respect of which a conformity assessment certificate must be issued before valid applications can be made for those kinds of medical devices to be included in the Register.

Note: The regulations may prescribe different levels of fees for different kinds of manufacturers and medical devices: see subsection 41LA(2).

41EB Applications

(1) An application for a conformity assessment certificate must:

(a) be made in accordance with a form approved, in writing, by the Secretary or in such other manner as is approved, in writing, by the Secretary; and

(b) be delivered to an office of the Department specified by the Secretary.

Note: A conformity assessment fee is payable under section 41LA for consideration of the application.

(2) An application is not effective if:

(a) the prescribed application fee has not been paid; or

(b) the application contains information that is false or misleading in a material particular.

Note: A person might also commit an offence, or contravene a civil penalty provision, if the person makes a statement in an application that is false or misleading in a material particular: see sections 41EI and 41EIA.

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(3) An approval of a form may require or permit an application or information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

(4) The Secretary may, by written notice given to an applicant for a conformity assessment certificate, require the applicant to allow an authorised person, at any reasonable time specified in the notice, to inspect:

(a) the premises (including premises outside Australia) and equipment, processes and facilities that are being or will be used to manufacture medical devices of the kind in question; and

(b) any other kinds of medical devices on those premises.

41EC Considering applications

(1) If the application is made in accordance with section 41EB, the Secretary must decide whether to issue the conformity assessment certificate.

(2) In deciding whether to issue the certificate, the Secretary must consider some or all aspects of whether the conformity assessment procedures relating to one or more of the following have been applied to the medical device:

(a) the application of quality management systems for the manufacture of medical devices;

(b) the certification of compliance with the essential principles;

(c) any other requirement of the conformity assessment procedures specified in regulations made for the purposes of this subsection.

(3) In deciding whether to issue the certificate, the Secretary must also consider:

(a) whether at least one of the following persons:

(i) the applicant;

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(ii) a person (a ***manager***) who makes, or participates in making, decisions that affect the whole, or a substantial part, of the applicant's affairs;

(iii) if the applicant is a body corporate—a major interest holder of the body corporate;

has, within the 10 years immediately before the application:

(iv) been convicted of an offence against this Act or a corresponding State law; or

(v) been convicted of an offence against a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(vi) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of this Act or a corresponding State law; or

(vii) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(viii) breached a condition of a conformity assessment document; or

(ix) had a conformity assessment document suspended or revoked; or

(x) been a manager, or a major interest holder, of a body corporate in respect of which subparagraph (iv), (v), (vi), (vii), (viii) or (ix) applies in that 10 year period, if the conduct resulting in that subparagraph applying occurred when the person was a manager or major interest holder of the body corporate; or

(b) whether any other circumstances prescribed by the regulations for the purposes of this paragraph exist.

(4) A reference in paragraph (3)(a) to a person convicted of an offence includes a reference to a person in respect of whom an order has been made relating to the offence under:

(a) section 19B of the *Crimes Act 1914*; or

(b) a corresponding provision of a law of a State or Territory.

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Note: Section 19B of the *Crimes Act 1914* empowers a court that has found a person to have committed an offence to take action without proceeding to record a conviction.

(5) Paragraph (3)(a) does not limit paragraph (3)(b).

(6) The Secretary may, by written notice given to the applicant, require the applicant:
  (a) to deliver to the office to which the application was made a reasonable number of samples of the kind of medical device to which the application relates within the period, of not less than 14 days after the day the notice is given, specified in the notice; and
  (b) to do so in a manner specified in the notice.

41ECA Conformity assessment (priority applicant) determinations

(1) The regulations may make provision for and in relation to empowering the Secretary to make conformity assessment (priority applicant) determinations.

(2) A ***conformity assessment (priority applicant) determination*** is a determination that, for the purposes of this Act, a specified person is a priority applicant in relation to any section 41EB application that may be made by the person for a conformity assessment certificate in relation to medical devices of a kind specified in the determination.

(3) The regulations may make provision for and in relation to the following matters:
  (a) applications for conformity assessment (priority applicant) determinations;
  (b) the approval by the Secretary of a form for such an application;
  (c) information that must accompany such an application;
  (d) the application fee for such an application;
  (e) empowering the Secretary to give the applicant a written notice requiring the applicant to give to the Secretary specified information or documents in connection with the

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application within a specified period (which must be at least 10 working days after the notice is given to the applicant).

(4) The regulations may make provision for and in relation to the following matters:

(a) empowering the Secretary to revoke a conformity assessment (priority applicant) determination;

(b) the consequences of the revocation of a conformity assessment (priority applicant) determination.

(5) Subsections (3) and (4) do not limit subsection (1).

(6) The regulations may make provision for and in relation to the priority to be given by the Secretary to consideration of a section 41EB application where the applicant is a priority applicant.

(7) The regulations may provide that, if:

(a) a person is a priority applicant in relation to a section 41EB application made by the person; and

(b) a decision is made on the application;

a statement setting out the decision may be published on the Department's website.

(8) The express references in this section to the Secretary do not, by implication, prevent the regulations from empowering the Secretary to delegate any or all of the Secretary's functions or powers under regulations made for the purposes of this section.

(9) If a conformity assessment (priority applicant) determination is in force under the regulations, the determination may be published on the Department's website.

(10) A conformity assessment (priority applicant) determination made under the regulations is not a legislative instrument.

(11) Subsection 33(3AB) of the *Acts Interpretation Act 1901* does not apply to the specification of a person in a conformity assessment (priority applicant) determination.

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Note: Subsection 33(3AB) of the *Acts Interpretation Act 1901* deals with specification by class.

41ED Time for making decisions on applications

If the application relates to the issuing of a conformity assessment certificate in relation to which a period has been prescribed under paragraph 63(2)(dc), a decision on the application must be made within that period, unless the application lapses under section 41EG.

41EE Procedure following making a decision whether to issue certificate

(1) After making a decision whether to issue a conformity assessment certificate, the Secretary must:

(a) notify the applicant in writing of his or her decision within 20 working days; and

(b) if the decision is not to issue the certificate—state in the notice the reasons for the decision; and

(c) if the decision is to issue the certificate and all assessment fees that are due and payable for the application have been paid:

(i) issue the certificate to the manufacturer in relation to whom the application was made; and

(ii) give the applicant a copy of the certificate (if the applicant is not the manufacturer).

(2) A conformity assessment certificate must specify whether it covers:

(a) all medical devices manufactured by the manufacturer; or

(b) only specified medical devices manufactured by the manufacturer.

(3) A conformity assessment certificate must contain any other information prescribed by the regulations for the purposes of this subsection.

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41EF Duration of certificate

(1) The conformity assessment certificate commences on the day specified for the purpose in the certificate. The certificate must specify the period for which it is to be in force (which must be no longer than 5 years).

(2) A conformity assessment certificate has effect at all times:
  (a) unless the certificate is suspended under Division 3; or
  (b) until the end of the period specified in the certificate, or if the Secretary extends that period, until the end of that extended period; or
  (c) until the certificate is revoked under Division 4.

Extensions

(3) The Secretary may, in writing and on his or her own initiative, extend the period for which a conformity assessment certificate is in force.

(4) An extension must be no longer than 12 months.

(5) Only one extension may be given.

(6) The Secretary:
  (a) must give notice of an extension to the manufacturer in relation to whom the certificate was issued; and
  (b) may give notice of an extension to the applicant for the certificate (if the applicant is not the manufacturer).

41EG Lapsing of applications

An application for a conformity assessment certificate lapses if:
  (a) the applicant does not deliver to the office to which the application was made such information (in a form approved in writing by the Secretary) as will allow the certificate to be issued; or
  (b) the applicant does not comply with a requirement by the Secretary under subsection 41EC(6) to deliver to the office to

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which the application was made a reasonable number of samples of the kind of medical device to which the application relates; or

(c) the applicant fails to comply with a notice under section 41JA to give to the Secretary information within a further 10 working days from the day specified in the notice; or

(d) information given to the Secretary by, or on behalf of, the applicant in connection with the application, including information given for the purpose of a notice under section 41JA, is false or misleading in a material particular; or

(e) the applicant fails to allow an authorised person to carry out any inspection as required under subsection 41EB(4); or

(f) for the whole or a part of the conformity assessment fee for the application that is due and payable in accordance with regulations made for the purposes of Part 4-10—the applicant fails to pay that whole or part in accordance with those regulations.

41EH Treating applications as having been refused

(1) The applicant for an application for a conformity assessment certificate may give the Secretary written notice that the applicant wishes to treat the application as having been refused if:

(a) a period is prescribed under paragraph 63(2)(dc) for making a decision on the application; and

(b) at the end of the period, the applicant has not been notified of a decision whether to issue the certificate.

(2) The notice may be given at any time before the applicant is notified of the decision.

(3) If a notice has been given, this Act (except for subsection 60(5)) has effect as if:

(a) the Secretary had decided not to issue the certificate; and

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(b) the Minister had made a decision under subsection 60(3) confirming the decision of the Secretary; and

(c) the Minister's decision had been made on the day on which notice was given to the Secretary.

41EI Criminal offences for making a false statement

(1) A person commits an offence if:

(a) the person makes a statement (whether orally, in a document or in any other way); and

(b) the statement is made in or in connection with an application for a conformity assessment certificate; and

(c) the person knows that the statement is false or misleading in a material particular; and

(d) either:

(i) the use of the kind of medical device has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the kind of medical device, if the kind of medical device were used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person makes a statement (whether orally, in a document or in any other way); and

(b) the statement is in or in connection with an application for a conformity assessment certificate; and

(c) the person knows that the statement is false or misleading in a material particular.

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Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(5) A person commits an offence if:

(a) the person makes a statement (whether orally, in a document or in any other way); and

(b) the statement is in or in connection with an application for a conformity assessment certificate; and

(c) the statement is false or misleading in a material particular.

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

41EIA Civil penalty for making a false statement

A person contravenes this section if:

(a) the person makes a statement (whether orally, in a document or in any other way); and

(b) the statement is false or misleading in a material particular; and

(c) the statement is in or in connection with an application for a conformity assessment certificate.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

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Division 2—Conditions

Note: Breaching conditions of the conformity assessment certificate may lead to suspension or revocation of the certificate (see Divisions 3 and 4), may be an offence (see subsections 41MN(5), (8) and (8A)), and may contravene a civil penalty provision (see subsection 41MNA(2)).

41EJ Automatic conditions on conformity assessment certificates

Entry and inspection powers

(1) A conformity assessment certificate is subject to the conditions that the manufacturer in respect of whom the certificate is issued will:

(a) allow an authorised person:

(i) to enter, at any reasonable time, premises (including premises outside Australia) at which the person or any other person deals with medical devices of a kind covered by the certificate; and

(ii) while on those premises, to inspect those premises and medical devices of any kind on those premises and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of medical devices of any kind on those premises or any thing on those premises that relates to medical devices of any kind; and

(iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises; and

(b) if requested to do so by an authorised person:

(i) produce to the person such documents relating to devices of a kind covered by the certificate, or to the manufacturer's quality management system, as the person requires; and

(ii) allow the person to copy the documents.

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Review

(2) A conformity assessment certificate is subject to the condition that the manufacturer in respect of whom the certificate is issued will cooperate in any review by the Secretary of the certificate to determine whether the conformity assessment procedures relating to the following matters have been applied to the kinds of medical devices covered by the certificate:

(a) the application of quality management systems for the manufacture of medical devices;

(b) the certification of compliance with the essential principles;

(c) any other requirement of the conformity assessment procedures specified in the regulations made for the purposes of subsection 41EC(2).

Notification of substantial changes

(3) A conformity assessment certificate is subject to the condition that the person in respect of whom the certificate is issued will notify the Secretary, in writing, of any plan for substantial changes to:

(a) quality management systems; or

(b) the product range covered by those systems; or

(c) the product design of kinds of medical devices;

in respect of which the certificate is issued.

Fees

(4) A conformity assessment certificate is subject to the condition that the applicant for the certificate will pay a fee, prescribed in the regulations, for a review under subsection (2), when the fee becomes due and payable.

(5) The regulations may prescribe different levels of fees for different kinds of manufacturers and medical devices.

Conditions in regulations

(5A) A conformity assessment certificate is subject to any conditions prescribed by the regulations for the purposes of this subsection.

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Conditions do not limit other conditions

(6) A condition imposed under this section is in addition to any conditions imposed under this Division.

41EK Conditions imposed when conformity assessment certificates are issued

If the Secretary issues a conformity assessment certificate in respect of a manufacturer, the Secretary may, in writing, impose conditions on the certificate in respect of:

(a) one or more kinds of medical devices covered by the certificate; or

(b) the manufacturer's quality management system.

41EL Conditions imposed after issuing a conformity assessment certificate

(1) The Secretary may, by written notice given to a manufacturer in respect of whom a conformity assessment certificate has been issued:

(a) impose new conditions on the certificate in respect of:

(i) one or more kinds of medical devices covered by the certificate; or

(ii) the manufacturer's quality management system; or

(b) vary or remove existing conditions.

The power may be exercised at the request of the applicant for the certificate or on the Secretary's own initiative.

(2) The imposition, variation or removal of a condition under this section takes effect:

(a) if the notice states that the action is necessary to prevent imminent risk of death, serious illness or serious injury—on the day on which the notice is given to the person; or

(aa) in the case of an imposition or variation requested by the person, and to which paragraph (a) does not apply—on the day specified in the notice, which must be at least 20 working

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days after the notice is given to the person, unless the person has agreed to an earlier day; or

(ab) in the case of a removal to which paragraph (a) does not apply—on the day specified in the notice, which must be at least 20 working days after the notice is given to the person, unless the person has agreed to an earlier day; or

(b) in any other case—on the day specified for the purpose in the notice, being a day not earlier than 20 working days after the notice is given to the person.

(3) For the purposes of paragraphs (2)(aa) and (ab), the earlier day must not be earlier than the day the notice is given to the person.

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Division 3—Suspension of conformity assessment certificates

41EM Suspension of conformity assessment certificates

(1) The Secretary may, by written notice given to the person in relation to whom a conformity assessment certificate is issued, suspend the certificate if the Secretary is satisfied that it is likely that there are grounds for revoking the certificate under section 41ET.

(2) The suspension may be limited to some medical devices of that kind, as specified in the notice.

(3) The notice must specify the period of the suspension. The period must not exceed 6 months.

Note: The period of the suspension may be extended under section 41EO.

41EN Notice of proposed suspension

(1) However, before suspending a conformity assessment certificate, the Secretary must:

(a) inform the person in writing that the Secretary proposes the suspension and set out the reasons for it; and

(b) give the person a reasonable opportunity to make submissions to the Secretary in relation to the proposed suspension.

(2) The Secretary is not to make a decision relating to the proposed suspension until the Secretary has had regard to any submissions the person makes under paragraph (1)(b).

(3) This section does not apply if the notice under section 41EM states that the suspension is necessary to prevent imminent risk of death, serious illness or serious injury.

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41EO Duration of suspension

(1) The suspension takes effect:

(a) if the notice under section 41EM states that the suspension is necessary to prevent imminent risk of death, serious illness or serious injury—on the day on which the notice is given to the person; or

(b) in any other case—on the day specified for the purpose in the notice, being a day not earlier than 20 working days after the notice is given to the person.

(2) The suspension has effect until:

(a) the Secretary revokes it under section 41EP; or

(b) the expiry of:

(i) the period specified in the notice under section 41EM; or

(ii) if the period is extended under subsection (3) of this section, the period as so extended.

Note: Unless a suspension of a conformity assessment certificate has been revoked, the certificate is automatically revoked: see section 41ER.

(3) If a person in relation to whom a kind of medical device is included in the Register shows that he or she has taken steps to address the grounds for revoking the certificate under section 41ET, the Secretary may, by written notice given to the person, extend the period specified in the notice under section 41EM by a further specified period not exceeding 6 months.

41EP Revocation of suspension

(1) The Secretary must revoke the suspension if the Secretary is satisfied that:

(a) the ground on which the conformity assessment certificate was suspended no longer applies; and

(b) there are no other grounds for suspending the certificate.

(2) The Secretary's power to revoke the suspension may be exercised:

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(a) if:
(i) the manufacturer in relation to whom the conformity assessment certificate was issued; or
(ii) the person who applied for the certificate (if the applicant was not the manufacturer);
applies in writing to the Secretary; or
(b) on the Secretary's own initiative.

(3) After revoking the suspension, the Secretary must, within 20 working days after the revocation, give written notice of the revocation to the person in relation to whom the conformity assessment certificate was issued.

(4) If the Secretary decides, after an application is made under paragraph (2)(a), not to revoke the suspension, the Secretary must:
(a) notify the applicant in writing of his or her decision within 20 working days after the decision is made; and
(b) state in the notice the reasons for the decision.

41EQ Powers of revocation of conformity assessment certificates unaffected

(1) This Division does not affect the Secretary's powers to revoke a conformity assessment certificate under Division 4.

(2) To the extent that a suspension under this Division relates to a conformity assessment certificate to which such a revocation relates, the suspension ceases to have effect.

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Division 4—Revocation of conformity assessment certificates

41ER Automatic revocation of conformity assessment certificates

The Secretary must, by written notice given to the person in relation to whom a conformity assessment certificate is issued, revoke the certificate if:

(a) the certificate has been suspended under section 41EM; and

(b) the period applying to the suspension under subsection 41EM(3) or 41EO(3) (as the case requires) expires before the suspension is revoked under section 41EP.

41ES Immediate revocation of conformity assessment certificates

(1) The Secretary may, by written notice given to the manufacturer in relation to whom a conformity assessment certificate is issued, revoke the certificate if the manufacturer requests in writing the revocation of the certificate.

(2) If:

(a) the Secretary revokes a certificate under subsection (1); and

(b) before the end of the period of 90 days beginning on the day the certificate was revoked, the manufacturer requests, in writing, the Secretary to withdraw the revocation; and

(c) the request is accompanied by the prescribed application fee (if any);

the Secretary may, by notice in writing given to the manufacturer, withdraw the revocation.

(3) If the revocation is withdrawn, the revocation is taken never to have occurred.

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41ET Revocation of conformity assessment certificates after notice of proposed revocation

(1) The Secretary may, by written notice given to the person in relation to whom a conformity assessment certificate is issued, revoke the certificate if:

(a) the conformity assessment procedures have not been applied to medical devices of a kind to which the certificate applies; or

(b) the manufacturer in relation to whom the certificate is issued refuses or fails to comply with a condition to which the certificate is subject; or

(c) the Secretary gives to the person a notice under section 41JA that requires the person to give to the Secretary information or documents and the person fails to comply with that notice within a further 10 working days from the day specified in that notice; or

(d) the manufacturer in respect of whom the certificate is issued no longer manufactures any of the kinds of medical devices to which the certificate applies; or

(e) at least one of the following persons:

(i) the person (the ***holder***) in relation to whom the certificate is issued;

(ii) a person (a ***manager***) who makes, or participates in making, decisions that affect the whole, or a substantial part, of the holder's affairs;

(iii) if the holder is a body corporate—a major interest holder of the body corporate;

has:

(iv) been convicted of an offence against this Act or a corresponding State law; or

(v) been convicted of an offence against a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

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(vi) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of this Act or a corresponding State law; or

(vii) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(viii) breached a condition of a conformity assessment document; or

(ix) had a conformity assessment document suspended or revoked; or

(x) been a manager, or a major interest holder, of a body corporate in respect of which subparagraph (iv), (v), (vi), (vii), (viii) or (ix) applies, if the conduct resulting in that subparagraph applying occurred when the person was a manager or major interest holder of the body corporate; or

(f) any other circumstances prescribed by the regulations for the purposes of this paragraph exist.

(1A) A reference in paragraph (1)(e) to a person convicted of an offence includes a reference to a person in respect of whom an order has been made relating to the offence under:

(a) section 19B of the *Crimes Act 1914*; or

(b) a corresponding provision of a law of a State or Territory.

Note: Section 19B of the *Crimes Act 1914* empowers a court that has found a person to have committed an offence to take action without proceeding to record a conviction.

(1B) Paragraph (1)(e) does not limit paragraph (1)(f).

(2) However, before revoking the certificate, the Secretary must:

(a) inform the person in writing that the Secretary proposes the revocation and set out the reasons for it; and

(b) give the person a reasonable opportunity to make submissions to the Secretary in relation to the proposed revocation.

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(3) The Secretary is not to make a decision relating to the proposed revocation until the Secretary has had regard to any submissions the person makes under paragraph (2)(b).

(4) Nothing in this section affects the operation of Part VIIC of the *Crimes Act 1914* (which includes provisions that, in certain circumstances, relieve persons from the requirement to disclose spent convictions and require persons aware of such convictions to disregard them).

41EU Limiting revocation of conformity assessment certificates to some medical devices of a particular kind

(1) If the Secretary is satisfied that the ground for revoking a conformity assessment certificate applies only to:

(a) some of the kinds of medical devices to which the certificate applies; or

(b) some medical devices of the kinds to which the certificate applies;

the Secretary must limit the revocation to the medical devices to which that ground or any other ground for revocation applies.

(2) If the revocation of the certificate is so limited, the Secretary must vary the certificate so that it no longer applies to the medical devices referred to in subsection (1).

41EV Publication of revocation etc. of conformity assessment certificates

The Secretary must cause to be published in the *Gazette* or on the Department's website, as soon as practicable after revoking a conformity assessment certificate, or varying a conformity assessment certificate under subsection 41EU(2), a notice setting out particulars of the revocation or variation.

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41EW Date of effect of revocation etc. of conformity assessment certificates

If the Secretary revokes a conformity assessment certificate, or varies a conformity assessment certificate under subsection 41EU(2), the revocation or variation has effect:

(a) if the revocation is under section 41ER or 41ES, or the variation relates to a ground of revocation in section 41ER or 41ES—on the day on which the notice of revocation or variation is given to the person in relation to whom the certificate was issued; or

(b) in any other case—on such later day as is specified in the notice.

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Part 4-4A—Australian conformity assessment bodies

41EWA Conformity assessment body determinations

(1) The regulations may make provision for and in relation to empowering the Secretary to make conformity assessment body determinations.

(2) A ***conformity assessment body determination*** is a determination that a specified Australian corporation is an ***Australian conformity assessment body*** for the purposes of this Act.

(3) The regulations may make provision for and in relation to the following matters:
  (a) applications for conformity assessment body determinations;
  (b) the approval by the Secretary of a form for such an application;
  (c) information that must accompany such an application;
  (d) the application fee for such an application;
  (e) the lapsing of such an application;
  (f) the assessment by the Secretary of whether a conformity assessment body determination should be made in response to such an application;
  (g) the assessment fee for such an assessment;
  (h) the duration of conformity assessment body determinations.

(4) A conformity assessment body determination:
  (a) may be of general application; or
  (b) may be limited to either or both of the following:
    (i) one or more specified medical devices;
    (ii) one or more specified conformity assessment procedures.

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(4A) If under the regulations the Secretary makes a conformity assessment body determination, the Secretary must assign a unique identification number to the body.

(4B) The Secretary must publish a list of the Australian conformity assessment bodies on the Department's website.

(4C) The Secretary may also publish on the Department's website any information relating to Australian conformity assessment bodies and either to conformity assessment body determinations or to certification-related activities of Australian conformity assessment bodies.

(5) The regulations may provide that a conformity assessment body determination is subject to:

(a) the conditions prescribed by the regulations; and

(b) such other conditions (if any) as are specified in the determination.

Note: See subsections 41MN(10) to (12) and 41MNA(3) for offences and a civil penalty for a breach of the conditions.

(6) The following are examples of conditions that may be prescribed:

(a) a condition that the body will allow an authorised person:

(i) to enter, at any reasonable time, premises used by the body to carry on certification-related activities; and

(ii) while on those premises, to inspect those premises and anything on those premises that concerns certification-related activities carried on by the body; and

(iii) while on those premises, to make any still or moving image or any recording of those premises or anything on those premises that concerns certification-related activities carried on by the body; and

(iv) while on those premises, to inspect, and make copies of, any documents that concern certification-related activities carried on by the body;

(b) a condition that the body will, if requested to do so by the Secretary, give the Secretary information, or produce to the

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Secretary documents, that concern certification-related activities carried on by the body.

(6A) The regulations may make provision for and in relation to the effect on an Australian conformity assessment body certificate of the Australian conformity assessment body ceasing to carry on certification-related activities.

(6B) Without limiting subsection (6A), regulations made for the purposes of that subsection may make provision in relation to a matter by conferring on the Secretary a power to make a decision of an administrative character.

(7) The regulations may make provision for and in relation to empowering the Secretary to revoke, suspend or vary a conformity assessment body determination.

(7A) If under the regulations the Secretary suspends a conformity assessment body determination, the conditions referred to in subsection (5) continue during the suspension.

(8) Subsections (3) to (7) do not limit subsection (1).

(9) The express references in this section to the Secretary do not, by implication, prevent the regulations from empowering the Secretary to delegate any or all of the Secretary's functions or powers under regulations made for the purposes of this section.

(10) If a conformity assessment body determination is in force under the regulations, the determination must be published on the Department's website.

(11) A conformity assessment body determination made under the regulations is not a legislative instrument.

(12) Subsection 33(3AB) of the *Acts Interpretation Act 1901* does not apply to the specification of an Australian corporation in a conformity assessment body determination.

Note: Subsection 33(3AB) of the *Acts Interpretation Act 1901* deals with specification by class.

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41EWB Content of Australian conformity assessment body certificates

(1) An Australian conformity assessment body certificate that is issued to a manufacturer of medical devices must specify whether it covers:

(a) all medical devices manufactured by the manufacturer; or

(b) only specified medical devices manufactured by the manufacturer.

(2) An Australian conformity assessment body certificate must contain any other information prescribed by the regulations for the purposes of this subsection.

(3) An Australian conformity assessment body certificate may be subject to conditions specified in the certificate.

41EWC Duration of Australian conformity assessment body certificates

(1) An Australian conformity assessment body certificate commences on the day specified for the purpose in the certificate. The certificate must specify the period for which it is to be in force (which must be no longer than 5 years).

(2) An Australian conformity assessment body certificate has effect at all times:

(a) unless the certificate is suspended by the Australian conformity assessment body; or

(b) until the end of the period specified in the certificate, or if the Australian conformity assessment body extends that period, until the end of that extended period; or

(c) until the certificate is revoked by the Australian conformity assessment body.

Extensions

(3) An Australian conformity assessment body that has issued an Australian conformity assessment body certificate may, in writing

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and on its own initiative, extend the period for which the certificate is in force.

(4) An extension must be no longer than 12 months.

(5) Only one extension may be given.

(6) The Australian conformity assessment body must give notice of an extension to the person to whom the certificate was issued.

41EWD Record-keeping

(1) If an Australian corporation:
   (a) is an Australian conformity assessment body; and
   (b) is required by a condition referred to in subsection 41EWA(5) to keep records relating to certification-related activities carried on by the corporation;

the Australian corporation must keep the records at all times while the corporation is an Australian conformity assessment body.

(2) If the Australian corporation ceases to be an Australian conformity assessment body, the corporation must keep the records referred to in subsection (1) for 15 years after that cessation.

Offences

(3) An Australian corporation commits an offence if:
   (a) the corporation is subject to a requirement under this section; and
   (b) the corporation contravenes the requirement.

Penalty: 1,200 penalty units.

(4) An Australian corporation commits an offence if:
   (a) the corporation is subject to a requirement under this section; and
   (b) the corporation contravenes the requirement.

Penalty: 300 penalty units.

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(5) An offence against subsection (4) is an offence of strict liability.

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Part 4-5—Including medical devices in the Register

41F What this Part is about

Kinds of medical devices can be included in the Register if they comply with the essential principles, and conformity assessment procedures have been applied to the kinds of devices or requirements, comparable to those procedures, have been applied to the kinds of devices (and certain other requirements are complied with).

Inclusions in the Register are subject to certain automatic conditions and the Secretary may impose further conditions.

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Division 1—Including medical devices in the Register

41FA What this Division is about

Kinds of medical devices are usually included in the Register once an application is made, together with the required certification and the application passes preliminary assessment. However, applications may be selected for audit, which involves checking some or all aspects of the application and certification.

Note 1: In some cases, an application relating to a kind of medical device will not pass preliminary assessment unless that kind of device is covered by a conformity assessment certificate under Part 4-4: see paragraph 41FDB(2)(e).

Note 2: Dealing in medical devices of a kind not included in the Register may be an offence or may contravene a civil penalty provision: see Division 3 of Part 4-11.

Subdivision A—Applications

41FC Making an application

(1) A person may make an application to the Secretary for a kind of medical device to be included in the Register.

(2) An application must not contain information that is false or misleading in a material particular.

Note: A person might also commit an offence, or contravene a civil penalty provision, if the person makes a statement in an application that is false or misleading in a material particular: see sections 41FE and 41FEA.

41FD Matters to be certified

The applicant must certify that:

(a) devices of the kind in question are medical devices; and

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(b) devices of that kind are intended for a specified purpose, as ascertained under subsection 41BD(2); and

(c) the kind of device is correctly classified according to the medical device classifications; and

(d) devices of that kind comply with the essential principles; and

(e) the applicant:

(i) has available sufficient information to substantiate that compliance with the essential principles; or

(ii) has procedures in place, including a written agreement with the manufacturer of the kind of devices setting out the matters required by the regulations, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and

(f) either:

(i) appropriate conformity assessment procedures have been applied to devices of that kind; or

(ii) requirements, comparable to the conformity assessment procedures, have been applied to devices of that kind; and

(g) the applicant:

(i) has available sufficient information to substantiate the application of the procedures referred to in subparagraph (f)(i) or the requirements referred to in subparagraph (f)(ii); or

(ii) has procedures in place, including a written agreement with the manufacturer of the kind of devices setting out the matters required by the regulations, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and

(h) both of the following are complied with in relation to devices of that kind:

(i) the applicable provisions of the Therapeutic Goods Advertising Code;

(ii) the other requirements (if any) relating to advertising applicable under Part 5-1 or 5-1A or under the regulations; and

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(ha) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3):

(i) if those prohibitions cover imports—any imports into Australia of devices of that kind by, or on behalf of the applicant, will not contravene those prohibitions; and

(ii) if those prohibitions cover exports—any exports from Australia of devices of that kind by, or on behalf of the applicant, will not contravene those prohibitions; and

(iii) if those prohibitions cover manufacture—any manufacture in Australia of devices of that kind by, or on behalf of the applicant, will not contravene those prohibitions; and

(iv) if those prohibitions cover supplies—any supplies in Australia of devices of that kind by, or on behalf of the applicant, will not contravene those prohibitions; and

(hb) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions:

(i) if those prohibitions cover imports—any imports into Australia of devices of that kind by, or on behalf of the applicant, will not contravene those conditions; and

(ii) if those prohibitions cover exports—any exports from Australia of devices of that kind by, or on behalf of the applicant, will not contravene those conditions; and

(iii) if those prohibitions cover manufacture—any manufacture in Australia of devices of that kind by, or on behalf of the applicant, will not contravene those conditions; and

(iv) if those prohibitions cover supplies—any supplies in Australia of devices of that kind by, or on behalf of the applicant, will not contravene those conditions; and

(i) devices of that kind do not contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; and

(ia) devices of that kind are not to be used exclusively for one or more of the purposes specified under section 41BEA; and

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(j) the information included in or with the application is complete and correct.

Note: See section 41BH for when a medical device complies with the essential principles, section 41BI for when conformity assessment procedures are taken not to have been applied to a medical device and section 41BIA for when requirements comparable to those procedures are taken not to have been applied to a medical device.

41FDA Basis of certification of conformity assessment procedures

(1) When certifying the matter referred to in paragraph 41FD(f), the applicant must also state that the certification of the matter is based:

(a) on a conformity assessment certificate that is in force; or

(b) on an Australian conformity assessment body certificate that is in force; or

(c) on an overseas regulator conformity assessment document that is in force.

(2) However, subsection (1) does not apply if devices of the kind in question are class I medical devices (within the meaning of regulations made for the purposes of this Chapter).

41FDB Preliminary assessment of applications

(1) If an application is made under section 41FC for a kind of medical device to be included in the Register in relation to a person, the Secretary must carry out an assessment of whether the requirements set out in subsection (2) have been met in relation to the application.

(2) The requirements are as follows:

(a) the application must be made:

(i) in accordance with the form approved, in writing, by the Secretary for that classification of medical device; or

(ii) in such other manner as is approved, in writing, by the Secretary for that classification of medical device;

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(b) the prescribed application fee for that classification of medical device must be paid;

(c) the application must be delivered to an office of the Department specified by the Secretary;

(d) the application must be accompanied by information that is:

(i) of a kind determined under subsection (7) for that classification of medical device; and

(ii) in a form determined under subsection (8) for that classification of medical device;

(e) if regulations made for the purposes of section 41EA require the manufacturer of the kind of device to have a conformity assessment certificate relating to the kind of medical device before an application under section 41FC can be made—such a certificate is in force;

(f) the applicant has certified the matters in section 41FD.

Passing preliminary assessment

(3) An application ***passes preliminary assessment*** if the Secretary:

(a) has carried out an assessment, under subsection (1), in relation to the application; and

(b) is satisfied that the requirements set out in subsection (2) have been met in relation to the application.

(4) If the application has not passed preliminary assessment, the Secretary must refuse the application.

Note: The Secretary is required to give notice of the refusal: see section 41FG.

Approval of forms etc.

(5) For the purposes of paragraph (2)(a), the Secretary may approve different forms and different manners for making applications for different medical device classifications.

(6) An approval of a form may require or permit an application or information to be given in accordance with specified software requirements:

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(a) on a specified kind of data processing device; or
(b) by way of a specified kind of electronic transmission.

Determination of kinds and forms of information

(7) The Secretary may, by legislative instrument, determine a kind of information for the purposes of the application of subparagraph (2)(d)(i) to medical devices of a particular classification.

(8) The Secretary may, by legislative instrument, determine a form of information for the purposes of the application of subparagraph (2)(d)(ii) to medical devices of a particular classification.

41FE Criminal offences for making a false statement

(1) A person commits an offence if:
(a) the person makes a statement (whether orally, in a document or in any other way); and
(b) the person knows that the statement is false or misleading in a material particular; and
(c) the statement is in or in connection with:
(i) an application for including a kind of medical device in the Register under this Chapter; or
(ii) a certification or purported certification under section 41FD; and
(d) either:
(i) the use of the kind of medical device has resulted in, will result in, or is likely to result in, harm or injury to any person; or
(ii) the use of the kind of medical device, if the kind of medical device were used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

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Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person makes a statement (whether orally, in a document or in any other way); and

(b) the person knows that the statement is false or misleading in a material particular; and

(c) the statement is in or in connection with:

(i) an application for including a kind of medical device in the Register under this Chapter; or

(ii) a certification or purported certification under section 41FD.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(5) A person commits an offence if:

(a) the person makes a statement (whether orally, in a document or in any other way); and

(b) the statement is false or misleading in a material particular; and

(c) the statement is in or in connection with:

(i) an application for including a kind of medical device in the Register under this Chapter; or

(ii) a certification or purported certification under section 41FD.

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

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41FEA Civil penalty for making a false statement

A person contravenes this section if:

(a) the person makes a statement (whether orally, in a document or in any other way); and

(b) the statement is false or misleading in a material particular; and

(c) the statement is in or in connection with:

(i) an application for including a kind of medical device in the Register under this Chapter; or

(ii) a certification or purported certification under section 41FD.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Subdivision B—Including kinds of medical devices in the Register

41FF Obligation to include kinds of medical devices in the Register

(1) If:

(a) an application for a kind of medical device to be included in the Register in relation to a person has passed preliminary assessment; and

(b) the application has not been selected for audit under section 41FH;

the Secretary must include the kind of device in the Register in relation to the person.

(1A) However, the Secretary must not include the kind of device in the Register in relation to the person if the Secretary is satisfied that the kind of device is to be used exclusively for one or more of the purposes specified under section 41BEA.

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(2) As soon as practicable after the kind of device has been included in the Register, the Secretary must make available to the applicant a certificate of the inclusion of the kind of device in the Register.

(3) The certificate must specify the day on which the inclusion of the kind of device in the Register commences.

41FG Notification of unsuccessful applications

(1) This section applies if an application under subsection 41FC(1) for a kind of medical device to be included in the Register:
  (a) is refused under subsection 41FDB(4); or
  (b) is refused under subsection 41FF(1A).

(2) The Secretary must notify the applicant in writing, of the refusal within 20 working days after the application has been received and the prescribed application fee has been paid.

Subdivision C—Auditing of applications

41FH Selecting applications for auditing

(1A) This section applies to applications that have passed preliminary assessment.

(1) The Secretary:
  (a) must select for auditing any application for a kind of medical device to be included in the Register that is an application of the kind prescribed by the regulations; and
  (b) may select for auditing any other application for a kind of medical device to be included in the Register.

Note: An application audit assessment fee is payable in respect of any application that the Secretary must select for auditing: see Part 4-10.

(2) If an application is selected for auditing:
  (a) the Secretary must give the applicant a written notice (the ***selection notice***) that:
    (i) informs the applicant of the selection; and

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(ii) requires the applicant to provide, within the period specified in the notice, information or documents that the Secretary is satisfied is relevant to the audit; and

(b) the application must be dealt with under this Subdivision and not under Subdivision B.

(3) The selection notice must be given within:

(a) 20 working days after the application is made and the prescribed application fee is paid; or

(b) if the regulations prescribe a longer period for that kind of application—that longer period.

(4) Subparagraph (2)(a)(ii) does not limit section 41JA (Secretary may require information).

41FI Auditing of applications

(1) In auditing the application, the Secretary may consider all or some aspects of one or both of the following matters:

(a) whether the application is in accordance with Subdivision A;

(b) whether matters as to which the applicant has certified under section 41FD are correct.

(1A) In auditing the application, the Secretary may, by written notice given to the applicant, require the applicant:

(a) to deliver to the office to which the application was made a reasonable number of samples of the kind of medical device to which the application relates within the period, of not less than 14 days after the day the notice is given, specified in the notice; and

(b) to do so in a manner specified in the notice.

(2) The Secretary must decide to include the kind of device to which the application relates in the Register, in relation to the person to whom the application relates, if the Secretary is satisfied as to all such aspects considered in the audit.

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(3) The Secretary must decide not to include the kind of device to which the application relates in the Register if the Secretary is not so satisfied.

41FIA Certificates issued by Australian conformity assessment bodies

(1) If:

(a) a section 41FC application is made for a kind of medical device to be included in the Register; and

(b) the application has been selected for audit; and

(c) a person has obtained a certificate issued by an Australian conformity assessment body to the effect that the body is satisfied that an appropriate conformity assessment procedure has been applied to devices of that kind; and

(d) the certificate has been given to the Secretary; and

(e) if the conformity assessment body determination that relates to the body is limited as mentioned in paragraph 41EWA(4)(b)—the Secretary is satisfied that the certificate has been issued consistently with the determination;

the Secretary may have regard to the certificate in auditing the application.

(2) This section does not, by implication, limit the matters to which the Secretary may have regard.

41FJ Procedure following audits

After auditing the application, the Secretary must:

(a) notify the applicant in writing of his or her decision within 20 working days after the decision is made; and

(b) if the decision is not to include the kind of device to which the application relates in the Register—state in the notice the reasons for the decision; and

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(c) if the decision is to include the kind of device in the Register and all assessment fees for the application that are due and payable have been paid:

(i) include the kind of device in the Register, in relation to the person in relation to whom the application was made; and

(ii) give the applicant a certificate of the inclusion of the kind of device in the Register.

41FK Lapsing of applications

An application that has been selected for auditing lapses if:

(a) the applicant fails to comply with a notice under section 41FH within 10 working days after the end of the period specified in the notice; or

(b) the applicant does not comply with a requirement by the Secretary under subsection 41FI(1A) to deliver to the office to which the application was made a reasonable number of samples of the kind of medical device to which the application relates; or

(c) the applicant fails to comply with a notice under section 41JA to give information relating to devices of that kind to the Secretary within a further 10 working days from the day specified in the notice; or

(d) information given to the Secretary by, or on behalf of, the applicant in connection with the application, including information given for the purpose of a requirement under section 41JA, is false or misleading in a material particular; or

(e) the applicant fails to pay an assessment fee for the application in accordance with section 41LB or 41LC.

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Subdivision D—Miscellaneous

41FKA Medical devices (priority applicant) determinations

(1) The regulations may make provision for and in relation to empowering the Secretary to make medical devices (priority applicant) determinations.

(2) A ***medical devices (priority applicant) determination*** is a determination that, for the purposes of this Act, a specified person is a priority applicant in relation to any section 41FC application that may be made by the person for the inclusion in the Register of a medical device of a kind specified in the determination.

(3) The regulations may make provision for and in relation to the following matters:
   (a) applications for medical devices (priority applicant) determinations;
   (b) the approval by the Secretary of a form for such an application;
   (c) information that must accompany such an application;
   (d) the application fee for such an application;
   (e) empowering the Secretary to give the applicant a written notice requiring the applicant to give to the Secretary specified information or documents in connection with the application within a specified period (which must be at least 10 working days after the notice is given to the applicant).

(4) The regulations may make provision for and in relation to the following matters:
   (a) empowering the Secretary to revoke a medical devices (priority applicant) determination;
   (b) the consequences of the revocation of a medical devices (priority applicant) determination.

(5) Subsections (3) and (4) do not limit subsection (1).

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(6) The regulations may make provision for and in relation to the priority to be given by the Secretary to consideration of a section 41FC application where the applicant is a priority applicant.

(7) The regulations may provide that, if:

(a) a person is a priority applicant in relation to a section 41FC application made by the person; and

(b) a decision is made on the application;

a statement setting out the decision may be published on the Department's website.

(8) The express references in this section to the Secretary do not, by implication, prevent the regulations from empowering the Secretary to delegate any or all of the Secretary's functions or powers under regulations made for the purposes of this section.

(9) If a medical devices (priority applicant) determination is in force under the regulations, the determination may be published on the Department's website.

(10) A medical devices (priority applicant) determination made under the regulations is not a legislative instrument.

(11) Subsection 33(3AB) of the *Acts Interpretation Act 1901* does not apply to the specification of a person in a medical devices (priority applicant) determination.

Note: Subsection 33(3AB) of the *Acts Interpretation Act 1901* deals with specification by class.

41FL Device number

If a kind of medical device is included in the Register, the Secretary is to assign a unique device number to it.

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41FM Duration of inclusion in the Register

(1) The inclusion of a kind of medical device in the Register commences on the day specified for the purpose in the certificate under section 41FF or 41FJ.

(2) The inclusion of a kind of medical device in the Register has effect at all times:

(a) unless the kind of device is suspended from the Register under Division 1 of Part 4-6; or

(b) until entry of the kind of device is cancelled from the Register under Division 2 of Part 4-6.

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Division 2—Conditions

Note: Breaching conditions of the inclusion of a kind of medical device may lead to suspension or cancellation of the entry of the kind of device from the Register (see Part 4-6), may be an offence (see subsections 41MN(1), (4) and (4A)), and may contravene a civil penalty provision (see subsection 41MNA(1)).

41FN Conditions applying automatically

Entry and inspection powers

(1) The inclusion of a kind of medical device in the Register is subject to the conditions that the person in relation to whom the kind of device is included in the Register will:

(a) allow an authorised person:

(i) to enter, at any reasonable time, any premises (including premises outside Australia) at which that person or any other person deals with medical devices of that kind; and

(ii) while on those premises, to inspect those premises and medical devices of any kind on those premises and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of medical devices of any kind on those premises or any thing on those premises that relates to medical devices of any kind; and

(iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises; and

(b) if requested to do so by an authorised person, produce to the person such documents relating to devices of the kind included in the Register as the person requires and allow the person to copy the documents.

Delivery of samples

(2) The inclusion of a kind of medical device in the Register is subject to a condition that the person in relation to whom the kind of

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device is included in the Register will deliver a reasonable number of samples of the kind of device if the Secretary so requests:

(a) within the period specified in the request; and

(b) in accordance with any other requirements specified in the request.

The period specified in the request must include at least 10 working days.

Availability etc. of information

(3) The inclusion of a kind of medical device in the Register is subject to conditions that:

(a) at all times while the inclusion in the Register has effect, the person in relation to whom the kind of device is included in the Register:

(i) has available sufficient information to substantiate compliance with the essential principles; or

(ii) has procedures in place, including a written agreement with the manufacturer of the kind of device, to ensure that such information can be obtained from the manufacturer within 20 working days; and

(b) at all times while the inclusion in the Register has effect, the person in relation to whom the kind of device is included in the Register:

(i) has available sufficient information to substantiate that the conformity assessment procedures have been applied to the kind of medical device or that requirements, comparable to those procedures, have been applied to the kind of medical device to the satisfaction of an overseas regulator; or

(ii) has procedures in place, including a written agreement with the manufacturer of the kind of device, to ensure that such information can be obtained from the manufacturer within 20 working days; and

(ba) at all times while the inclusion in the Register has effect, the person in relation to whom the kind of device is included in the Register:

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(i) has available information relating to changes to the kind of medical device, the product range or quality management system by the manufacturer of the kind of device; or

(ii) has procedures in place, including a written agreement with the manufacturer of the kind of device, to ensure that such information can be obtained from the manufacturer within 20 working days; and

(c) at any time while the inclusion in the Register has effect, the person in relation to whom the kind of device is included in the Register will, if asked to do so by the Secretary, give the information to the Secretary; and

(d) the person in relation to whom the kind of device is included in the Register will give information of a kind mentioned in subsection 41MP(2) or 41MPA(2) to the Secretary within the period specified in the regulations; and

(e) the person in relation to whom the kind of device is included in the Register will give the manufacturer of the kind of medical device information relevant to:

(i) the manufacturer's obligations under the conformity assessment procedures or requirements comparable to those procedures; and

(ii) whether medical devices of that kind comply with the essential principles.

(4) The regulations may prescribe the amount, standard or kind of information or evidence required for the purposes of paragraphs (3)(c), (d) and (e).

Advertising material

(5) The inclusion of a kind of medical device in the Register is subject to a condition that advertising material relating to medical devices of that kind is consistent with the intended purpose as certified under section 41FD.

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Conditions prescribed by the regulations

(5A) The inclusion of a kind of medical device in the Register is subject to such conditions (if any) as are prescribed by the regulations.

Conditions determined by the Minister

(5B) The inclusion of a kind of medical device in the Register is subject to such conditions (if any) as are determined under subsection (5C).

(5C) The Minister may, by legislative instrument, determine one or more conditions for the purposes of subsection (5B).

Conditions do not limit other conditions

(6) A condition imposed under this section is in addition to any conditions imposed under this Division.

41FO Conditions imposed when kinds of medical devices are included in the Register

(1) If the Secretary includes a kind of medical device in the Register in relation to a person, the Secretary may, in writing, impose conditions on the inclusion of the kind of device in the Register.

(2) Conditions referred to in subsection (1) may relate to:
- (a) manufacture of devices of that kind; or
- (b) custody, intended purpose, supply, disposal or destruction of devices of that kind; or
- (c) keeping of records relating to devices of that kind, including records relating to the tracking and location of devices of that kind after their supply; or
- (d) matters dealt with in, or matters additional to matters dealt with in, the essential principles; or
- (e) such other matters relating to devices of that kind as the Secretary thinks appropriate.

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41FP Conditions imposed after kinds of medical devices are included in the Register

(1) The Secretary may, by written notice given to the person in relation to whom a kind of medical device is included in the Register:

(a) impose new conditions on including the kind of device in the Register under this Chapter; or

(b) vary or remove existing conditions.

The power may be exercised at the person's request or on the Secretary's own initiative.

(2) The imposition, variation or removal of a condition under this section takes effect:

(a) if the notice states that the action is necessary to prevent imminent risk of death, serious illness or serious injury—on the day on which the notice is given to the person; or

(aa) in the case of an imposition or variation requested by the person, and to which paragraph (a) does not apply—on the day specified in the notice, which must be at least 20 working days after the notice is given to the person, unless the person has agreed to an earlier day; or

(ab) in the case of a removal to which paragraph (a) does not apply—on the day specified in the notice, which must be at least 20 working days after the notice is given to the person, unless the person has agreed to an earlier day; or

(b) in any other case—on the day specified for the purpose in the notice, being a day not earlier than 20 working days after the notice is given to the person.

(3) For the purposes of paragraphs (2)(aa) and (ab), the earlier day must not be earlier than the day the notice is given to the person.

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Part 4-6—Suspension and cancellation from the Register

Division 1—Suspension from the Register

Subdivision A—General power of suspension

41G What this Part is about

> Inclusions in the Register may be suspended in certain circumstances, such as when a conformity assessment document is suspended. A kind of medical device that is suspended is taken not to be included in the Register for most purposes.
>
> Inclusions in the Register may also be cancelled in certain circumstances.

41GA Suspension of kinds of medical devices from the Register

(1) The Secretary may, by written notice given to the person in relation to whom a kind of medical device is included in the Register, suspend the kind of device from the Register if:

(a) the Secretary is satisfied that:

(i) there is a potential risk of death, serious illness or serious injury if the kind of device continues to be included in the Register; and

(ii) it is likely that the person will, within the period of the suspension, be able to take the action necessary to ensure that the kind of device would not cause a potential risk of death, serious illness or serious injury if it were to continue to be included in the Register; or

(b) the Secretary is satisfied that it is likely that there are grounds for cancelling the entry of the kind of device from the

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Register under Division 2 (other than under paragraph 41GL(a), (d) or (f) or section 41GM).

(2) The suspension may be limited to some medical devices of that kind, as specified in the notice.

(3) The notice must specify the period of the suspension. The period must not exceed 6 months.

Note: The period of the suspension may be extended under section 41GC.

(4) The Secretary must cause to be published in the *Gazette* or on the Department's website, as soon as practicable after the suspension, a notice setting out particulars of the suspension.

41GB Notice of proposed suspension must be given in certain cases

(1) However, before suspending a kind of medical device from the Register because it is likely that there are grounds for cancelling the entry of the kind of device from the Register under section 41GN, the Secretary must:

(a) inform the person by written notice that the Secretary proposes the suspension and set out the reasons for it; and

(b) give the person a reasonable opportunity to make submissions to the Secretary in relation to the proposed suspension.

(2) The Secretary is not to make a decision relating to the proposed suspension until the Secretary has had regard to any submissions the person makes under paragraph (1)(b).

41GC Duration of suspension

(1) The suspension takes effect:

(a) if the notice under subsection 41GA(1) states that the suspension is necessary to prevent a potential risk of death, serious illness or serious injury—on the day on which the notice is given to the person; or

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(b) in any other case—on the day specified for the purpose in the notice, being a day not earlier than 20 working days after the notice is given to the person.

(2) The suspension has effect until:

(a) the Secretary revokes it under section 41GD; or

(b) the end of:

(i) the period specified in the notice under subsection 41GA(3); or

(ii) if the period is extended under subsection (3) of this section, the period as so extended.

Note: Unless a suspension of a kind of medical device has been revoked, the entry of the kind of medical device is automatically cancelled from the Register: see section 41GK.

(3) If a person in relation to whom a kind of medical device is included in the Register shows that he or she has taken steps to remove the grounds for cancelling the entry of the kind of device from the Register under section 41GN, the Secretary may, by written notice given to the person, extend the period specified in the notice under subsection 41GA(1) by a further specified period not exceeding 6 months.

(4) The Secretary must cause to be published in the *Gazette* or on the Department's website, as soon as practicable after the extension, a notice setting out particulars of the extension.

41GD Revocation of suspension

(1) The Secretary must revoke the suspension if the Secretary is satisfied that:

(a) the ground on which the kind of medical device concerned was suspended from the Register no longer applies; and

(b) there are no other grounds for suspending the kind of device from the Register.

(2) The Secretary's power to revoke the suspension may be exercised:

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(a) if the person in relation to whom the kind of medical device concerned is included in the Register applies in writing to the Secretary; or

(b) on the Secretary's own initiative.

(3) After revoking the suspension, the Secretary must:

(a) within 20 working days after the revocation, give written notice of the revocation to the person in relation to whom the kind of medical device concerned is included in the Register; and

(b) as soon as practicable after the revocation, cause to be published in the *Gazette* or on the Department's website a notice setting out particulars of the revocation.

(4) If the Secretary decides, after an application is made under paragraph (2)(a), not to revoke the suspension, the Secretary must:

(a) notify the applicant in writing of his or her decision within 20 working days after the decision is made; and

(b) state in the notice the reasons for the decision.

41GE Treating applications for revocation as having been refused

(1) The applicant for the suspension to be revoked may give the Secretary written notice that the applicant wishes to treat the application as having been refused if:

(a) a period is prescribed under paragraph 63(2)(dd) for the Secretary to make a decision on the application; and

(b) at the end of the period, the Secretary has not made a decision.

(2) The notice may be given at any time before the Secretary makes a decision on the application.

(3) If a notice has been given, this Act (except for subsection 60(5)) has effect as if:

(a) the Secretary had decided not to revoke the suspension; and

(b) the Minister had made a decision under subsection 60(3) confirming the decision of the Secretary; and

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(c) the Minister's decision had been made on the day on which notice was given to the Secretary.

Subdivision B—Suspension as a result of suspension of conformity assessment document

41GF Suspension where conformity assessment certificate suspended

(1) The Secretary may, by written notice given to the person in relation to whom a kind of medical device is included in the Register, suspend the kind of device from the Register if the conformity assessment certificate applying to that kind of device is suspended under Division 3 of Part 4-4.

(2) If the suspension under Division 3 of Part 4-4 is limited to some medical devices of that kind, the suspension under this section is taken to be limited to the same extent.

(3) The Secretary must cause to be published in the *Gazette* or on the Department's website, as soon as practicable after the suspension, a notice setting out particulars of the suspension.

41GFA Suspension where other certificates or documents are suspended

(1) The Secretary may, by written notice given to the person in relation to whom a kind of medical device is included in the Register, suspend the kind of device from the Register if:

(a) an Australian conformity assessment body certificate that applies to the kind of device is suspended by the Australian conformity assessment body; or

(b) an overseas regulator conformity assessment document that applies to the kind of device is suspended by the overseas regulator.

(2) However, before suspending the kind of device from the Register, the Secretary must:

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(a) inform the person in writing that the Secretary proposes the suspension and set out the reasons for it; and

(b) give the person a reasonable opportunity to make submissions to the Secretary in relation to the proposed suspension.

(3) The Secretary is not to make a decision relating to the proposed suspension until the Secretary has had regard to any submissions the person makes under paragraph (2)(b).

(4) The Secretary must cause to be published on the Department's website, as soon as practicable after the suspension, a notice setting out particulars of the suspension.

41GG Duration of suspension

(1) A suspension under section 41GF or 41GFA takes effect on the day on which the notice is given to the person.

(2) The suspension has effect until the Secretary revokes it under section 41GH.

41GH Revocation of suspension

(1) The Secretary must revoke a suspension under section 41GF if:

(a) the suspension under Division 3 of Part 4-4 ceases to have effect; and

(b) the Secretary is satisfied that there are no other grounds for suspending the kind of device from the Register.

(1A) The Secretary may revoke a suspension under section 41GFA if:

(a) either:

(i) the suspension referred to in paragraph 41GFA(1)(a) or (b) ends; or

(ii) the person in relation to whom the kind of medical device is included in the Register provides the Secretary with another conformity assessment document that applies to the kind of device; and

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(b) the Secretary is satisfied that there are no other grounds for suspending the kind of device from the Register.

(2) After making a revocation under subsection (1) or (1A), the Secretary must:

(a) within 20 working days after the revocation, give written notice of the revocation to the person in relation to whom the kind of medical device concerned is included in the Register; and

(b) as soon as practicable after the revocation, cause to be published in the *Gazette* or on the Department's website a notice setting out particulars of the revocation.

Subdivision C—Effect of suspension

41GI Effect of suspension

If all or some medical devices of a particular kind are suspended, they are taken, for the purposes of this Act (other than Division 2 of Part 4-5, this Division and Part 4-8), not to be included in the Register while the suspension has effect.

Note: Dealing in medical devices that are not included in the Register may be an offence or may contravene a civil penalty provision: see Division 3 of Part 4-11.

41GJ Powers of cancellation from Register unaffected

(1) This Subdivision does not affect the Secretary's powers to cancel the entry of kinds of medical devices from the Register under Division 2.

(2) To the extent that a suspension under this Division relates to medical devices to which such a cancellation relates, the suspension ceases to have effect.

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Division 2—Cancellation of entries from the Register

41GK Automatic cancellation of entries of kinds of medical devices from the Register

(1) The Secretary must, by written notice given to the person in relation to whom a kind of medical device is included in the Register, cancel the entry of the kind of device from the Register if:

(a) the kind of device has been suspended from the Register under section 41GA, and the period applying to the suspension under subsection 41GA(3) or 41GC(3) (as the case requires) expires before the suspension is revoked under section 41GD; or

(b) a conformity assessment certificate applying to that kind of device is revoked under Division 4 of Part 4-4.

(2) The Secretary must, by written notice given to the person in relation to whom a kind of medical device is included in the Register, cancel the entry of the kind of device from the Register if the Secretary is satisfied that:

(a) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—imports into Australia, exports from Australia, the manufacture in Australia or supplies in Australia of the kind of device would contravene one or more of those prohibitions; or

(b) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—imports into Australia, exports from Australia, the manufacture in Australia or supplies in Australia of the kind of device would contravene one or more of those conditions.

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41GL Immediate cancellation of entries of kinds of medical devices from the Register

The Secretary may, by written notice given to the person in relation to whom a kind of medical device is included in the Register, cancel the entry of the kind of device from the Register if:

(a) the Secretary is satisfied that there would be an imminent risk of death, serious illness or serious injury if the kind of device continues to be included in the Register; or

(b) devices of that kind are no longer therapeutic goods; or

(c) devices of that kind are no longer medical devices; or

(ca) the kind of medical device is covered by an exemption under paragraph 41HA(1)(b); or

(d) the person requests in writing the cancellation of the entry of the kind of device from the Register; or

(e) the Secretary is satisfied that a statement made in or in connection with:

(i) the application for including the kind of device in the Register; or

(ii) the certification or purported certification under section 41FD relating to the application;

was false or misleading in a material particular; or

(f) the annual charge payable under subsection 4(1B) of the *Therapeutic Goods (Charges) Act 1989* in respect of the inclusion of the kind of device in the Register is not paid within 20 working days after it becomes payable; or

(g) the person contravenes a direction, or a condition of a direction, given to the person under subsection 42DV(1) or 42DZK(1) in relation to the advertising of the kind of device and the Secretary is satisfied that the contravention is significant; or

(ga) if the person is a body corporate—a related body corporate of the person contravenes a direction, or a condition of a direction, given to the related body corporate under subsection 42DV(1) or 42DZK(1) in relation to the

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advertising of the kind of device and the Secretary is satisfied that the contravention is significant; or

(h) there is a breach, involving the kind of device, of an applicable provision of the Therapeutic Goods Advertising Code or any other requirement relating to advertising applicable under Part 5-1 or 5-1A or under the regulations, and the Secretary is satisfied that:

(i) the breach is significant; and

(ii) as a result of the breach, the presentation of devices of that kind is misleading to a significant extent.

41GLA Revocation of cancellation of entries upon request

(1) If:

(a) the Secretary cancels the entry of a kind of medical device because of the request of a person made under paragraph 41GL(d); and

(b) before the end of the period of 90 days beginning on the day the kind of device ceased to be included in the Register, the person requests, in writing, the Secretary to revoke the cancellation; and

(c) the request is accompanied by the prescribed application fee (if any);

the Secretary may, by notice in writing given to the person, revoke the cancellation.

(2) If the cancellation is revoked, the cancellation is taken never to have occurred.

41GLB Revocation of cancellation of entries—payment of annual charge

(1) If:

(a) the Secretary cancels the entry of a kind of medical device because the annual charge payable by a person under subsection 4(1B) of the *Therapeutic Goods (Charges) Act 1989* in respect of the inclusion of the kind of device in the

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Register was not paid within 20 working days after it becomes payable; and

(b) before the end of the period of 90 days beginning on the day the kind of device ceased to be included in the Register, the person in relation to whom the kind of device was included in the Register requests, in writing, the Secretary to revoke the cancellation; and

(c) the annual charge payable under subsection 4(1B) of the *Therapeutic Goods (Charges) Act 1989* in respect of the inclusion of the kind of device in the Register has been paid; and

(d) the request is accompanied by the prescribed application fee (if any);

the Secretary may, by notice in writing given to the person, revoke the cancellation.

(2) If the cancellation is revoked, the cancellation is taken never to have occurred.

41GM Cancellation of entries of kinds of medical devices from the Register after section 41JA notice

(1) The Secretary may, by written notice given to the person in relation to whom a kind of medical device is included in the Register, cancel the entry of the kind of device from the Register if:

(a) the Secretary gives to the person a notice under section 41JA requiring the person to give to the Secretary information or documents relating to the kind of device; and

(b) the notice under section 41JA is given for the purposes of ascertaining whether any of the certifications by the person under section 41FD in relation to the kind of device are incorrect; and

(c) the person fails to comply with the notice under section 41JA within a further 10 working days from the day specified in that notice.

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(2) The Secretary may, by written notice given to the person in relation to whom a kind of medical device is included in the Register, cancel the entry of the kind of device from the Register if:

(a) the Secretary gives to the person a notice under section 41JA requiring the person to give to the Secretary information or documents relating to whether medical devices of that kind are being:

(i) supplied in Australia; or

(ii) imported into Australia; or

(iii) exported from Australia; and

(b) either:

(i) the information or documents given are to the effect that medical devices of that kind are not being supplied in Australia, imported into Australia or exported from Australia; or

(ii) the person fails to comply with the notice under section 41JA within a further 10 working days from the day specified in that notice.

41GN Cancellation of entries of kinds of medical devices from the Register after notice of proposed cancellation

(1) The Secretary may, by written notice given to the person in relation to whom a kind of medical device is included in the Register, cancel the entry of the kind of device from the Register if:

(a) medical devices that were devices of that kind when the kind of device was included in the Register have changed so those medical devices are no longer devices of that kind; or

(b) the person in relation to whom the kind of medical device is included in the Register refuses or fails to comply with a condition to which that inclusion is subject; or

(c) the Secretary gives to the person a notice under section 41JA:

(i) that requires the person to give to the Secretary information or documents relating to the kind of device; and

(ii) in respect of which section 41GM does not apply;

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and the person fails to comply with that notice within a further 10 working days from the day specified in that notice; or

(d) the person contravenes subsection 41MP(1) or 41MPA(1) in relation to the kind of device; or

(e) the Secretary is satisfied that the safety or performance of the kind of device is unacceptable; or

(f) the Secretary is satisfied that any certification, or part of a certification, under section 41FD in relation to the application for inclusion of the kind of device in the Register is incorrect, or is no longer correct, in a material particular; or

(g) a conformity assessment document that applies to the kind of device expires; or

(h) either of the following applies:

(i) an Australian conformity assessment body certificate that applies to the kind of device is revoked by the Australian conformity assessment body;

(ii) an overseas regulator conformity assessment document that applies to the kind of device is revoked by the overseas regulator; or

(i) the person contravenes a direction, or a condition of a direction, given to the person under subsection 42DV(1) or 42DZK(1) in relation to the advertising of the kind of device; or

(j) if the person is a body corporate—a related body corporate of the person contravenes a direction, or a condition of a direction, given to the related body corporate under subsection 42DV(1) or 42DZK(1) in relation to the advertising of the kind of device; or

(k) either of the following has not been complied with in relation to the kind of device:

(i) an applicable provision of the Therapeutic Goods Advertising Code;

(ii) any other requirement relating to advertising applicable under Part 5-1 or 5-1A or the regulations.

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(2) However, before cancelling the entry of the kind of device from the Register, the Secretary must:

(a) inform the person in writing that the Secretary proposes the cancellation and set out the reasons for it; and

(b) give the person a reasonable opportunity to make submissions to the Secretary in relation to the proposed cancellation.

(3) The Secretary is not to make a decision relating to the proposed cancellation until the Secretary has had regard to any submissions the person makes under paragraph (2)(b).

41GO Limiting cancellation of entries from Register to some medical devices of a particular kind

(1) If the Secretary is satisfied that the ground for cancelling the entry of a kind of medical device from the Register applies only to some medical devices of that kind, the Secretary must limit the cancellation to the medical devices to which that ground or any other ground for cancellation applies.

(2) If the cancellation of the entry of a kind of medical device from the Register is limited to some medical devices of that kind, the Secretary:

(a) must vary the entry in the Register accordingly; and

(b) must not delete the entry from the Register because of the cancellation.

41GP Publication of cancellation of entry from Register

The Secretary must cause to be published in the *Gazette* or on the Department's website, as soon as practicable after cancelling an entry from the Register of a kind of medical device, or of some devices of a particular kind, a notice setting out particulars of the cancellation.

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41GQ Date of effect of cancellation of entries from Register

If the Secretary cancels an entry of a kind of medical device, or some devices of a particular kind, from the Register, the cancellation has effect:

(a) if the cancellation is under section 41GK or 41GL—on the day on which the notice of cancellation is given to the person in relation to whom the kind of device was included in the Register; or

(b) in any other case—on such later day as is specified in the notice, being a day not earlier than 20 working days after the notice is given to the person.

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Part 4-6A—Exempting medical devices to deal with emergencies

41GR What this Part is about

The Minister may exempt certain medical devices from various provisions of this Chapter so that the devices may be stockpiled to deal with possible future emergencies or made available urgently to deal with actual emergencies.

Note 1: There are offences and civil penalty provisions related to the making of exemptions under this Part: see Division 3A of Part 4-11.

Note 2: Some of the other provisions of this Act about medical devices exempt under this Part are:

(a) section 41JCA (providing information to the Secretary); and

(b) section 41KA (public notification and recall of medical devices); and

(c) section 46A (search of premises).

41GS Minister may make exemptions

(1) The Minister may, by writing, exempt specified kinds of medical devices from the operation of the following:

(a) Division 1 of Part 4-2 (essential principles);

(b) Division 1 of Part 4-3 (conformity assessment procedures);

(c) Part 4-4 (conformity assessment certificates);

(d) Part 4-5 (including medical devices in the Register).

(1A) The Minister may exempt devices under subsection (1) only if the Minister is satisfied of the matter in subsection (2) or (2A).

(2) The matter in this subsection is that in the national interest, the exemption should be made so that:

(a) the devices may be stockpiled as quickly as possible in order to create a preparedness to deal with a potential threat to

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public health that may be caused by a possible future emergency; or

(b) the devices can be made available urgently in Australia in order to deal with an actual threat to public health caused by an emergency that has occurred.

(2A) The matter in this subsection is that:

(a) a national emergency declaration is in force; and

(b) either of the following apply:

(i) the exemption should be made so that the devices may be stockpiled to deal with a potential threat to public health that may be caused by the emergency to which the national emergency declaration relates;

(ii) the exemption should be made so that the devices can be made available urgently in Australia in order to deal with an actual threat to public health caused by the emergency to which the national emergency declaration relates; and

(c) the Minister is satisfied that the exemption is in the national interest.

Period of exemption

(3) An exemption under subsection (1) comes into force:

(a) on the day the exemption is made; or

(b) on a later day specified in the exemption.

(4) An exemption under subsection (1) remains in force for the period specified in the exemption, unless revoked earlier.

Note: Section 41GU deals with variation and revocation of the exemption.

Effect of inclusion of kind of medical device in the Register

(5) An exemption under subsection (1) ceases to have effect in relation to a particular kind of medical device when that kind of medical device becomes included in the Register under Part 4-5.

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Exemption not a legislative instrument

(6) An exemption under subsection (1) is not a legislative instrument.

Disregard section 41BE

(7) For the purposes of this Act, disregard section 41BE in working out the kinds of medical devices covered by an exemption under subsection (1) of this section.

41GT Conditions of exemptions

An exemption under section 41GS is subject to conditions specified in the exemption about any of the following:

(a) the quantity of medical devices that are exempt;

(b) the source of those medical devices;

(c) the persons or class of persons who may import, manufacture, supply or export those medical devices;

(d) the supply of those medical devices (including the persons or class of persons to whom medical devices may be supplied for use and the circumstances under which a stockpile of medical devices may be supplied for use);

(e) the storage and security of those medical devices;

(ea) compliance with the requirements referred to in subsection 41CA(3) (about unique device identifiers of medical devices);

(f) the keeping and disclosure of, and access to, records about those medical devices;

(g) the disposal of those medical devices;

(h) the manner in which any of those medical devices are to be dealt with if a condition of the exemption is breached;

(i) any other matters that the Minister thinks appropriate.

Whether or not medical devices are exempt under section 41GS is not affected by whether or not there is a breach of a condition under this section in relation to those medical devices.

Note 1: There are offences and civil penalty provisions related to the breach of a condition of an exemption: see Division 3A of Part 4-11.

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Note 2: Section 41GU deals with variation and revocation of the conditions.

41GU Variation or revocation of exemption

Variation of exemption

(1) The Minister may, by writing, vary an exemption made under section 41GS by removing specified kinds of medical devices from the exemption.

Revocation of exemption

(2) The Minister may, by writing, revoke an exemption made under section 41GS.

Variation or revocation of conditions

(3) The Minister may, by writing:
  (a) vary the conditions of an exemption made under section 41GS (including by imposing new conditions); or
  (b) revoke the conditions of an exemption made under section 41GS.

When variation or revocation takes effect

(4) A variation or revocation under this section takes effect:
  (a) if the Minister states in the variation or revocation that the variation or revocation is necessary to prevent imminent risk of death, serious illness or serious injury—on the day the variation or revocation is made; or
  (b) in any other case—on a later day specified in the variation or revocation (which must not be earlier than 28 days after the day the variation or revocation is made).

41GV Informing persons of exemption etc.

If the Minister makes an exemption under section 41GS, the Minister must take reasonable steps to give a copy of the following to each person covered by paragraph 41GT(c):

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(a) the exemption;
(b) any variation or revocation of the exemption under section 41GU.

41GW Notification and tabling

Notification

(1) The Secretary must cause a notice setting out particulars of the following:
(a) an exemption made under section 41GS because of paragraph 41GS(2)(b) or subparagraph (2A)(b)(ii);
(b) a variation or revocation under section 41GU, to the extent that the variation or revocation relates to an exemption made under section 41GS because of paragraph 41GS(2)(b) or subparagraph (2A)(b)(ii);

to be published in the *Gazette* within 5 working days after the day on which the exemption, variation or revocation is made. However, the exemption, variation or revocation is not invalid merely because of a failure to comply with this subsection.

Tabling

(2) The Minister must cause a document setting out particulars of the following:
(a) an exemption made under section 41GS because of paragraph 41GS(2)(b) or subparagraph (2A)(b)(ii);
(b) a variation or revocation under section 41GU, to the extent that the variation or revocation relates to an exemption made under section 41GS because of paragraph 41GS(2)(b) or subparagraph (2A)(b)(ii);

to be tabled in each House of the Parliament within 5 sitting days of that House after the day on which the exemption, variation or revocation is made. However, the exemption, variation or revocation is not invalid merely because of a failure to comply with this subsection.

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41GY Disposal of unused medical devices

(1) This section applies to a medical device if:

(a) an exemption under section 41GS in relation to that kind of medical device ceases to have effect otherwise than because that kind of medical device becomes included in the Register under Part 4-5; and

(b) the medical device has not been used before the exemption so ceases to have effect.

(2) The Secretary may arrange for the disposal of the medical device in accordance with the regulations.

(3) Regulations made for the purposes of subsection (2) may set out the methods by which the medical device is to be stored, supplied, destroyed, exported or otherwise disposed of.

(4) A method set out in the regulations under subsection (3) must not enable or permit any benefit to be conferred on a person (including the Commonwealth) other than the owner of the medical device.

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Part 4-7—Other exemptions from including medical devices in the Register

41H What this Part is about

In addition to Part 4-6A, there are 4 other kinds of exemptions from the prohibitions in Division 3 of Part 4-11 on dealing in medical devices that are not included in the Register:

(a) medical devices exempted under the regulations;

(b) approval for medical devices to be used for special treatment of individuals or for experimental purposes;

(c) authorisation of health practitioners to supply specified medical devices;

(d) medical devices exempted if substitutes are unavailable or in short supply or may, in the reasonably foreseeable future, become unavailable or be in short supply.

41HA Devices exempted from inclusion in the Register

(1) The regulations may exempt from the operation of Division 3 of Part 4-11:

(a) all medical devices, except those medical devices of the kinds prescribed for the purposes of this paragraph; or

(b) specified kinds of medical devices.

Note: Division 3 of Part 4-11 contains offences and civil penalty provisions relating to dealing in medical devices that are not included in the Register.

(2) An exemption may be subject to conditions that are prescribed in the regulations.

Note: Breach of the conditions may be an offence: see subsections 41MN(9), (9A) and (9B).

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(3) An exemption under paragraph (1)(a) has effect only for classes of persons prescribed in the regulations for the purposes of this subsection.

(4) If the regulations revoke an exemption, the revocation takes effect on the day specified. The day must not be earlier than 20 working days after the day on which the regulations are made.

41HB Approvals for special and experimental uses

(1) The Secretary may grant a written approval to a person for:

(a) the importation into Australia; or

(b) the exportation from Australia; or

(c) the supply in Australia;

of a specified medical device or kind of medical device (other than medical devices included in the Register or exempt devices):

(d) for use in the treatment of another person; or

(e) for use solely for experimental purposes in humans.

Note: For variation of an approval for use of the kind referred to in paragraph (1)(e), see subsection (8).

(1A) An approval for use of the kind referred to in paragraph (1)(d) must not be granted to a person unless the person is a health practitioner.

(2) The approval may be given subject to conditions specified in the approval, including a condition relating to charging for medical devices of the kinds in question.

Note: Breach of the conditions may be an offence: see subsections 41MN(9), (9A) and (9B).

(3) In addition, the regulations may prescribe conditions that apply to a person's approval to use specified kinds of medical devices solely for experimental purposes in humans. The conditions may relate to one or more of the following:

(a) the preconditions on another person's use of devices of those kinds for those purposes;

(b) the principles to be followed in another person's use of devices of those kinds for those purposes;

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(c) the monitoring of another person's use, and the results of that use, of devices of those kinds for those purposes;

(d) the circumstances in which that other person must cease using devices of those kinds for those purposes.

(4) An application to use specified medical devices in the treatment of another person must be in a form (if any) approved, in writing, by the Secretary and be accompanied by any information about the devices that is required by the Secretary.

(5) An application to use specified kinds of medical devices solely for experimental purposes in humans must:

(a) be in a form (if any) approved, in writing, by the Secretary; and

(b) be accompanied by any information about the kinds of devices that is required by the Secretary; and

(c) be accompanied by the prescribed fee.

(6) The Secretary must:

(a) consider any application under this section; and

(b) assess any information submitted with the application; and

(c) notify the applicant, within 20 working days of making the decision:

(i) of the decision; and

(ii) in the case of a decision not to grant the approval—of the reasons for the decision.

(7) The use by a person for experimental purposes in humans of specified kinds of medical devices that are the subject of an approval granted to someone else under paragraph (1)(e) is subject to the conditions (if any) specified in the regulations relating to one or more of the following:

(a) the preconditions on the use of devices of those kinds for those purposes;

(b) the principles to be followed in the use of devices of those kinds for those purposes;

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(c) the monitoring of the use, and the results of the use, of devices of those kinds for those purposes;

(d) the circumstances in which the person must cease the use of devices of those kinds for those purposes.

Note: Breach of the conditions may be an offence: see subsections 41MN(9), (9A) and (9B).

Varying approval for use solely for experimental purposes in humans

(8) If:

(a) the Secretary grants an approval to a person under subsection (1) for use of the kind referred to in paragraph (1)(e); and

(b) the person requests the Secretary to do either or both of the following:

(i) vary the medical device or kind of medical device specified in the approval;

(ii) vary the conditions imposed under subsection (2) on the approval; and

(c) the request is in a form (if any) approved, in writing, by the Secretary; and

(d) the request is accompanied by such information relating to the medical device or kind of medical device as is required by the Secretary; and

(e) the request is accompanied by the fee prescribed by the regulations;

the Secretary must, by notice in writing, vary or refuse to vary the approval. Any variation may be different than the variation requested and may involve imposing new conditions on the approval or varying or removing existing conditions.

(9) The Secretary must notify the person making the request under subsection (8) of:

(a) the Secretary's decision on the request; and

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(b) for a decision to vary the approval in a way that is different than the variation requested or a decision to refuse to vary the approval—the reasons for the decision.

(10) A variation under subsection (8) takes effect at the time the Secretary notifies the person under subsection (9) of the variation.

41HC Authorities for health practitioners

(1) The Secretary may authorise, in writing, a specified medical practitioner to supply specified kinds of medical devices for use in the treatment of humans to a specified class of recipients.

(1A) An application for an authority under subsection (1) must be in a form (if any) approved, in writing, by the Secretary.

(2) An authority under subsection (1) may be given subject to conditions specified in the authority.

(3) The Secretary may impose conditions (or further conditions) on the authority given to a person under subsection (1) by giving the person written notice of the conditions.

(4) An authority under subsection (1) may only be given:

(a) to a medical practitioner included in a class of medical practitioners prescribed by the regulations for the purposes of this paragraph; and

(b) to a medical practitioner who has the approval of an ethics committee to supply the specified kinds of medical devices or the specified class of such devices; and

(c) in relation to a class or classes of recipients prescribed by the regulations for the purposes of this paragraph.

However, the regulations may prescribe circumstances in which paragraph (b) does not apply.

(5) The regulations may prescribe circumstances in which medical devices may be supplied under an authority under subsection (1).

(6) The Minister may, by legislative instrument, make rules authorising any health practitioner who is included in a specified

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class of health practitioners to supply a specified kind of medical device, for use in the treatment of humans, to the class or classes of recipients specified in those rules, so long as:

(a) that kind of medical device is supplied in the circumstances specified in those rules; and

(b) the conditions (if any) specified in those rules are satisfied.

(6A) In making rules under subsection (6), the Minister must comply with:

(a) such requirements (if any) as are prescribed by the regulations; and

(b) such restrictions (if any) as are prescribed by the regulations; and

(c) such limitations (if any) as are prescribed by the regulations.

(6B) If:

(a) a person is authorised, by subsection (6) rules, to supply a specified kind of medical device; and

(b) the person supplies a medical device of that kind in accordance with those rules;

the person must:

(c) notify the supply to the Secretary; and

(d) do so within 28 days after the supply.

(6C) A notification under subsection (6B) must:

(a) be in accordance with a form that is approved, in writing, by the Secretary; and

(b) contain such information as is prescribed by the regulations.

(6D) An approval of a form may require or permit information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

(6E) A person commits an offence if:

(a) the person is subject to a requirement under subsection (6B); and

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(b) the person omits to do an act; and
(c) the omission breaches the requirement.

Penalty: 10 penalty units.

(6F) An offence against subsection (6E) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

(6FA) Subsection (6E) does not apply in relation to a person and a requirement to notify a supply of a medical device if a health practitioner, on behalf of the person, does the following:
(a) notifies the supply to the Secretary within 28 days after the supply;
(b) makes the notification in accordance with the requirements referred to in subsection (6C).

Note: A defendant bears an evidential burden in relation to the matter in subsection (6FA): see subsection 13.3(3) of the *Criminal Code*.

(6G) In recommending to the Governor-General that regulations should be made for the purposes of paragraph (6C)(b), the Minister must have regard to the principle that information should only be prescribed for the purposes of that paragraph if the information is reasonably required for the responsible scrutiny by the Secretary of the operation of the scheme embodied in subsection (6).

41HD Approvals if substitutes for medical devices are unavailable etc.

(1) The Secretary may, by notice in writing, grant an approval to a person for:
(a) the importation into Australia of a specified medical device; or
(b) the importation into Australia of a specified medical device and the supply in Australia of that device;

if the Secretary is satisfied that:

(c) the kinds of medical devices included in the Register that could act as a substitute for the medical device:
(i) are unavailable or are in short supply; or

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(ii) may, in the reasonably foreseeable future, become unavailable or be in short supply; and

(d) either:

(i) the medical device is registered or approved for general marketing in at least one foreign country specified in a determination under subsection (5); or

(ii) an application has been made in accordance with section 41FC for inclusion in the Register of the kind of medical device that includes the medical device and the application has passed preliminary assessment; and

(e) the medical device is specified in a determination under subsection (6); and

(f) the approval is necessary in the interests of public health.

Note: For specification by class, see the *Acts Interpretation Act 1901* and subsection 13(3) of the *Legislation Act 2003*.

(1A) The Secretary may, by notice in writing, grant an approval to a person for:

(a) the importation into Australia of a specified medical device; or

(b) the importation into Australia of a specified medical device and the supply in Australia of that device;

if the Secretary is satisfied that:

(c) the kinds of medical devices included in the Register that could act as a substitute for the medical device:

(i) are unavailable or are in short supply; or

(ii) may, in the reasonably foreseeable future, become unavailable or be in short supply; and

(d) either:

(i) the medical device is not registered or approved for general marketing in any of the foreign countries specified in a determination under subsection (5); or

(ii) the medical device is registered or approved for general marketing in at least one foreign country specified in a determination under subsection (5), but is not readily

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available for importation into, and supply in, Australia; and

(e) the medical device is registered or approved for general marketing in a foreign country; and

(f) the manufacturing and quality control procedures used in the manufacture of the medical device are acceptable; and

(g) the medical device is specified in a determination under subsection (6); and

(h) the approval is necessary in the interests of public health.

Note: For specification by class, see the *Acts Interpretation Act 1901* and subsection 13(3) of the *Legislation Act 2003*.

(2) The Secretary may, by notice in writing, grant an approval to a person for:

(a) the importation into Australia of a specified medical device; or

(b) the importation into Australia of a specified medical device and the supply in Australia of that device;

if the Secretary is satisfied that:

(c) there are no kinds of medical devices that are included in the Register that could act as a substitute for the medical device; and

(d) an application has been made in accordance with section 41FC for inclusion in the Register of the kind of medical device that includes the medical device and the application has passed preliminary assessment; and

(e) the medical device is specified in a determination under subsection (6); and

(f) the approval is necessary in the interests of public health.

Note: For specification by class, see the *Acts Interpretation Act 1901* and subsection 13(3) of the *Legislation Act 2003*.

Application for approval

(3) An application for an approval must:

(a) be made to the Secretary; and

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(b) be accompanied by such information relating to the medical device as is required by the Secretary.

Notification of Secretary's decision

(4) If an application for an approval is made, the Secretary must, as soon as practicable after deciding the application, notify the applicant of:
(a) the decision; and
(b) if the decision is not to grant the approval—the reasons for the decision.

Determinations

(5) The Secretary may, by legislative instrument, make a determination specifying foreign countries for the purposes of subparagraph (1)(d)(i).

(6) The Secretary may, by legislative instrument, make a determination specifying medical devices that can be the subject of an approval under this section.

Conditions

(7) The Secretary may grant an approval subject to any conditions that are specified in the notice of approval.

Note: Breach of the conditions may be an offence: see subsections 41MN(9), (9A) and (9B).

Period of approval

(8) The Secretary may grant an approval for such period as is specified in the notice of approval.

When approval lapses

(9) The approval lapses if:
(a) the period specified in the notice of approval expires; or

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(b) a decision has been made on an application that has been made for inclusion in the Register of the kind of medical device that includes the medical device.

(10) The approval lapses if:

(a) the Secretary is satisfied that paragraph (1)(c), (d), (e) or (f), paragraph (1A)(c), (d), (e), (f), (g) or (h), or paragraph (2)(c), (d), (e) or (f), as the case requires, no longer applies in relation to the medical device, or that a condition of the approval has been contravened; and

(b) the Secretary has given to the person to whom the approval was granted a notice stating that the Secretary is so satisfied.

(11) The lapsing of the approval on the expiry of the period specified in the notice of approval does not prevent another approval being granted under this section in relation to the medical device before that lapsing. The other approval may be expressed to take effect on the expiry of that period.

Approval not a legislative instrument

(12) An approval under subsection (1), (1A) or (2) is not a legislative instrument.

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Part 4-8—Obtaining information

41J What this Part is about

The Secretary may seek information or documents relating to:

- the application of conformity assessment procedures or requirements comparable to those procedures;
- compliance with the essential principles;
- compliance with other requirements;
- distribution of, and other matters relating to, medical devices covered by exemptions under Part 4-6A or Part 4-7.

Note: There are additional obligations relating to notifying defects in medical devices: see sections 41MP, 41MPA, 41MQ and 41MR.

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Division 1—Information relating to compliance with requirements and other matters

41JA Secretary may require information or documents

(1) The Secretary may, by written notice given to a person:

(a) who is an applicant for a conformity assessment certificate that would relate to a kind of medical device; or

(b) who holds a conformity assessment certificate, or an Australian conformity assessment body certificate, that relates to a kind of medical device; or

(ba) who held, at any time during the notice period under subsection (2), a conformity assessment certificate, or an Australian conformity assessment body certificate, that related to a kind of medical device; or

(c) who is an applicant for the inclusion of a kind of medical device in the Register; or

(d) in relation to whom a kind of medical device is included in the Register; or

(da) in relation to whom a kind of medical device was, at any time during the notice period under subsection (2), included in the Register;

require the person to give to the Secretary information or documents, relating to devices of that kind, that are relevant to one or more of the following:

(e) whether the devices comply with the essential principles;

(f) whether the conformity assessment procedures have been applied to the devices or whether requirements, comparable to those procedures, have been applied to the devices;

(g) whether the devices comply with conditions (if any) imposed on a conformity assessment certificate issued in respect of the device or the inclusion of the device in the Register;

(h) whether either of the following has not been complied with in relation to the devices:

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(i) an applicable provision of the Therapeutic Goods Advertising Code;

(ii) any other requirement relating to advertising applicable under Part 5-1 or 5-1A or under the regulations;

(i) if the kind of medical device is included in the Register in relation to the person—whether medical devices of that kind are being:

(i) supplied in Australia; or

(ii) imported into Australia; or

(iii) exported from Australia;

(iaa) if the kind of medical device is included in the Register in relation to the person and there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—whether any supplies in Australia, any imports into Australia, any exports from Australia or any manufacture in Australia of medical devices of that kind contravene those prohibitions;

(iab) if the kind of medical device is included in the Register in relation to the person and there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—whether any supplies in Australia, any imports into Australia, any exports from Australia or any manufacture in Australia of medical devices of that kind contravene those conditions;

(ia) the safety and efficacy of the devices for the purposes for which they are to be used;

(ib) the regulatory history of the devices in another country;

(j) any other matter prescribed by the regulations for the purposes of this paragraph.

(1AA) If a notice is given under subsection (1) to a person covered by paragraph (1)(ba), then paragraphs (1)(e) to (j) (to the extent to which they are relevant) apply in relation to the period the person held the certificate.

(1AB) If a notice is given under subsection (1) to a person covered by paragraph (1)(da), then paragraphs (1)(e) to (j) (to the extent to

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which they are relevant) apply in relation to the period the kind of medical device was included in the Register.

(1A) The Secretary may, by written notice given to a person who is an applicant for a conformity assessment certificate, require the person to give to the Secretary such further information concerning the application as is specified in the notice.

(1B) Requirements under subsections (1) and (1A) may be included in the same notice.

(1C) The Secretary may, by written notice given to a person who holds a conformity assessment certificate, require the person to give to the Secretary specified information to be used by the Secretary in deciding whether to suspend the certificate under section 41EM, or to revoke the certificate under section 41ET, in relation to the circumstances referred to in paragraph 41ET(1)(e).

(1D) Requirements under subsections (1) and (1C) may be included in the same notice.

(1E) The Secretary may, by written notice given to an Australian corporation that has been an Australian conformity assessment body require the corporation to give to the Secretary specified information, or specified documents, relating to:

(a) the certification-related activities carried on by the corporation while the corporation was an Australian conformity assessment body; or

(b) the conditions referred to in subsection 41EWA(5) that applied while the corporation was an Australian conformity assessment body.

(2) For the purposes of paragraphs (1)(ba) and (da), the notice period is the period:

(a) of the length specified in the regulations; and

(b) ending on the day before the Secretary gives the notice under subsection (1).

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(3) Nothing in this section affects the operation of Part VIIC of the *Crimes Act 1914* (which includes provisions that, in certain circumstances, relieve persons from the requirement to disclose spent convictions and require persons aware of such convictions to disregard them).

41JB Complying with the Secretary's requirements

(1) The person must give the information or documents to the Secretary:

(a) within such reasonable time, being not less than 10 working days from the day on which the notice is given, as is specified in the notice; and

(b) in such form as is specified in the notice.

(2) The form may require or permit information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

Offence for failing to comply with a notice

(3) A person commits an offence if:

(a) the person is given a notice under section 41JA; and

(aa) the person is covered by paragraph 41JA(1)(b), (ba), (d) or (da) or subsection 41JA(1E); and

(b) the person fails to comply with the notice.

Penalty: 500 penalty units.

Note: Failure to comply with the notice might also lead to suspension or revocation of a conformity assessment certificate (see Divisions 3 and 4 of Part 4-4) or suspension or cancellation of the entry of a kind of medical device in the Register (see Part 4-6).

(3A) Subsection (3) does not apply if the person has a reasonable excuse.

Note: A defendant bears an evidential burden in relation to the matter in subsection (3A): see subsection 13.3(3) of the *Criminal Code*.

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(3B) A person commits an offence if:

(a) the person is given a notice under section 41JA; and

(b) the person is covered by paragraph 41JA(1)(b), (ba), (d) or (da) or subsection 41JA(1E); and

(d) the person fails to comply with the notice.

Penalty: 100 penalty units.

(3C) An offence against subsection (3B) is an offence of strict liability.

(3D) Subsection (3B) does not apply if the person has a reasonable excuse.

Note: A defendant bears an evidential burden in relation to the matter in subsection (3D): see subsection 13.3(3) of the *Criminal Code*.

Offences for giving false or misleading information in purported compliance with a notice

(4) A person commits an offence if:

(a) the person is given a notice under section 41JA in relation to a kind of medical device; and

(b) the person gives information in purported compliance with the notice; and

(c) the information is false or misleading in a material particular; and

(d) either:

(i) the use of the kind of medical device has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the kind of medical device, if the kind of medical device were used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (7) instead: see section 53A.

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Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(7) A person commits an offence if:
(a) the person is given a notice under section 41JA; and
(b) the person gives information in purported compliance with the notice; and
(c) the information is false or misleading in a material particular.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(8) A person commits an offence if:
(a) the person is given a notice under section 41JA; and
(b) the person gives information in purported compliance with the notice; and
(c) the information is false or misleading in a material particular.

Penalty: 100 penalty units.

(9) An offence against subsection (8) is an offence of strict liability.

41JBA Civil penalty for giving false or misleading information in purported compliance with a notice

A person contravenes this section if:
(a) the person is given a notice under section 41JA; and
(b) the person gives information in purported compliance with the notice; and
(c) the information is false or misleading in a material particular.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

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41JC Self-incrimination

(1) A person is not excused from giving information or a document under section 41JB on the ground that to do so would tend to incriminate the person or expose the person to a penalty.

(2) However, in the case of an individual:

(a) the information given; or

(b) the giving of the document; or

(c) any information, document or thing obtained as a direct or indirect consequence of giving the information or document;

is not admissible in evidence in:

(d) criminal proceedings against the individual, except proceedings under, or arising out of, subsection 41JB(4), (7) or (8); or

(e) proceedings for a pecuniary penalty order against the individual for a contravention of a civil penalty provision, except civil proceedings under, or arising out of, section 41JBA.

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Division 2—Information relating to medical devices covered by exemptions

41JCA Secretary may require information etc. about medical devices exempt under Part 4-6A

(1) This section applies to a person who is required to comply with a condition of an exemption of a kind of medical device under section 41GS.

(2) The Secretary may, by written notice given to the person, require the person to give to the Secretary specified information or documents relating to one or more of the following:
  (a) the supply of devices of that kind;
  (b) the handling of devices of that kind;
  (c) the monitoring of the supply of devices of that kind;
  (d) the results of the supply of devices of that kind;
  (e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to devices of that kind.

(3) The notice must specify a reasonable period within which the person to whom the notice is given must comply. The period must be at least 10 working days starting on the day on which the notice is given.

(4) The notice may require information to be given in accordance with specified software requirements:
  (a) on a specified kind of data processing device; or
  (b) by way of a specified kind of electronic transmission.

41JD Secretary may require information etc. about devices exempted under section 41HA from inclusion in the Register

(1) The Secretary may give the sponsor of kinds of medical devices exempted under subsection 41HA(1) from Division 3 of Part 4-11,

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a written notice requiring the sponsor to give to the Secretary specified information or documents relating to one or more of the following:

(a) the supply of devices of those kinds;
(b) the handling of devices of those kinds;
(c) the monitoring of the supply of devices of those kinds;
(d) the results of the supply of devices of those kinds;
(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to devices of those kinds.

(2) If a medical device is exempt under subsection 41HA(1) because a medical practitioner has signed a statement in accordance with regulations made for the purposes of this section, the Secretary may give the medical practitioner a written notice requiring the medical practitioner to give to the Secretary specified information or documents relating to one or more of the following:

(a) the condition of the person to whom the medical device is to be given or is given;
(b) the supply of the device;
(c) the handling of the device;
(d) the monitoring of the supply of the device;
(e) the results of the supply of the device;
(f) any other matter prescribed by the regulations for the purposes of this paragraph in relation to medical devices of that kind.

(3) A notice under this section must specify a reasonable period within which the person must comply. The period must be at least 10 working days starting on the day on which the notice is given.

(4) A notice under this section may require information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or
(b) by way of a specified kind of electronic transmission.

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41JE Secretary may require information relating to approvals under section 41HB

Approval under subsection 41HB(1)

(1) The Secretary may give to a person granted an approval under subsection 41HB(1) (special and experimental uses), in relation to specified kinds of medical devices, a written notice requiring the person to give to the Secretary specified information or documents relating to one or more of the following:

(a) the supply of devices of those kinds;

(b) the handling of devices of those kinds;

(c) the monitoring of the supply of devices of those kinds;

(d) the results of the supply of devices of those kinds;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to devices of those kinds.

Approval under subsection 41HB(1)—use by another person

(2) The Secretary may give to a person using specified kinds of medical devices, that are the subject of an approval granted to someone else under paragraph 41HB(1)(e) (use solely for experimental purposes in humans), a written notice requiring the person to give to the Secretary specified information or documents relating to either of both of the following:

(a) the use of devices of those kinds;

(b) any other matter prescribed by the regulations for the purposes of this paragraph in relation to devices of those kinds.

Compliance period

(3) A notice under this section must specify a reasonable period within which the person to whom the notice is given must comply. The period must be at least 10 working days starting on the day on which the notice is given.

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Information may need to be given in accordance with specified software requirements

(4) A notice under this section may require information to be given in accordance with specified software requirements:
  (a) on a specified kind of data processing device; or
  (b) by way of a specified kind of electronic transmission.

41JF Secretary may require information relating to health practitioner authorisations

(1) The Secretary may give to a person who is granted an authority under subsection 41HC(1) (exemptions for medical practitioners), in relation to specified kinds of medical devices, a written notice requiring the person to give to the Secretary specified information or documents relating to one or more of the following:
  (a) the supply of devices of those kinds;
  (b) the handling of devices of those kinds;
  (c) the monitoring of the supply of devices of those kinds;
  (d) the results of the supply of devices of those kinds;
  (e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to devices of those kinds.

(1A) If a person is authorised, by subsection 41HC(6) rules, to supply a specified kind of medical device, the Secretary may give the person a written notice requiring the person to give the Secretary specified information or documents relating to one or more of the following:
  (a) the supply of devices of that kind;
  (b) the handling of devices of that kind;
  (c) the monitoring of the supply of devices of that kind;
  (d) the results of the supply of devices of that kind;
  (e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to devices of that kind.

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(2) A notice under subsection (1) or (1A) must specify a reasonable period within which the person to whom the notice is given must comply. The period must be at least 10 working days starting on the day on which the notice is given.

(3) A notice under subsection (1) or (1A) may require information to be given in accordance with specified software requirements:
  (a) on a specified kind of data processing device; or
  (b) by way of a specified kind of electronic transmission.

41JFA Secretary may require information relating to approvals under section 41HD

(1) The Secretary may give to a person who is granted an approval under subsection 41HD(1), (1A) or (2) in relation to a medical device a written notice requiring the person to give to the Secretary specified information or documents relating to one or more of the following:
  (a) the supply of the medical device;
  (b) the handling of the medical device;
  (c) the monitoring of the supply of the medical device;
  (d) the results of the supply of the medical device;
  (e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to the kind of medical device that includes the medical device.

(2) The notice must specify a reasonable period within which the person must comply. The period must be at least 10 working days starting on the day on which the notice is given.

(3) The notice may require information to be given in accordance with specified software requirements:
  (a) on a specified kind of data processing device; or
  (b) by way of a specified kind of electronic transmission.

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41JG Criminal offences for failing to give information or documents sought under this Division

(1) A person commits an offence if:

(a) the person is given a notice under section 41JCA, 41JD, 41JE, 41JF or 41JFA; and

(b) the person fails to comply with the notice.

Penalty: 400 penalty units.

(2) A person commits an offence if:

(a) the person is given a notice under section 41JCA, 41JD, 41JE, 41JF or 41JFA; and

(b) the person fails to comply with the notice.

Penalty: 100 penalty units.

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

41JH False or misleading information

(1) A person to whom a notice is given under section 41JCA, 41JD, 41JE, 41JF or 41JFA commits an offence if:

(a) the person gives information to the Secretary; and

(b) the person knows that the information:

(i) is false or misleading; or

(ii) omits any matter or thing without which the information is misleading; and

(c) the information is given in compliance or purported compliance with the notice.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) A person to whom a notice is given under section 41JCA, 41JD, 41JE, 41JF or 41JFA commits an offence if:

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(a) the person gives information to the Secretary; and
(b) the information:
(i) is false or misleading; or
(ii) omits any matter or thing without which the information is misleading; and
(c) the information is given in compliance or purported compliance with the notice.

Penalty: 100 penalty units.

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

(4) Subsection (1) or (2) does not apply as a result of subparagraph (1)(b)(i) or (2)(b)(i) if the information is not false or misleading in a material particular.

Note: A defendant bears an evidential burden in relation to the matter in subsection (4): see subsection 13.3(3) of the *Criminal Code*.

(5) Subsection (1) or (2) does not apply as a result of subparagraph (1)(b)(ii) or (2)(b)(ii) if the information did not omit any matter or thing without which the information is misleading in a material particular.

Note: A defendant bears an evidential burden in relation to the matter in subsection (5): see subsection 13.3(3) of the *Criminal Code*.

41JI False or misleading documents

(1) A person commits an offence if:
(a) the person produces a document to the Secretary; and
(b) the person knows that the document is false or misleading; and
(c) the document is produced in compliance or purported compliance with a notice given under section 41JCA, 41JD, 41JE, 41JF or 41JFA.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

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Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(1A) A person commits an offence if:

(a) the person produces a document to the Secretary; and

(b) the document is false or misleading; and

(c) the document is produced in compliance or purported compliance with a notice given under section 41JCA, 41JD, 41JE, 41JF or 41JFA.

Penalty: 100 penalty units.

(1B) An offence against subsection (1A) is an offence of strict liability.

(1C) Subsection (1) or (1A) does not apply if the document is not false or misleading in a material particular.

Note: A defendant bears an evidential burden in relation to the matter in subsection (1C): see subsection 13.3(3) of the *Criminal Code*.

(2) Subsection (1) or (1A) does not apply to a person who produces a document if the document is accompanied by a written statement signed by the person or, in the case of a body corporate, by a competent officer of the body corporate:

(a) stating that the document is, to the knowledge of the first-mentioned person, false or misleading in a material particular; and

(b) setting out, or referring to, the material particular in which the document is, to the knowledge of the first-mentioned person, false or misleading.

Note: A defendant bears an evidential burden in relation to the matter in subsection (2) (see subsection 13.3(3) of the *Criminal Code*).

41JJ Self-incrimination

(1) A person is not excused from giving information or a document under a notice given under section 41JCA, 41JD, 41JE, 41JF or 41JFA on the ground that to do so would tend to incriminate the person or expose the person to a penalty.

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(2) However, in the case of an individual:

(a) the information given; or

(b) the giving of the document; or

(c) any information, document or thing obtained as a direct or indirect consequence of giving the information or document;

is not admissible in evidence in:

(d) criminal proceedings against the individual, except proceedings under, or arising out of, section 41JH or 41JI; or

(e) proceedings for a pecuniary penalty order against the individual for a contravention of a civil penalty provision.

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Part 4-8A—Mandatory reporting of adverse events by healthcare facilities

Division 1—Preliminary

41JK Simplified outline of this Part

The chief executive officer (however described) of a healthcare facility is required to give a report to the Secretary about an adverse event involving a reportable medical device in certain circumstances.

Civil penalties apply to the chief executive officer of a healthcare facility for failing to give such a report to the Secretary.

41JL Purposes of this Part

The purposes of this Part are to facilitate the following:

(a) monitoring and enforcing compliance with the requirements of this Chapter;

(b) monitoring the safety and performance of medical devices;

(c) any activities that are incidental to the above purposes.

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Division 2—Mandatory reporting of adverse events

41JM Requirement to report adverse events involving reportable medical devices

Report to be given to the Secretary

(1) The chief executive officer (however described) of a healthcare facility must give a report to the Secretary if subsection (2), (3) or (4) applies to the healthcare facility in relation to a reportable medical device and a person.

(2) This subsection applies to a healthcare facility if:
  (a) a reportable medical device is used in the facility; and
  (b) the use of the device has resulted in the death, or a serious deterioration in the health, of a person while the device is used in the facility.

(3) This subsection applies to a healthcare facility if:
  (a) a reportable medical device is not used in the facility because of the intervention of a person in the facility; and
  (b) the use of the device, if the device were used, would result in, or would be likely to result in, the death, or a serious deterioration in the health, of a person.

(4) This subsection applies to a healthcare facility if:
  (a) a health practitioner provides treatment to a person in the facility for a serious deterioration in the health of the person; and
  (b) the use of a reportable medical device has resulted in the serious deterioration in the health of the person.

Report requirements

(5) The report must include the following information about the reportable medical device and the person:
  (a) the name, or a description, of the reportable medical device;

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(b) a description of the matters covered in subsection (2), (3) or (4);

(c) any other information prescribed by regulations made for the purposes of this paragraph.

Note: For the release of information included in, or relating to, a report, see section 61.

(6) The report must be given to the Secretary:

(a) within the period prescribed by regulations made for the purposes of this subparagraph or such longer period as the Secretary allows in a particular case; and

(b) in the manner prescribed by regulations made for the purposes of this subparagraph.

Exception

(7) Subsection (1) does not apply if the chief executive officer (however described) of the healthcare facility has reported the matters covered by subsection (2), (3) or (4) to:

(a) the chief executive officer of the Australian Commission on Safety and Quality in Health Care; or

(b) the head (however described) of a Department of State of a State or Territory that has responsibility for matters relating to health; or

(c) any other person prescribed by regulations made for the purposes of this paragraph.

Civil penalty

(8) A person contravenes this subsection if:

(a) the person is required to give a report to the Secretary in accordance with this section; and

(b) the person fails to comply with the requirement.

Maximum civil penalty: 30 penalty units.

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Part 4-9—Public notification, and recall, of medical devices

41K What this Part is about

The Secretary can require action to recall medical devices, or to inform the public about medical devices, that do not comply with requirements or cannot lawfully be supplied.

41KA Public notification, and recall, of medical devices

(1) The Secretary may, in writing, impose requirements, relating to a kind of medical device, on a person if:

(a) any of the circumstances referred to in the second column of an item in the following table occur in relation to the kind of device; and

(b) the person is referred to in the third column of that item of the table.

Circumstances in which requirements may be imposed

Item	Circumstance relating to a kind of medical device	Person subject to requirements
1.	It is supplied while it is included in the Register, but the Secretary is satisfied that medical devices of that kind do not comply with the essential principles	The person in relation to whom it is included in the Register
2.	It is supplied while it is included in the Register, but the Secretary is satisfied that the conformity assessment procedures have not been applied to medical devices of that kind and that requirements, comparable to those procedures, have not been applied to medical devices of that kind	The person in relation to whom it is included in the Register

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Section 41KA

Circumstances in which requirements may be imposed		
Item	**Circumstance relating to a kind of medical device**	**Person subject to requirements**
3.	It is supplied while: (a) medical devices of that kind are exempt devices; or (b) there is an approval under section 41HB relating to devices of that kind; or (c) there is an authority under section 41HC relating to devices of that kind; or (d) there is an approval under subsection 41HD(1), (1A) or (2) relating to devices of that kind; but the Secretary is satisfied that medical devices of that kind do not comply with the essential principles	The person supplying the kind of medical device
4.	It is supplied while: (a) medical devices of that kind are exempt devices; or (b) there is an approval under section 41HB relating to devices of that kind; or (c) there is an authority under section 41HC relating to devices of that kind; or (d) there is an approval under subsection 41HD(1), (1A) or (2) relating to devices of that kind; but the Secretary is satisfied that the conformity assessment procedures have not been applied to medical devices of that kind and that requirements, comparable to those procedures, have not been applied to medical devices of that kind	The person supplying the kind of medical device
4A.	It is supplied and the Secretary is satisfied that: (a) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—the supply	The person supplying the kind of medical device

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Circumstances in which requirements may be imposed		
Item	**Circumstance relating to a kind of medical device**	**Person subject to requirements**
	contravenes one or more of those prohibitions; or (b) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—the supply contravenes one or more of those conditions	
5.	It is supplied while: (a) it is not included in the Register; and (aa) it is not covered by an exemption in force under section 41GS; and (b) it is not an exempt device; and (c) there is not an approval under section 41HB relating to devices of that kind; and (d) there is not an authority under section 41HC relating to devices of that kind; and (e) there is not an approval under subsection 41HD(1), (1A) or (2) relating to devices of that kind.	The person supplying the kind of medical device
5A.	It is supplied while it is covered by an exemption in force under section 41GS, and the Secretary is satisfied that it is not fit to be used for its intended purpose	The person supplying the kind of medical device
5B.	It is supplied while it is included in the Register, but it appears to the Secretary that the quality, safety or performance of medical devices of that kind is unacceptable	The person in relation to whom the kind of medical device is included in the Register
6.	It has been suspended from the Register	The person in relation to whom it was included in the Register

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Circumstances in which requirements may be imposed		
Item	**Circumstance relating to a kind of medical device**	**Person subject to requirements**
7.	Its entry has been cancelled from the Register	The person in relation to whom it was included in the Register
8.	It is counterfeit goods (within the meaning of section 42E)	The person supplying the kind of medical device

(2) The requirements may be one or more of the following:

(a) to take specified steps, in the specified manner and within such reasonable period as is specified, to recall medical devices of that kind that have been distributed;

(b) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, to the effect that the circumstances referred to in paragraph (1)(a) have occurred in relation to medical devices of that kind;

(c) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, of specified information, or of information of a specified kind, relating to either or both of the following:

(i) medical devices of that kind;

(ii) the circumstances referred to in paragraph (1)(a);

(d) to publish, in the specified manner and within such reasonable period as is specified, specified information, or information of a specified kind, relating to the manufacture or distribution of medical devices of that kind;

(e) to notify the Secretary, in the specified manner and within such reasonable period as is specified, of specified information, or of information of a specified kind, relating to the persons to whom medical devices of that kind have been supplied.

(3) If the circumstances referred to in paragraph (1)(a) apply only to some medical devices of that kind, the Secretary may limit the

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imposition of the requirements to the medical devices of that kind to which those circumstances apply.

(4) A requirement to recall medical devices under this section does not apply to a medical device that cannot be recalled because it has been administered to, or applied in the treatment of, a person.

41KB Publication of requirements

The Secretary must cause to be published in the *Gazette* or on the Department's website, as soon as practicable after imposing a requirement under section 41KA, a notice setting out particulars of the requirement.

41KC Criminal offences for failing to comply with requirements relating to a kind of medical device

(1) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches a requirement imposed on the person under section 41KA; and

(c) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches a requirement imposed on the person under section 41KA.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

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(5) A person commits an offence if:
  (a) the person does an act or omits to do an act; and
  (b) the act or omission breaches a requirement imposed on the person under section 41KA.

  Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

41KCA Civil penalty for failing to comply with requirements relating to a kind of medical device

A person contravenes this section if:
  (a) the person does an act or omits to do an act; and
  (b) the act or omission contravenes a requirement imposed on the person under section 41KA.

Maximum civil penalty:
  (a) for an individual—5,000 penalty units; and
  (b) for a body corporate—50,000 penalty units.

41KD Powers of suspension and cancellation unaffected

Imposition of a requirement under section 41KA does not affect the Secretary's powers to:
  (a) suspend the entry of a kind of medical device, or some medical devices of a particular kind, from the Register under Part 4-6; or
  (b) cancel the entry of a kind of medical device, or some medical devices of a particular kind, in the Register under Part 4-6.

41KE Saving of other laws

This Part is not intended to exclude or limit the operation of any other law of the Commonwealth or any law of a State or Territory.

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Part 4-10—Assessment fees

41L What this Part is about

Conformity assessment fees must be paid for consideration of applications for conformity assessment certificates. Application audit assessment fees must be paid for auditing applications that are required to be selected for auditing under paragraph 41FH(1)(a).

41LA Assessment fees

(1) A conformity assessment fee specified in or determined in accordance with the regulations is payable by a person in respect of consideration of an application for a conformity assessment certificate under Part 4-4.

(2) The regulations may prescribe different levels of conformity assessment fees in relation to any one or more of the following:
  (a) different kinds of manufacturers;
  (b) different kinds of medical devices;
  (c) different parts of the conformity assessment procedures that are considered in relation to an application for a conformity assessment certificate under Part 4-4.

(3) An application audit assessment fee specified in or determined in accordance with the regulations is payable by a person in respect of the auditing of an application for inclusion of a kind of medical device in the Register under Part 4-5, if paragraph 41FH(1)(a) required the Secretary to select the application for audit.

(4) The regulations may prescribe different levels of application audit assessment fees in relation to any one or more of the following:
  (a) different kinds of manufacturers;
  (b) different kinds of medical devices;

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(c) different levels of assessment of kinds of medical devices.

(5) The application audit assessment fee payable because of subsection (3) is payable only in respect of considering the matters set out in subsection 41FI(1).

41LB When assessment fee due for payment

Subject to sections 41LC and 41LE, an assessment fee payable by an applicant is due and payable on the day, and in the manner, specified in the regulations.

41LC Payment of assessment fee by instalments

(1) The regulations may provide for the payment of an assessment fee to be made by such instalments and at such times as are ascertained in accordance with the regulations, and the assessment fee is due and payable accordingly.

(2) Regulations made for the purposes of subsection (1) may provide that a person is not allowed to pay an assessment fee by instalments if any part of an instalment of:

(a) that or any other assessment fee payable by the person; or

(b) any evaluation fee under section 24 payable by the person;

was unpaid immediately after the time when it became due for payment.

(3) Subsection (2) does not limit the generality of subsection (1).

41LD Recovery of assessment fee

An assessment fee may be recovered by the Commonwealth as a debt due to the Commonwealth.

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41LE Reduction of conformity assessment fee where decision not made within prescribed period

(1) Nothing in section 41LA, 41LB or 41LC requires the applicant to pay more than 3/4 of the conformity assessment fee before the making of the decision if:

(a) the application is for the issuing of a conformity assessment certificate under Part 4-4; and

(b) consideration of the application will involve an examination of the design of medical devices; and

(c) a period is prescribed under paragraph 63(2)(dc) for making a decision on the application.

(2) If the decision is not made within that period, the conformity assessment fee is 3/4 of the fee that, apart from this subsection, would have been the conformity assessment fee.

(3) If:

(a) the decision is made within that period; and

(b) part of the conformity assessment fee under section 41LA is, because of subsection (1) of this section, unpaid when the decision is made;

that part becomes due and payable on the making of the decision.

(4) For the purposes of this section, a decision is taken to be made on the application when the applicant is notified under subsection 41EE(1) of the Secretary's decision on the application.

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Part 4-11—Offences and civil penalty provisions relating to medical devices

41M What this Part is about

This Part contains offences and civil penalty provisions that are aimed at ensuring that:

- the essential principles are complied with (see Division 1);
- the conformity assessment procedures have been applied to kinds of medical devices or requirements, comparable to those procedures, have been applied to kinds of medical devices (see Division 2);
- administrative processes put in place by Parts 4-4 to 4-9 are followed (see Divisions 3, 3A and 4).

Note: There are also some offences and civil penalty provisions in the earlier Parts of this Chapter. They generally relate to matters ancillary to administrative processes in those Parts (e.g. false or misleading statements in applications).

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Division 1—Non-compliance with essential principles

41MA Criminal offences for importing, supplying or exporting a medical device that does not comply with essential principles

Offences relating to importing a medical device

(1) A person commits an offence if:

(a) the person imports a medical device into Australia; and

(b) the medical device does not comply with the essential principles relating to matters other than the labelling of the device; and

(c) the Secretary has not consented to the importation; and

(ca) the device is not of a kind covered by an exemption in force under section 41GS; and

(d) either:

(i) the use of the device has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the device, if the device were used, would result in, or would be likely to result in, harm or injury to any person; and

(e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because the device does not comply with the essential principles.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person imports a medical device into Australia; and

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(b) the medical device does not comply with the essential principles relating to matters other than the labelling of the device; and
(c) the Secretary has not consented to the importation; and
(d) the device is not of a kind covered by an exemption in force under section 41GS.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(4A) A person commits an offence if:
(a) the person imports a medical device into Australia; and
(b) the medical device does not comply with the essential principles relating to matters other than the labelling of the device; and
(c) the Secretary has not consented to the importation; and
(d) the device is not of a kind covered by an exemption in force under section 41GS.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

Offences relating to supplying a medical device

(5) A person commits an offence if:
(a) the person supplies a medical device for use in Australia; and
(b) the medical device does not comply with the essential principles; and
(c) the Secretary has not consented to the supply; and
(ca) the device is not of a kind covered by an exemption in force under section 41GS; and
(d) either:
(i) the use of the device has resulted in, will result in, or is likely to result in, harm or injury to any person; or

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(ii) the use of the device, if device were used, would result in, or would be likely to result in, harm or injury to any person; and

(e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because the device does not comply with the essential principles.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (8) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(8) A person commits an offence if:

(a) the person supplies a medical device for use in Australia; and

(b) the medical device does not comply with the essential principles; and

(c) the Secretary has not consented to the supply; and

(d) the device is not of a kind covered by an exemption in force under section 41GS.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(8A) A person commits an offence if:

(a) the person supplies a medical device for use in Australia; and

(b) the medical device does not comply with the essential principles; and

(c) the Secretary has not consented to the supply; and

(d) the device is not of a kind covered by an exemption in force under section 41GS.

Penalty: 100 penalty units.

(8B) An offence against subsection (8A) is an offence of strict liability.

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Offences relating to exporting a medical device

(9) A person commits an offence if:

(a) the person exports a medical device from Australia; and

(b) the medical device does not comply with the essential principles relating to matters other than the labelling of the device for supply in Australia; and

(c) the Secretary has not consented to the exportation; and

(ca) the device is not of a kind covered by an exemption in force under section 41GS; and

(d) either:

(i) the use of the device has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the device, if the device were used, would result in, or would be likely to result in, harm or injury to any person; and

(e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because the device does not comply with the essential principles.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (12) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(12) A person commits an offence if:

(a) the person exports a medical device from Australia; and

(b) the medical device does not comply with the essential principles relating to matters other than the labelling of the device for supply in Australia; and

(c) the Secretary has not consented to the exportation; and

(d) the device is not of a kind covered by an exemption in force under section 41GS.

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Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(13) A person commits an offence if:
(a) the person exports a medical device from Australia; and
(b) the medical device does not comply with the essential principles relating to matters other than the labelling of the device for supply in Australia; and
(c) the Secretary has not consented to the exportation; and
(d) the device is not of a kind covered by an exemption in force under section 41GS.

Penalty: 100 penalty units.

(14) An offence against subsection (13) is an offence of strict liability.

41MAA Civil penalties for importing, supplying or exporting a medical device that does not comply with essential principles

Civil penalty relating to importing a medical device

(1) A person contravenes this subsection if:
(a) the person imports a medical device into Australia; and
(b) the medical device does not comply with the essential principles relating to matters other than the labelling of the device; and
(c) the Secretary has not consented to the importation; and
(d) the device is not of a kind covered by an exemption in force under section 41GS.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

Civil penalty relating to supplying a medical device

(2) A person contravenes this subsection if:

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(a) the person supplies a medical device for use in Australia; and
(b) the medical device does not comply with the essential principles; and
(c) the Secretary has not consented to the supply; and
(d) the device is not of a kind covered by an exemption in force under section 41GS.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

Civil penalty relating to exporting a medical device

(3) A person contravenes this subsection if:
(a) the person exports a medical device from Australia; and
(b) the medical device does not comply with the essential principles relating to matters other than the labelling of the device for supply in Australia; and
(c) the Secretary has not consented to the exportation; and
(d) the device is not of a kind covered by an exemption in force under section 41GS.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

41MAB Giving of consent by Secretary

The Secretary is not required to consider giving a consent mentioned in section 41MA or 41MAA to a person unless the person has paid the fee that is prescribed by the regulations for the person's application for such a consent.

41MB Exceptions

(1) Sections 41MA and 41MAA do not apply if:

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(a) the medical device complies with one or more medical device standards that apply to it; and

(b) the medical device fails to comply with the essential principles only in respect of a part or parts of the essential principles to which that medical device standard, or one or more of those medical device standards, relate.

Note: Medical device standards are determined under Division 2 of Part 4-2.

(2) For the purposes of this section, a medical device standard relates to a part or parts of the essential principles only if the standard specifies that part or parts.

Note 1: In the prosecution for an offence, the defendant bears an evidential burden in relation to the matters in this section (see subsection 13.3(3) of the *Criminal Code*).

Note 2: In proceedings for the contravention of a civil penalty provision, the defendant must prove the matters in this section.

41MC Criminal offences relating to breaching a condition of a consent

(1) The consent of the Secretary under section 41MA or 41MAA may be given:

(a) unconditionally or subject to conditions; or

(b) in respect of particular medical devices or kinds of medical devices.

(2) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches a condition of a consent; and

(c) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

Penalty: 2,000 penalty units.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (5) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

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(5) A person commits an offence if:
(a) the person does an act or omits to do an act; and
(b) the act or omission breaches a condition of a consent.

Penalty: 500 penalty units.

(6) A person commits an offence if:
(a) the person does an act or omits to do an act; and
(b) the act or omission breaches a condition of a consent.

Penalty: 100 penalty units.

(7) An offence against subsection (6) is an offence of strict liability.

41MCA Civil penalty relating to breaching a condition of a consent

A person contravenes this section if:
(a) the person does an act or omits to do an act; and
(b) the act or omission breaches a condition of a consent imposed under section 41MC.

Maximum civil penalty:
(a) for an individual—3,000 penalty units; and
(b) for a body corporate—30,000 penalty units.

41MD Treating medical devices as prohibited imports or exports

If:
(a) the importation or exportation of a medical device is an offence under subsection 41MA(1), (4), (4A), (9), (12) or (13) or a contravention of subsection 41MAA(1) or (3); and
(b) the Secretary notifies the Comptroller-General of Customs in writing that the Secretary wishes the *Customs Act 1901* to apply to that importation or exportation;

the *Customs Act 1901* has effect as if the device included in that importation or exportation were goods described as forfeited to the Crown under section 229 of that Act because they were:
(c) prohibited imports within the meaning of that Act; or

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(d) prohibited exports within the meaning of that Act;

as the case requires.

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Division 2—Failure to apply conformity assessment procedures

41ME Criminal offences for failing to apply conformity assessment procedures—manufacturers

Offences relating to supplying a medical device

(1) A person commits an offence if:

(a) the person manufactures a medical device; and

(b) the person supplies the device in Australia; and

(c) the conformity assessment procedures have not been applied to the device; and

(ca) the device is not of a kind covered by an exemption in force under section 41GS; and

(d) either:

(i) the use of the device has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the device, if the device were used, would result in, or would be likely to result in, harm or injury to any person; and

(e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because the conformity assessment procedures have not been applied to the device.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person manufactures a medical device; and

(b) the person supplies the device in Australia; and

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(c) the conformity assessment procedures have not been applied to the device; and

(d) the device is not of a kind covered by an exemption in force under section 41GS.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(4A) A person commits an offence if:

(a) the person manufactures a medical device; and

(b) the person supplies the device in Australia; and

(c) the conformity assessment procedures have not been applied to the device; and

(d) the device is not of a kind covered by an exemption in force under section 41GS.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

Offences relating to exporting a medical device

(5) A person commits an offence if:

(a) the person manufactures a medical device; and

(b) the person exports the device from Australia; and

(c) the conformity assessment procedures have not been applied to the device; and

(ca) the device is not of a kind covered by an exemption in force under section 41GS; and

(d) either:

(i) the use of the device has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the device, if the device were used, would result in, or would be likely to result in, harm or injury to any person; and

(e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because the

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conformity assessment procedures have not been applied to the device.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (8) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(8) A person commits an offence if:

(a) the person manufactures a medical device; and

(b) the person exports the device from Australia; and

(c) the conformity assessment procedures have not been applied to the device; and

(d) the device is not of a kind covered by an exemption in force under section 41GS.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(9) A person commits an offence if:

(a) the person manufactures a medical device; and

(b) the person exports the device from Australia; and

(c) the conformity assessment procedures have not been applied to the device; and

(d) the device is not of a kind covered by an exemption in force under section 41GS.

Penalty: 100 penalty units.

(10) An offence against subsection (9) is an offence of strict liability.

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41MEA Civil penalties for failing to apply conformity assessment procedures—manufacturers

Civil penalty relating to supplying a medical device

(1) A person contravenes this subsection if:
  (a) the person supplies a medical device in Australia; and
  (b) the person has manufactured the device; and
  (c) the conformity assessment procedures have not been applied to the device; and
  (d) the device is not of a kind covered by an exemption in force under section 41GS.

Maximum civil penalty:
  (a) for an individual—5,000 penalty units; and
  (b) for a body corporate—50,000 penalty units.

Civil penalty relating to exporting a medical device

(2) A person contravenes this subsection if:
  (a) the person exports a medical device from Australia; and
  (b) the person has manufactured the device; and
  (c) the conformity assessment procedures have not been applied to the device; and
  (d) the device is not of a kind covered by an exemption in force under section 41GS.

Maximum civil penalty:
  (a) for an individual—5,000 penalty units; and
  (b) for a body corporate—50,000 penalty units.

41MF Criminal offences for failing to apply conformity assessment procedures—sponsors

Offences relating to supplying a medical device

(1) A person commits an offence if:

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(a) the person supplies a medical device in Australia; and
(b) the conformity assessment procedures have not been applied to the device; and
(ba) the device is not of a kind covered by an exemption in force under section 41GS; and
(c) either:
(i) the use of the device has resulted in, will result in, or is likely to result in, harm or injury to any person; or
(ii) the use of the device, if the device were used, would result in, or would be likely to result in, harm or injury to any person; and
(d) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because the conformity assessment procedures have not been applied to the device.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (2) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) A person commits an offence if:
(a) the person supplies a medical device in Australia; and
(b) the conformity assessment procedures have not been applied to the device; and
(c) the device is not of a kind covered by an exemption in force under section 41GS.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Offences relating to exporting a medical device

(3) A person commits an offence if:
(a) the person exports a medical device from Australia; and

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(b) the conformity assessment procedures have not been applied to the device; and

(ba) the device is not of a kind covered by an exemption in force under section 41GS; and

(c) either:

(i) the use of the device has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the device, if the device were used, would result in, or would be likely to result in, harm or injury to any person; and

(d) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because the conformity assessment procedures have not been applied to the device.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person exports a medical device from Australia; and

(b) the conformity assessment procedures have not been applied to the device; and

(c) the device is not of a kind covered by an exemption in force under section 41GS.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Exception

(5) This section does not apply if the defendant was not the sponsor of the device at the time of the supply or exportation, as the case may be.

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Note: A defendant bears an evidential burden in relation to the matters in subsection (5): see subsection 13.3(3) of the *Criminal Code*.

41MG Exceptions

(1) Sections 41ME, 41MEA and 41MF do not apply to the extent that:

(a) the quality management systems applied to the medical device comply with one or more conformity assessment standards that apply to them; and

(b) the conformity assessment procedures have not been applied to the device only in respect of a part or parts of the conformity assessment procedures to which one or more of those conformity assessment standards relate.

Note: Conformity assessment standards are determined under Division 2 of Part 4-3.

(2) For the purposes of this section, a conformity assessment standard relates to a part or parts of the conformity assessment procedures only if the standard specifies that part or parts.

(3) Sections 41ME, 41MEA and 41MF do not apply if an overseas regulator conformity assessment document is in force in relation to the medical device.

Note 1: In the prosecution for an offence, the defendant bears an evidential burden in relation to the matters in this section (see subsection 13.3(3) of the *Criminal Code*).

Note 2: In proceedings for the contravention of a civil penalty provision, the defendant must prove the matters in this section.

41MH Criminal offence for making false statements in declarations

A person commits an offence if:

(a) the person makes a statement in or in connection with a declaration, relating to the application of conformity assessment procedures, or the application of requirements comparable to those procedures, to a medical device that the person has manufactured; and

(b) the statement is false or misleading in a material particular.

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Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

41MHA Civil penalty for making false statements in declarations

A person contravenes this section if:

(a) the person manufactures a medical device; and

(b) the person makes a statement in or in connection with a declaration relating to the application of conformity assessment procedures, or the application of requirements comparable to those procedures, to the device; and

(c) the statement is false or misleading in a material particular.

Maximum civil penalty:

(a) for an individual—3,000 penalty units; and

(b) for a body corporate—30,000 penalty units.

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Division 3—Medical devices not included in the Register and related matters

41MI Criminal offences for importing, exporting, supplying or manufacturing a medical device not included in the Register

(1) A person commits an offence if:

(a) the person:

(i) imports a medical device into Australia; or

(ii) exports a medical device from Australia; or

(iii) supplies a medical device in Australia; or

(iv) manufactures a medical device in Australia; and

(b) none of the following subparagraphs applies in relation to the device:

(i) the device is of a kind included in the Register in relation to the person;

(ia) the device is of a kind covered by an exemption in force under section 41GS;

(ii) the device is an exempt device;

(iii) the device is the subject of an approval under section 41HB or an authority under section 41HC;

(iv) the device is the subject of an approval under subsection 41HD(1), (1A) or (2) that is held by the person; and

(c) either:

(i) the use of the device has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the device, if the device were used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

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Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person:

(i) imports a medical device into Australia; or

(ii) exports a medical device from Australia; or

(iii) supplies a medical device in Australia; or

(iv) manufactures a medical device in Australia; and

(b) none of the following subparagraphs applies in relation to the device:

(i) the device is of a kind included in the Register in relation to the person;

(ia) the device is of a kind covered by an exemption in force under section 41GS;

(ii) the device is an exempt device;

(iii) the device is the subject of an approval under section 41HB or an authority under section 41HC;

(iv) the device is the subject of an approval under subsection 41HD(1), (1A) or (2) that is held by the person.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(5) A person commits an offence if:

(a) the person:

(i) imports a medical device into Australia; or

(ii) exports a medical device from Australia; or

(iii) supplies a medical device in Australia; or

(iv) manufactures a medical device in Australia; and

(b) none of the following subparagraphs applies in relation to the device:

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(i) the device is of a kind included in the Register in relation to the person;
(ii) the device is of a kind covered by an exemption in force under section 41GS;
(iii) the device is an exempt device;
(iv) the device is the subject of an approval under section 41HB or an authority under section 41HC;
(v) the device is the subject of an approval under subsection 41HD(1), (1A) or (2) that is held by the person.

Penalty: 100 penalty units.

(5A) An offence against subsection (5) is an offence of strict liability.

Defence if person was not the sponsor of the goods

(6) It is a defence to a prosecution under subsection (1), (4) or (5) if the defendant proves that the defendant was not the sponsor of the device at the time of the importation, exportation, supply, or manufacture, as the case may be.

Note: A defendant bears a legal burden in relation to the matters in subsection (6): see section 13.4 of the *Criminal Code*.

Exception

(7) Subsection (1) does not apply if:
(a) harm or injury did not, will not, or is not likely to, directly result from:
(i) the quality, safety or performance of the medical device; or
(ii) a matter relating to the labelling or packaging of the medical device; or
(iii) the improper use of the medical device; or
(b) harm or injury would not, or would not be likely to, directly result from:
(i) the quality, safety or performance of the medical device; or

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(ii) a matter relating to the labelling or packaging of the medical device; or

(iii) the improper use of the medical device.

Note: A defendant bears an evidential burden in relation to the matters in subsection (7): see subsection 13.3(3) of the *Criminal Code*.

41MIA Notice required to adduce evidence in support of exception under subsection 41MI(7)

(1) If:

(a) a defendant is committed for trial for an offence against subsection 41MI(1); or

(b) an offence against subsection 41MI(1) is to be heard and determined by a court of summary jurisdiction;

the committing magistrate or the court must:

(c) inform the defendant of the requirements of this section; and

(d) cause a copy of this section to be given to the defendant.

(2) A defendant must not, without leave of the court, adduce evidence in support of the exception under subsection 41MI(7) unless:

(a) if paragraph (1)(a) applies—more than 21 days before the trial begins; or

(b) if paragraph (1)(b) applies—more than 21 days before the hearing of the offence begins;

he or she gives notice of particulars of the exception.

(3) A defendant must not, without leave of the court, call any other person to give evidence in support of the exception unless:

(a) the notice under subsection (2) includes the name and address of the person or, if the name and address is not known to the defendant at the time he or she gives the notice, any information in his or her possession that might be of material assistance in finding the person; and

(b) if the name or the address is not included in the notice—the court is satisfied that the defendant before giving the notice took, and after giving the notice continued to take, all reasonable steps to ascertain the name or address; and

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(c) if the name or address is not included in the notice, but the defendant subsequently ascertains the name or address or receives information that might be of material assistance in finding the person—the defendant immediately gives notice of the name, address or other information, as the case may be; and

(d) if the defendant is told by or on behalf of the prosecutor that the person has not been found by the name, or at the address, given by the defendant:

(i) the defendant immediately gives notice of any information in the defendant's possession that might be of material assistance in finding the person; or

(ii) if the defendant later receives any such information—the defendant immediately gives notice of the information.

(4) A notice purporting to be given under this section on behalf of the defendant by his or her legal practitioner is, unless the contrary is proved, taken as having been given with the authority of the defendant.

(5) Any evidence tendered to disprove that the exception applies may, subject to direction by the court, be given before or after evidence is given in support of the exception.

(6) A notice of particulars of the exception must be given, in writing, to the Director of Public Prosecutions. A notice is taken as having been given if it is:

(a) delivered to or left at the Office of the Director of Public Prosecutions; or

(b) sent by certified mail addressed to the Director of Public Prosecutions at the Office of the Director of Public Prosecutions.

(7) In this section:

Director of Public Prosecutions means a person holding office as, or acting as, the Director of Public Prosecutions under the *Director of Public Prosecutions Act 1983*.

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41MIB Civil penalty for importing, exporting, supplying or manufacturing a medical device not included in the Register

(1) A person contravenes this section if:

(a) the person does any of the following:

(i) imports a medical device into Australia;

(ii) exports a medical device from Australia;

(iii) supplies a medical device in Australia;

(iv) manufactures a medical device in Australia; and

(b) none of the following subparagraphs apply in relation to the device:

(i) the device is of a kind included in the Register in relation to the person;

(ia) the device is of a kind covered by an exemption in force under section 41GS;

(ii) the device is an exempt device;

(iii) the device is the subject of an approval under section 41HB or an authority under section 41HC;

(iv) the device is the subject of an approval under subsection 41HD(1), (1A) or (2) that is held by the person.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Exception

(2) Subsection (1) does not apply if the defendant proves that the defendant was not the sponsor of the device at the time of the importation, exportation, supply, or manufacture, as the case may be.

41MJ Treating medical devices as prohibited imports or exports

If:

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(a) the importation or exportation of a medical device is an offence under subsection 41MI(1), (4) or (5) or a contravention of section 41MIB; and

(b) the Secretary notifies the Comptroller-General of Customs in writing that the Secretary wishes the *Customs Act 1901* to apply to that importation or exportation;

the *Customs Act 1901* has effect as if the device included in that importation or exportation were goods described as forfeited to the Crown under section 229 of that Act because they were:

(c) prohibited imports within the meaning of that Act; or

(d) prohibited exports within the meaning of that Act;

as the case requires.

41MK Wholesale supply of medical devices not included in the Register

A person commits an offence if:

(a) the person supplies a medical device in Australia; and

(b) none of the following subparagraphs applies in relation to the device:

(i) the device is of a kind included in the Register;

(ia) the device is of a kind covered by an exemption in force under section 41GS;

(ii) the device is an exempt device;

(iii) the device is the subject of an approval under section 41HB or an authority under section 41HC;

(iv) the device is the subject of an approval under subsection 41HD(1), (1A) or (2) that is held by the person; and

(c) the person to whom the device is supplied is not the ultimate consumer of the device.

Penalty: 120 penalty units.

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41ML False advertising about medical devices

(1) A person commits an offence if:

(a) the person, by any means, advertises a medical device as being for a purpose; and

(b) the device is of a kind included in the Register; and

(c) the purpose is not a purpose accepted in relation to that inclusion; and

(d) either:

(i) the use of the medical device for the advertised purpose has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the medical device for the advertised purpose, if the medical device were so used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(2) A person commits an offence if:

(a) the person, by any means, advertises a medical device as being for a purpose; and

(b) the device is of a kind included in the Register; and

(c) the purpose is not a purpose accepted in relation to that inclusion.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(3) A person commits an offence if:

(a) the person, by any means, advertises a medical device as being for a purpose; and

(b) the device is of a kind included in the Register; and

(c) the purpose is not a purpose accepted in relation to that inclusion.

Penalty: 100 penalty units.

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(4) An offence against subsection (3) is an offence of strict liability.

41MLA Civil penalty for making misrepresentations about medical devices

(1) A person contravenes this section if:
  (a) the person makes a representation of a kind referred to in subsection (2); and
  (b) the representation is false or misleading.

Maximum civil penalty:
  (a) for an individual—5,000 penalty units; and
  (b) for a body corporate—50,000 penalty units.

(2) Subsection (1) applies to the following representations:
  (a) representations that medical devices are of a kind included in the Register;
  (b) representations that medical devices are exempt devices;
  (c) representations that medical devices are the subject of an approval under section 41HB or an authority under section 41HC;
  (d) representations that medical devices are the subject of an approval under subsection 41HD(1), (1A) or (2).

41MLB Civil penalty for false advertising about medical devices

A person contravenes this section if:
  (a) the person, by any means, advertises a medical device as being for a purpose; and
  (b) the device is of a kind included in the Register; and
  (c) the purpose is not a purpose accepted in relation to that inclusion.

Maximum civil penalty:
  (a) for an individual—5,000 penalty units; and
  (b) for a body corporate—50,000 penalty units.

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41MN Criminal offences relating to breaches of conditions

Offences relating to breaching a condition of the inclusion of a kind of medical device in the Register

(1) A person commits an offence if:

(a) a kind of medical device is included in the Register in relation to the person; and

(b) the person does an act or omits to do an act; and

(c) the act or omission breaches a condition of the inclusion of the kind of device in the Register; and

(d) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) a kind of medical device is included in the Register in relation to the person; and

(b) the person does an act or omits to do an act; and

(c) the act or omission breaches a condition of the inclusion of the kind of device in the Register.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(4A) A person commits an offence if:

(a) a kind of medical device is included in the Register in relation to the person; and

(b) the person does an act or omits to do an act; and

(c) the act or omission breaches a condition of the inclusion of the kind of device in the Register.

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Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

Offences relating to breaching a condition of a conformity assessment certificate

(5) A person commits an offence if:
(a) a conformity assessment certificate is issued in respect of the person; and
(b) the person does an act or omits to do an act; and
(c) the act or omission breaches a condition of the conformity assessment certificate; and
(d) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to a person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (8) instead: see section 53A.

(8) A person commits an offence if:
(a) a conformity assessment certificate is issued in respect of the person; and
(b) the person does an act or omits to do an act; and
(c) the act or omission breaches a condition of the conformity assessment certificate.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(8A) A person commits an offence if:
(a) a conformity assessment certificate is issued in respect of the person; and
(b) the person does an act or omits to do an act; and
(c) the act or omission breaches a condition of the conformity assessment certificate.

Penalty: 100 penalty units.

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(8B) An offence against subsection (8A) is an offence of strict liability.

Offences relating to breaching a condition of an exemption, approval or authority, or a condition applicable under regulations

(9) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches:

(i) a condition of an exemption applicable under regulations made for the purposes of section 41HA; or

(ii) a condition of an approval under section 41HB; or

(iii) a condition applicable under regulations made for the purposes of subsection 41HB(7); or

(iiia) a condition of an authority under section 41HC; or

(iv) a condition of an approval under subsection 41HD(1), (1A) or (2); and

(c) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (9A) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(9A) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches:

(i) a condition of an exemption applicable under regulations made for the purposes of section 41HA; or

(ii) a condition of an approval under section 41HB; or

(iii) a condition applicable under regulations made for the purposes of subsection 41HB(7); or

(iiia) a condition of an authority under section 41HC; or

(iv) a condition of an approval under subsection 41HD(1), (1A) or (2).

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Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(9B) A person commits an offence of strict liability if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches:

(i) a condition of an exemption applicable under regulations made for the purposes of section 41HA; or

(ii) a condition of an approval under section 41HB; or

(iii) a condition applicable under regulations made for the purposes of subsection 41HB(7); or

(iiia) a condition of an authority under section 41HC; or

(iv) a condition of an approval under subsection 41HD(1), (1A) or (2).

Penalty: 100 penalty units.

Offences relating to breaching a condition of a conformity assessment body determination

(10) An Australian corporation commits an offence if:

(a) the corporation does an act or omits to do an act; and

(b) the act or omission breaches a condition referred to in subsection 41EWA(5); and

(c) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

Penalty: 20,000 penalty units.

(11) An Australian corporation commits an offence if:

(a) the corporation does an act or omits to do an act; and

(b) the act or omission breaches a condition referred to in subsection 41EWA(5).

Penalty: 5,000 penalty units.

(12) An Australian corporation commits an offence if:

(a) the corporation does an act or omits to do an act; and

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(b) the act or omission breaches a condition referred to in subsection 41EWA(5).

Penalty: 500 penalty units.

(13) An offence against subsection (12) is an offence of strict liability.

41MNA Civil penalties for breaching conditions

(1) A person contravenes this subsection if:
(a) a kind of medical device is included in the Register in relation to the person; and
(b) the person does an act or omits to do an act; and
(c) the act or omission breaches a condition of the inclusion of the kind of device in the Register.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

(2) A person contravenes this subsection if:
(a) a conformity assessment certificate is issued in respect of the person; and
(b) the person does an act or omits to do an act; and
(c) the act or omission breaches a condition of the conformity assessment certificate.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

(2A) A person contravenes this subsection if:
(a) the person does an act or omits to do an act; and
(b) the act or omission breaches:
(i) a condition of an exemption applicable under regulations made for the purposes of section 41HA; or
(ii) a condition of an approval under section 41HB; or

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(iii) a condition applicable under regulations made for the purposes of subsection 41HB(7); or

(iiia) a condition of an authority under section 41HC; or

(iv) a condition of an approval under subsection 41HD(1), (1A) or (2).

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

(3) An Australian corporation contravenes this subsection if:

(a) the corporation does an act or omits to do an act; and

(b) the act or omission breaches a condition referred to in subsection 41EWA(5).

Maximum civil penalty: 50,000 penalty units.

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Division 3A—Offences and civil penalties related to exemptions under Part 4-6A

41MNB Criminal offences for breaching a condition of an exemption

(1) A person commits an offence if:

(a) the person does an act or omits to do an act in relation to a medical device; and

(b) the device is of a kind covered by an exemption in force under section 41GS; and

(c) the act or omission results in the breach of a condition of the exemption; and

(d) the act or omission is likely to cause a serious risk to public health.

Penalty: Imprisonment for 5 years or 2,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) Strict liability applies to paragraph (1)(b).

Note: For strict liability, see section 6.1 of the *Criminal Code*.

(3) A person commits an offence if:

(a) the person does an act or omits to do an act in relation to a medical device; and

(b) the device is of a kind covered by an exemption in force under section 41GS; and

(c) the act or omission results in the breach of a condition of the exemption.

Penalty: Imprisonment for 4 years or 240 penalty units, or both.

(4) Strict liability applies to paragraph (3)(b).

Note: For strict liability, see section 6.1 of the *Criminal Code*.

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(5) A person commits an offence if:

(a) the person does an act or omits to do an act in relation to a medical device; and

(b) the device is of a kind covered by an exemption in force under section 41GS; and

(c) the act or omission results in the breach of a condition of the exemption.

Penalty: 60 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

41MNC Civil penalty for breaching a condition of an exemption

A person contravenes this section if:

(a) the person does an act or omits to do an act in relation to a medical device; and

(b) the device is of a kind covered by an exemption in force under section 41GS; and

(c) the act or omission results in the breach of a condition of the exemption.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

41MND Civil penalty for making misrepresentations about medical devices

A person contravenes this section if:

(a) the person makes a representation that medical devices are of a kind covered by an exemption in force under section 41GS; and

(b) the representation is false or misleading.

Maximum civil penalty:

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(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

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Division 4—Other offences and civil penalty provisions

41MO Criminal offences for misusing medical devices exempted for special or experimental uses

(1) A person commits an offence if:

(a) the person has been granted an authority under subsection 41HC(1) relating to a specified kind of medical device; and

(b) the person supplies a medical device of that kind:

(i) otherwise than in accordance with the authority; or

(ii) otherwise than in accordance with any conditions to which the authority is subject; or

(iii) otherwise than in accordance with any regulations made for the purpose of subsection 41HC(5); and

(c) either:

(i) the use of the device has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the device, if the device were used, would result in, or would be likely to result in, harm or injury to any person; and

(d) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because:

(i) the supply is not in accordance with the authority; or

(ii) the supply is not in accordance with the conditions to which the authority is subject; or

(iii) the supply is not in accordance with regulations made for the purpose of subsection 41HC(5).

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (4) instead: see section 53A.

(4) A person commits an offence if:

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(a) the person has been granted an authority under subsection 41HC(1) relating to a specified kind of medical device; and

(b) the person supplies a medical device of that kind:

(i) otherwise than in accordance with the authority; or

(ii) otherwise than in accordance with any conditions to which the authority is subject; or

(iii) otherwise than in accordance with any regulations made for the purpose of subsection 41HC(5).

Penalty: 500 penalty units.

(4AA) A person commits an offence if:

(a) the person has been granted an authority under subsection 41HC(1) relating to a specified kind of medical device; and

(b) the person supplies a medical device of that kind:

(i) otherwise than in accordance with the authority; or

(ii) otherwise than in accordance with any conditions to which the authority is subject; or

(iii) otherwise than in accordance with any regulations made for the purpose of subsection 41HC(5).

Penalty: 100 penalty units.

(4AB) An offence against subsection (4AA) is an offence of strict liability.

(4A) A person commits an offence if:

(a) the person is a health practitioner; and

(b) the person is included in a class of health practitioners specified in subsection 41HC(6) rules; and

(c) the person supplies a medical device of a kind specified in those rules; and

(d) any of the following applies:

(i) the supply is not in accordance with those rules;

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(ii) the supply is not in the circumstances specified in those rules;

(iii) the supply is not in accordance with the conditions specified in those rules; and

(e) either:

(i) the use of the device has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the device, if the device were used, would result in, or would be likely to result in, harm or injury to any person; and

(f) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because:

(i) the supply is not in accordance with those rules; or

(ii) the supply is not in the circumstances specified in those rules; or

(iii) the supply is not in accordance with the conditions specified in those rules.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(4C) A person commits an offence if:

(a) the person is a health practitioner; and

(b) the person is included in a class of health practitioners specified in subsection 41HC(6) rules; and

(c) the person supplies a medical device of a kind specified in those rules; and

(d) any of the following applies:

(i) the supply is not in accordance with those rules;

(ii) the supply is not in the circumstances specified in those rules;

(iii) the supply is not in accordance with the conditions specified in those rules.

Penalty: 500 penalty units.

(4D) A person commits an offence if:

(a) the person is a health practitioner; and

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(b) the person is included in a class of health practitioners specified in subsection 41HC(6) rules; and

(c) the person supplies a medical device of a kind specified in those rules; and

(d) any of the following applies:

(i) the supply is not in accordance with those rules;

(ii) the supply is not in the circumstances specified in those rules;

(iii) the supply is not in accordance with the conditions specified in those rules.

Penalty: 100 penalty units.

(4E) An offence against subsection (4D) is an offence of strict liability.

(5) A person commits an offence if:

(a) the person has been granted an approval under section 41HB relating to a specified medical device or specified kind of medical device; and

(b) the person uses a medical device of that kind:

(i) in the treatment of another person; or

(ii) solely for experimental purposes in humans;

otherwise than in accordance with the approval; and

(c) either:

(i) the use of the device has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the device, if the device were used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (8) instead: see section 53A.

(8) A person commits an offence if:

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(a) the person has been granted an approval under section 41HB relating to a specified medical device or specified kind of medical device; and

(b) the person uses a medical device of that kind:

(i) in the treatment of another person; or

(ii) solely for experimental purposes in humans;

otherwise than in accordance with the approval.

Penalty: 500 penalty units.

(9) A person commits an offence if:

(a) the person has been granted an approval under section 41HB relating to a specified medical device or specified kind of medical device; and

(b) the person uses a medical device of that kind:

(i) in the treatment of another person; or

(ii) solely for experimental purposes in humans;

otherwise than in accordance with the approval.

Penalty: 100 penalty units.

(10) An offence against subsection (9) is an offence of strict liability.

41MP Criminal offence for failing to notify adverse events etc.

(1) A person commits an offence if:

(a) the person is a person in relation to whom a kind of medical device is included in the Register; and

(b) the person knows that particular information is information of a kind mentioned in subsection (2); and

(c) the person fails to give that information to the Secretary within the period specified in the regulations (whether or not the person has already given to the Secretary other information relating to the same matter).

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

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Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) The information with which subsection (1) is concerned is information of the following kinds:

(a) information relating to:

(i) any malfunction or deterioration in the characteristics or performance of the kind of device; or

(ii) any inadequacy in the design, production, labelling, instructions for use or advertising materials of the kind of device; or

(iii) any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health;

(b) information relating to any technical or medical reason for a malfunction or deterioration of a kind referred to in subparagraph (a)(i) that has led the manufacturer to take steps to recall devices of that kind that have been distributed;

(c) information that indicates that a device of that kind does not comply with the essential principles;

(d) information that indicates that a certificate or other document (other than a certificate or other document issued by the Secretary under this Act) used for the purpose of an application under subsection 41FC(1) to signify:

(i) compliance with the essential principles; or

(ii) the application of relevant conformity assessment procedures to a device of that kind or the application of requirements, comparable to those procedures, to a device of that kind;

has been restricted, suspended, revoked or is no longer in effect.

41MPA Civil penalty for failing to notify adverse events etc.

(1) A person contravenes this section if:

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(a) a kind of medical device is included in the Register in relation to the person; and
(b) the information is of a kind mentioned in subsection (2); and
(c) the person does not give information of a kind mentioned in subsection (2) to the Secretary within the period specified in the regulations (whether or not the person has already given to the Secretary other information relating to the same matter).

Maximum civil penalty:
(a) for an individual—3,000 penalty units; and
(b) for a body corporate—30,000 penalty units.

(2) The information with which subsection (1) is concerned is information of the following kinds:
(a) information relating to:
(i) any malfunction or deterioration in the characteristics or performance of the kind of device; or
(ii) any inadequacy in the design, production, labelling, instructions for use or advertising materials of the kind of device; or
(iii) any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;
that might lead, or might have led, to the death of a patient or user of the device, or to a serious deterioration in his or her state of health;
(b) information relating to any technical or medical reason for a malfunction or deterioration of a kind referred to in subparagraph (a)(i) that has led the manufacturer to take steps to recall devices of that kind that have been distributed;
(c) information that indicates that a device of that kind does not comply with the essential principles;
(d) information that indicates that a certificate or other document (other than a certificate or other document issued by the Secretary under this Act) used for the purpose of an application under subsection 41FC(1) to signify:
(i) compliance with the essential principles; or

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(ii) the application of relevant conformity assessment procedures to a device of that kind or the application of requirements, comparable to those procedures, to a device of that kind;

has been restricted, suspended, revoked or is no longer in effect.

41MPB Relief from liability for contraventions for failing to notify adverse events etc.

(1) If:

(a) proceedings for the contravention of section 41MPA (a civil penalty provision) are brought against a person; and

(b) in the proceedings it appears to the Court that the person has, or may have, contravened that section but that:

(i) the person has a reasonable excuse; and

(ii) having regard to all the circumstances of the case, the person ought fairly to be excused for the contravention;

the Court may relieve the person either wholly or partly from a liability to which the person would otherwise be subject, or that might otherwise be imposed on the person, because of the contravention.

(2) If a person thinks that proceedings for the contravention of section 41MPA will or may be begun against them, they may apply to the Court for relief.

(3) On an application under subsection (2), the Court may grant relief under subsection (1) as if proceedings had been begun in the Court.

(4) For the purposes of subsection (2) as applying for the purposes of a case tried by a judge with a jury:

(a) a reference in that subsection to the Court is a reference to the judge; and

(b) the relief that may be granted includes withdrawing the case in whole or in part from the jury and directing judgment to be entered for the person on such terms as to costs as the judge thinks appropriate.

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41MQ Notification of adverse events etc. where application withdrawn or lapses

(1) If an application for inclusion of a kind of medical device in the Register is withdrawn or lapses, the Secretary may give the applicant written notice requiring the applicant:

(a) to inform the Secretary in writing whether the applicant is aware of any information of a kind mentioned in subsection 41MP(2) or 41MPA(2) relating to the kind of device; and

(b) if the applicant is aware of such information, to give the information to the Secretary in writing.

(2) Notice under subsection (1) may only be given within 10 working days after an application is withdrawn or lapses.

(3) A person commits an offence if the person fails to comply with the requirements of a notice under subsection (1) within 20 working days after the notice is given to the person.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(4) A person commits an offence if:

(a) the person gives information in purported compliance with a notice under this section; and

(b) the information is false or misleading in a material particular.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

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41MR Civil penalties for failing to notify adverse effects etc. where application withdrawn or lapses

Civil penalty for failing to comply with requirements of a notice

(1) A person contravenes this subsection if the person does not comply with the requirements of a notice under subsection 41MQ(1) within 20 working days after the day on which the notice is given to the person.

Maximum civil penalty:

(a) for an individual—3,000 penalty units; and

(b) for a body corporate—30,000 penalty units.

Civil penalty for giving false or misleading information in purported compliance with requirements of a notice

(2) A person contravenes this subsection if:

(a) the person gives information in purported compliance with a notice under subsection 41MQ(1); and

(b) the information is false or misleading in a material particular.

Maximum civil penalty:

(a) for an individual—3,000 penalty units; and

(b) for a body corporate—30,000 penalty units.

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Chapter 4A—Vaping goods

Part 4A-1—Introduction

Division 1—Introduction

41N Simplified outline of this Chapter

The importation into Australia of vaping goods, and the manufacture, supply or possession of vaping goods in Australia, is prohibited, subject to some exceptions. A person may commit an offence or be liable to a civil penalty for contravening the prohibitions (see Part 4A-2).

Definitions of ***vaping goods*** and related terms are set out in Division 2 of this Part. Vaping goods includes vaping substances, vaping accessories, vaping devices and goods determined by the Minister to be vaping goods.

The Minister may, by legislative instrument, determine that specified vaping goods, or a specified class of vaping goods, may be supplied or possessed in Australia:

(a) by a specified person, or a specified class of persons; and

(b) in the circumstances (if any) specified in the determination; and

(c) subject to the conditions (if any) specified in the determination (see Part 4A-3).

The Secretary may, on application by a person, give the person consent to manufacture, supply or possess vaping goods. The consent may be given unconditionally or subject to conditions, and in respect of particular vaping goods or classes of vaping goods. In deciding whether to give a consent, the Secretary must comply with the decision-making principles (if any) determined by the

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Minister by legislative instrument. A person may commit an offence or be liable to a civil penalty if conditions of a consent are breached (see Part 4A-3).

41NA Relationship with other Chapters of this Act

An offence provision or civil penalty provision in this Chapter does not limit the generality of an offence provision or civil penalty provision in any other Chapter, and those provisions in other Chapters do not limit the generality of offence provisions or civil penalty provisions in this Chapter.

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Division 2—Interpretation

41P Meaning of *vaping goods* and related terms

(1) In this Act:

vaping accessory means a cartridge, capsule, pod or other vessel:

(a) that is for use in, or with, a vaping device; and

(b) whether or not the cartridge, capsule, pod or other vessel:

(i) contains a vaping substance; or

(ii) is designed or intended to be refilled.

vaping device means:

(a) a device (whether or not filled with a vaping substance) that generates or releases, or is designed or intended to generate or release, using a heating element and by electronic means, an aerosol, vapour or mist for direct inhalation by its user; or

(b) a device to which paragraph (a) would apply if the device were not temporarily or permanently inoperable, incomplete, damaged or unfinished.

Note: Examples of devices that are not vaping devices include the following:

(a) humidifiers;

(b) diffusers;

(c) nebulisers;

(d) inhalers.

vaping goods means any of the following goods:

(a) a vaping substance;

(b) a vaping accessory;

(c) a vaping device;

(d) goods the presentation of which includes an express or implied representation that the goods are of a kind referred to in paragraph (a), (b) or (c);

(e) goods that are, or are included in a class of goods that are, determined to be vaping goods under subsection (3).

Note: This definition is affected by subsection (2).

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vaping substance:

(a) means:

(i) nicotine in solution in any concentration (including in a salt or base form); or

(ii) any liquid or other substance for use in, or with, a vaping device; and

(b) includes a container (other than a vaping accessory or vaping device), or part of such a container, in which a liquid or other substance referred to in subparagraph (a)(i) or (ii) is present.

(2) For the purposes of paragraph (d) of the definition of ***vaping goods*** in subsection (1):

(a) the presentation of goods includes matters in relation to:

(i) the name of the goods; and

(ii) the labelling and packaging of the goods; and

(iii) any advertising or informational material associated with the use or supply of the goods; and

(b) goods are taken to be presented as being a particular kind of goods even if the presentation:

(i) is capable of being misleading or confusing as to the content or proper use or identification of the goods; or

(ii) suggests that the goods have ingredients, components or characteristics that they do not have.

Minister may determine that goods are or are not vaping goods etc.

(3) The Minister may, by legislative instrument, determine that, for the purposes of this Act, specified goods or specified classes of goods:

(a) are or are not vaping goods; or

(b) when used, advertised, or presented for use or supply in a particular way, are or are not vaping goods.

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Part 4A-2—Offences and civil penalty provisions relating to vaping goods

Division 1—General

41Q Offences and civil penalty provision—importing vaping goods into Australia

Offences

(1) A person commits an offence if the person imports vaping goods into Australia.

Penalty: Imprisonment for 7 years or 5,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) A person commits an offence of strict liability if the person imports vaping goods into Australia.

Penalty: 200 penalty units.

Civil penalty provision

(3) A person contravenes this subsection if the person imports vaping goods into Australia.

Maximum civil penalty:

(a) for an individual—7,000 penalty units; and

(b) for a body corporate—70,000 penalty units.

(4) A person who contravenes subsection (3) commits a separate contravention of that subsection in respect of each unit of vaping goods imported by the person into Australia.

Note: For ***unit*** of vaping goods, see subsection 3(1).

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Exception

(5) Subsections (1) to (4) do not apply if the importation of the vaping goods is not prohibited under the *Customs Act 1901*.

Note: The person bears an evidential burden in relation to the matter in subsection (5): see subsection 13.3(3) of the *Criminal Code* and section 41QE of this Act.

41QA Offences and civil penalty provision—manufacturing vaping goods in Australia

Offences

(1) A person commits an offence if the person manufactures, or carries out a step in the manufacture of, vaping goods in Australia.

Penalty: Imprisonment for 7 years or 5,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) A person commits an offence of strict liability if the person manufactures, or carries out a step in the manufacture of, vaping goods in Australia.

Penalty: 200 penalty units.

Civil penalty provision

(3) A person contravenes this subsection if the person manufactures, or carries out a step in the manufacture of, vaping goods in Australia.

Maximum civil penalty:

(a) for an individual—7,000 penalty units; and
(b) for a body corporate—70,000 penalty units.

(4) A person who contravenes subsection (3) commits a separate contravention of that subsection in respect of the manufacture, or the carrying out of the step in the manufacture, by the person of each unit of vaping goods.

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Note: For ***unit*** of vaping goods, see subsection 3(1).

Exceptions

(5) Subsections (1) to (4) do not apply if:

(a) the vaping goods are therapeutic goods; and

(b) one of the following subparagraphs applies:

(i) the person is the holder of a licence in force under Part 3-3 that authorises the manufacture of the vaping goods, or the carrying out of the step in the manufacture of the vaping goods, at the manufacturing site where the manufacture, or the step, is carried out;

(ii) the person is the holder of a conformity assessment document that applies to the vaping goods;

(iii) the Secretary has given the person a consent under subsection 41RC(1) to manufacture the vaping goods, or carry out the step in the manufacture of the vaping goods, and the manufacture, or the step, is carried out in accordance with the consent.

Note: The person bears an evidential burden in relation to the matter in subsection (5): see subsection 13.3(3) of the *Criminal Code* and section 41QE of this Act.

41QB Offences and civil penalty provision—supplying vaping goods

Offences

(1) A person commits an offence if the person supplies vaping goods in Australia.

Penalty: Imprisonment for 7 years or 5,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) A person commits an offence of strict liability if the person supplies vaping goods in Australia.

Penalty: 200 penalty units.

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Civil penalty provision

(3) A person contravenes this subsection if the person supplies vaping goods in Australia.

Maximum civil penalty:

(a) for an individual—7,000 penalty units; and

(b) for a body corporate—70,000 penalty units.

(4) A person who contravenes subsection (3) commits a separate contravention of that subsection in respect of each unit of vaping goods supplied by the person in Australia.

Note: For ***unit*** of vaping goods, see subsection 3(1).

Exceptions—general

(5) Subsections (1) to (4) do not apply if:

(a) subsections (6), (7) and (8) apply in relation to the supply of the vaping goods by the person; or

(b) subsections (9), (10) and (11) apply in relation to the supply of the vaping goods by the person.

Note: The person bears an evidential burden in relation to the matters in subsections (6), (7) and (8) or subsections (9), (10) and (11): see subsection 13.3(3) of the *Criminal Code* and section 41QE of this Act.

Exceptions—wholesale supply chain

(6) This subsection applies in relation to the supply of the vaping goods by the person if:

(a) the vaping goods are therapeutic goods that are entered on the Register; or

(b) both of the following apply:

(i) the vaping goods are therapeutic goods that are exempt goods under regulations made for the purposes of subsection 18(1) or an exempt device under regulations made for the purposes of subsection 41HA(1), and the sponsor has given the Secretary a notice in compliance with the exemption;

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(ii) the vaping goods are not the subject of a determination by the Secretary under the regulations, published on the Department's website, that the supply of the goods be stopped or should cease; or

(c) the vaping goods are covered by a determination made by the Minister under section 41R.

(7) This subsection applies in relation to the supply of the vaping goods by the person if:

(a) the person:

(i) is the holder of a licence and a permission, granted under regulations made for the purposes of section 50 of the *Customs Act 1901*, to import the vaping goods; or

(ii) is otherwise approved under those regulations to import the vaping goods; or

(b) the person is the holder of a licence in force under Part 3-3 that authorises a step in the manufacture of the vaping goods; or

(c) the person is the holder of a conformity assessment document that applies to the vaping goods; or

(d) both of the following apply:

(i) the person is a wholesaler who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 3 to the current Poisons Standard under a law of the State or Territory in which the supply occurs;

(ii) the supply occurs in accordance with the licence or authority; or

(e) both of the following apply:

(i) the Secretary has given the person a consent under subsection 41RC(1) to supply the vaping goods;

(ii) the supply occurs in accordance with the consent; or

(f) in the case of vaping goods that are covered by a determination made by the Minister under section 41R:

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(i) the person is specified in the determination, or is included in a class of persons specified in the determination, in relation to those goods; and

(ii) the supply occurs in accordance with the determination.

(8) This subsection applies in relation to the supply of the vaping goods by the person if:

(a) the person (the ***recipient***) to whom the vaping goods are supplied is the holder of a licence in force under Part 3-3 of this Act that authorises a step in the manufacture of vaping goods; or

(b) the recipient is a wholesaler, pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 3 to the current Poisons Standard under a law of the State or Territory in which the recipient carries on a business, practises or is employed; or

(c) the Secretary has given the recipient a consent under subsection 41RC(1) to supply the vaping goods; or

(d) in the case of vaping goods that are covered by a determination made by the Minister under section 41R—the recipient is specified in the determination, or is included in a class of persons specified in the determination, in relation to those goods.

Exceptions—retail supply chain

(9) This subsection applies in relation to the supply of the vaping goods by the person if:

(a) the vaping goods are therapeutic goods that are entered on the Register; or

(b) both of the following apply:

(i) the vaping goods are therapeutic goods that are exempt goods under regulations made for the purposes of subsection 18(1) or an exempt device under regulations made for the purposes of subsection 41HA(1), and the

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sponsor has given the Secretary a notice in compliance with the exemption;

(ii) the vaping goods are not the subject of a determination by the Secretary under the regulations, published on the Department's website, that the supply of the goods be stopped or should cease; or

(c) the vaping goods are covered by a determination made by the Minister under section 41R.

(10) This subsection applies in relation to the supply of the vaping goods by the person if:

(a) the person is a pharmacist; or

(b) the person is a medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 3 to the current Poisons Standard under a law of the State or Territory in which the supply occurs.

(11) This subsection applies in relation to the supply of the vaping goods by the person if:

(a) the supply is:

(i) to another person for use by that person for smoking cessation, management of nicotine dependence or another indication determined by the Minister under section 41RA; or

(ii) to another person, who is the carer of a third person, for use by the third person for smoking cessation, management of nicotine dependence or another indication determined by the Minister under section 41RA; and

(b) if the vaping goods are, or contain, a vaping substance—the vaping substance is in final dosage form; and

(c) the supply is:

(i) in accordance with this Act (apart from this section); and

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(ii) consistent with the person's authority to supply the vaping goods under a law of the State or Territory in which the supply occurs.

*Meaning of **final dosage form***

(12) For the purposes of paragraph (11)(b), a vaping substance is in ***final dosage form*** if the vaping substance is in a form that can be administered to a person without any change or modification (other than vaporisation).

41QC Offences and civil penalty provision—possessing at least commercial quantity of vaping goods

Offences—possessing at least commercial quantity but less than 100 times commercial quantity

(1) A person commits an offence if:

(a) the person possesses a quantity of a kind of vaping goods in Australia; and

(b) the quantity is at least the commercial quantity, but less than 100 times the commercial quantity, of that kind of vaping goods.

Penalty: Imprisonment for 2 years or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) Absolute liability applies to paragraph (1)(b).

(3) A person commits an offence of strict liability if:

(a) the person possesses a quantity of a kind of vaping goods in Australia; and

(b) the quantity is at least the commercial quantity, but less than 100 times the commercial quantity, of that kind of vaping goods.

Penalty: 120 penalty units.

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Offences—possessing at least 100 times commercial quantity but less than 1,000 times commercial quantity

(4) A person commits an offence if:

(a) the person possesses a quantity of a kind of vaping goods in Australia; and

(b) the quantity is at least 100 times the commercial quantity, but less than 1,000 times the commercial quantity, of that kind of vaping goods.

Penalty: Imprisonment for 4 years or 3,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(5) Absolute liability applies to paragraph (4)(b).

(6) A person commits an offence of strict liability if:

(a) the person possesses a quantity of a kind of vaping goods in Australia; and

(b) the quantity is at least 100 times the commercial quantity, but less than 1,000 times the commercial quantity, of that kind of vaping goods.

Penalty: 240 penalty units.

Offences—possessing 1,000 times commercial quantity or more

(7) A person commits an offence if:

(a) the person possesses a quantity of a kind of vaping goods in Australia; and

(b) the quantity is 1,000 times the commercial quantity, or more, of that kind of vaping goods.

Penalty: Imprisonment for 7 years or 5,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(8) Absolute liability applies to paragraph (7)(b).

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(9) A person commits an offence of strict liability if:
(a) the person possesses a quantity of a kind of vaping goods in Australia; and
(b) the quantity is 1,000 times the commercial quantity, or more, of that kind of vaping goods.

Penalty: 420 penalty units.

Civil penalty provision

(10) A person contravenes this subsection if:
(a) the person possesses a quantity of a kind of vaping goods in Australia; and
(b) the quantity is at least the commercial quantity of that kind of vaping goods.

Maximum civil penalty:
(a) for an individual—7,000 penalty units; and
(b) for a body corporate—70,000 penalty units.

(11) A person who contravenes subsection (10) in relation to a kind of vaping goods commits a separate contravention of that subsection in respect of each unit of the quantity of vaping goods of that kind possessed by the person in Australia.

Note: For ***unit*** of vaping goods, see subsection 3(1).

Exception—possession for personal use

(11A) Subsections (1) to (3) and (10) and (11) do not apply in relation to the possession of a quantity of a kind of vaping goods by the person if:
(a) the vaping goods have been lawfully supplied to the person; and
(b) the vaping goods are for use by the person personally; and
(c) the quantity is less than 5 times the commercial quantity of that kind of vaping goods.

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Note: The person bears an evidential burden in relation to the matters in subsection (11A): see subsection 13.3(3) of the *Criminal Code* and section 41QE of this Act.

Exceptions—general

(12) Subsections (1) to (11) do not apply if subsections (13) and (14) apply in relation to the possession of the vaping goods by the person.

Note: The person bears an evidential burden in relation to the matters in subsections (13) and (14): see subsection 13.3(3) of the *Criminal Code* and section 41QE of this Act.

(13) This subsection applies in relation to the possession of the vaping goods by the person if:

(a) the vaping goods are therapeutic goods that are entered on the Register; or

(b) both of the following apply:

(i) the vaping goods are therapeutic goods that are exempt goods under regulations made for the purposes of subsection 18(1) or an exempt device under regulations made for the purposes of subsection 41HA(1), and the sponsor has given the Secretary a notice in compliance with the exemption;

(ii) the vaping goods are not the subject of a determination by the Secretary under the regulations, published on the Department's website, that the supply of the goods be stopped or should cease; or

(c) the vaping goods are covered by a determination made by the Minister under section 41R.

(14) This subsection applies in relation to the possession of the vaping goods by the person if:

(a) the person:

(i) is the holder of a licence and a permission, granted under regulations made for the purposes of section 50 of the *Customs Act 1901*, to import the vaping goods; or

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(ii) is otherwise approved under those regulations to import the vaping goods; or

(b) the person is the holder of a licence in force under Part 3-3 of this Act that authorises a step in the manufacture of the vaping goods; or

(c) the person is the holder of a conformity assessment document that applies to the vaping goods; or

(d) both of the following apply:

(i) the person is a wholesaler, pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 3 to the current Poisons Standard under a law of the State or Territory in which the person possesses the goods;

(ii) the possession of the goods is in accordance with the licence or authority; or

(e) both of the following apply:

(i) the Secretary has given the person a consent under subsection 41RC(1) to possess the vaping goods;

(ii) the possession is in accordance with the consent; or

(f) in the case of vaping goods that are covered by a determination made by the Minister under section 41R:

(i) the person is specified in the determination, or is included in a class of persons that is specified in the determination, in relation to those goods; and

(ii) the possession is in accordance with the determination.

41QD Offences and civil penalty provision—possessing less than commercial quantity of vaping goods

Offences

(1) A person commits an offence if:

(a) the person is a retailer in relation to retail premises in Australia; and

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(b) the person possesses a quantity of a kind of vaping goods at the retail premises; and
(c) the quantity is less than the commercial quantity of that kind of vaping goods.

Penalty: Imprisonment for 12 months or 500 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) Absolute liability applies to paragraph (1)(b).

(3) A person commits an offence of strict liability if:
(a) the person is a retailer in relation to retail premises in Australia; and
(b) the person possesses a quantity of a kind of vaping goods at the retail premises; and
(c) the quantity is less than the commercial quantity of that kind of vaping goods.

Penalty: 60 penalty units.

Civil penalty provision

(4) A person contravenes this subsection if:
(a) the person is a retailer in relation to retail premises in Australia; and
(b) the person possesses a quantity of a kind of vaping goods at the retail premises; and
(c) the quantity is less than the commercial quantity of that kind of vaping goods.

Maximum civil penalty:
(a) for an individual—1,000 penalty units; and
(b) for a body corporate—10,000 penalty units.

(5) A person who contravenes subsection (4) in relation to a kind of vaping goods commits a separate contravention of that subsection

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in respect of each unit of the quantity of vaping goods of that kind possessed by the person at the retail premises in Australia.

Note: For ***unit*** of vaping goods, see subsection 3(1).

Exceptions—general

(6) Subsections (1) to (5) do not apply if subsections (7) and (8) apply in relation to the possession of the vaping goods by the person.

Note: The person bears an evidential burden in relation to the matters in subsections (7) and (8): see subsection 13.3(3) of the *Criminal Code* and section 41QE of this Act.

(7) This subsection applies in relation to the possession of the vaping goods by the person if:

(a) the vaping goods are therapeutic goods that are entered on the Register; or

(b) both of the following apply:

(i) the vaping goods are therapeutic goods that are exempt goods under regulations made for the purposes of subsection 18(1) or an exempt device under regulations made for the purposes of subsection 41HA(1), and the sponsor has given the Secretary a notice in compliance with the exemption;

(ii) the vaping goods are not the subject of a determination by the Secretary under the regulations, published on the Department's website, that the supply of the goods be stopped or should cease; or

(c) the vaping goods are covered by a determination made by the Minister under section 41R.

(8) This subsection applies in relation to the possession of the vaping goods by the person if:

(a) both of the following apply:

(i) the person is a pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 3 to the current Poisons Standard

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under a law of the State or Territory in which the person possesses the goods;

(ii) the possession of the goods is in accordance with the licence or authority; or

(b) both of the following apply:

(i) the Secretary has given the person a consent under subsection 41RC(1) to possess the vaping goods;

(ii) the possession is in accordance with the consent; or

(c) in the case of vaping goods that are covered by a determination made by the Minister under section 41R:

(i) the person is specified in the determination, or is included in a class of persons that is specified in the determination, in relation to those goods; and

(ii) the possession is in accordance with the determination.

Exception—possession for personal use

(9) Subsections (1) to (5) do not apply in relation to the possession of a quantity of a kind of vaping goods by the person if:

(a) the vaping goods are for use by the person personally; and

(b) the quantity is not more than the permitted quantity of that kind of vaping goods.

Note: The person bears an evidential burden in relation to the matters in subsection (9): see subsection 13.3(3) of the *Criminal Code* and section 41QE of this Act.

Definitions

(10) In this section:

permitted quantity of a kind of vaping goods means the quantity of that kind of vaping goods prescribed by the regulations.

retailer in relation to retail premises in Australia means any of the following:

(a) an owner, lessee or occupier of retail premises in Australia;

(b) a person conducting a business or undertaking at, or in connection or association with, retail premises in Australia;

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(c) a director, officer or agent of a person referred to in paragraph (a) or (b);

(d) a person performing work in any capacity (including, but not limited to, an employee or a contractor) for, or on behalf of, a person referred to in paragraph (a), (b) or (c) at, or in connection or association with, retail premises in Australia.

retail premises means premises:

(a) from which goods or services are available for supply, or are supplied, to a consumer; or

(b) that are used in connection with the supply of goods or services to a consumer;

(whether or not the premises are used wholly or predominantly for that purpose).

Note: For ***premises***, see subsection 3(1).

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Division 2—Miscellaneous

41QE Exceptions etc. to civil penalty provisions—burden of proof

If, in proceedings for a pecuniary penalty order against a person for a contravention of a civil penalty provision in this Chapter, the person wishes to rely on any exception, exemption, excuse, qualification or justification that applies in relation to the civil penalty provision, then the person bears an evidential burden in relation to that matter.

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Part 4A-3—Other provisions

Division 1—Determinations by Minister

41R Minister may determine that specified vaping goods may be supplied or possessed in Australia in specified circumstances etc.

The Minister may, by legislative instrument, determine that specified vaping goods, or a specified class of vaping goods, may be supplied or possessed in Australia:

(a) by a specified person, or a specified class of persons; and

(b) in the circumstances (if any) specified in the determination; and

(c) subject to the conditions (if any) specified in the determination.

Note: Conditions may, for example, relate to the value or amount of specified vaping goods or the manner in which specified vaping goods may be supplied.

41RA Minister may determine other indications for which vaping goods may be used

The Minister may, by legislative instrument, determine, for the purposes of paragraph 41QB(11)(a), indications (other than smoking cessation or management of nicotine dependence) for which vaping goods may be used.

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Division 2—Consent of Secretary

41RB Application to Secretary for consent to manufacture, supply or possess vaping goods

(1) A person may apply to the Secretary for consent to manufacture, supply or possess vaping goods.

(2) An application under subsection (1) must be in accordance with a form approved by the Secretary and be accompanied by the fee (if any) prescribed by the regulations.

Further information

(3) The Secretary may, by notice in writing given to the applicant, require the applicant to give to the Secretary, within such reasonable time as is specified in the notice, such further information concerning the application as is specified in the notice.

Applications or information may be given electronically

(4) An approval of a form referred to in subsection (2), or a notice referred to in subsection (3), may require or permit an application or information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

41RC Secretary may give consent

(1) If:

(a) a person (the ***applicant***) has applied to the Secretary under section 41RB for consent to manufacture, supply or possess vaping goods; and

(aa) the application is accompanied by the fee (if any) prescribed by the regulations for the purposes of subsection 41RB(2); and

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(b) the applicant has complied with any requirements made by the Secretary under subsection 41RB(3) in relation to the application;

the Secretary must decide whether to give, or refuse to give, the consent.

(2) The Secretary may give a consent under subsection (1):

(a) unconditionally or subject to conditions; or

(b) in respect of particular vaping goods or classes of vaping goods.

Note: A person may commit an offence or be liable to a civil penalty if the person does an act or omits to do an act and the act or omission breaches a condition of a consent given under subsection (1): see section 41RD.

(2A) In making a decision under subsection (1), the Secretary must comply with the decision-making principles (if any) determined under subsection (2B).

(2B) The Minister may, by legislative instrument, determine principles (***decision-making principles***) that the Secretary must comply with in making a decision under subsection (1).

(2C) Without limiting subsection (2B), the decision-making principles may set out any of the following:

(a) circumstances in which a consent under subsection (1) must not be given;

(b) matters that must be taken into account in making a decision under subsection (1);

(c) matters that must not be taken into account in making a decision under subsection (1);

(d) matters that may be taken into account in making a decision under subsection (1).

(3) The Secretary must, as soon as practicable after making a decision to give a consent under subsection (1), cause particulars of the decision to be published on the Department's website.

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(4) If the Secretary decides to refuse to give a consent under subsection (1), the Secretary must, within 28 days after making the decision, notify the applicant in writing of the decision and the reasons for the decision.

41RD Offences and civil penalty provision—breaching condition of a consent

Offences

(1) A person commits an offence if:
  (a) the person does an act or omits to do an act; and
  (b) the act or omission breaches a condition of a consent imposed under subsection 41RC(2); and
  (c) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

Penalty: 2,000 penalty units.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) A person commits an offence if:
  (a) the person does an act or omits to do an act; and
  (b) the act or omission breaches a condition of a consent imposed under subsection 41RC(2).

Penalty: 500 penalty units.

(3) A person commits an offence of strict liability if:
  (a) the person does an act or omits to do an act; and
  (b) the act or omission breaches a condition of a consent imposed under subsection 41RC(2).

Penalty: 100 penalty units.

Civil penalty provision

(4) A person contravenes this subsection if:

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(a) the person does an act or omits to do an act; and
(b) the act or omission breaches a condition of a consent imposed under subsection 41RC(2).

Maximum civil penalty:
(a) for an individual—3,000 penalty units; and
(b) for a body corporate—30,000 penalty units.

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Chapter 5—Advertising, counterfeit therapeutic goods and product tampering

Part 5-1—Advertising and generic information

Division 1—Preliminary

42AA This Part not to apply to advertisements directed at health professionals etc.

(1) This Part does not apply to advertisements directed exclusively to:

(a) health practitioners; or

(aa) persons who, under a law of a State or internal Territory, are registered or licensed to practice in any of the following health professions:

(i) chiropractic;

(ii) dental therapy, dental hygiene, dental prosthetics or oral health therapy;

(iii) osteopathy;

(iv) paramedicine; or

(b) persons who are:

(i) engaged in the business of wholesaling therapeutic goods; or

(ii) purchasing officers in hospitals; or

(iii) purchasing therapeutic goods on behalf of a registered charity; or

(iv) purchasing therapeutic goods on behalf of a government or government authority (including a foreign government or foreign government authority); or

(v) purchasing officers, or practice managers, for a person mentioned in paragraph (a) or (aa) (other than a person in a retail pharmacy who, under a law of a State or

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internal Territory, is registered or licensed to practice in the health profession of pharmacy); or

(c) herbalists, homoeopathic practitioners, naturopaths, nutritionists or practitioners of traditional Chinese medicine registered under a law of a State or Territory; or

(d) a class of persons specified under subsection (1A).

(1A) The Minister may, by legislative instrument, specify a class of persons for the purposes of paragraph (1)(d).

(2) This Part does not apply to advertisements directed exclusively to persons who are members of an Australian branch (however described) of one of the bodies prescribed for the purposes of this subsection.

(3) For the purposes of subsection (2), a person is taken to be a member of an Australian branch of one of those bodies if, and only if, the person has the qualifications and training that are necessary or appropriate for membership of the relevant body.

(4) This Part does not apply to advice or information given directly to a patient by a person referred to in paragraph (1)(a), (aa) or (c) or subsection (2) in the course of treatment of that patient.

42AB This Part not to apply to advertisements for goods not for human use

This Part does not apply to advertisements in respect of goods that are not for use in humans.

42AC This Part not to apply to advertisements for exported goods

(1) Subject to subsection (2), this Part does not apply to advertisements solely for therapeutic goods that have been exported or are intended exclusively for export.

(2) Sections 42DKB, 42DLA and 42DLC and Divisions 5 and 6 apply in relation to advertisements of that kind.

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42AD This Part not to apply to advertisements or generic information about vaping goods

(1) This Part does not apply in relation to advertisements about vaping goods.

Note: Part 5-1A deals with advertisements about vaping goods.

(2) This Part does not apply in relation to generic information in relation to vaping goods.

Note: Part 5-1A deals with generic information in relation to vaping goods.

(3) In this section:

generic information, in relation to vaping goods, has the same meaning as in Part 5-1A.

42B Definitions

In this Part, unless the contrary intention appears:

generic information, in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, about the composition, properties or other characteristics of therapeutic goods, but does not include:

(a) an advertisement about the goods; or
(b) generic information included in an advertisement about the goods; or
(c) bona fide news.

prohibited representation means a representation referred to in subsection 42DJ(1).

registered charity means an entity that is registered under the *Australian Charities and Not-for-profits Commission Act 2012* as the type of entity mentioned in column 1 of item 1 of the table in subsection 25-5(5) of that Act.

required representation means a representation referred to in subsection 42DJ(2).

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restricted representation means a representation referred to in section 42DD.

42BAA Therapeutic Goods Advertising Code

(1) The Minister may, by legislative instrument, make a code relating to advertisements about therapeutic goods.

(2) Despite subsection 14(2) of the *Legislation Act 2003*, an instrument under subsection (1) of this section may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

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Division 3—General provisions about advertising therapeutic goods

42DA Simplified outline of this Division

Representations in advertisements about therapeutic goods may be restricted representations, required representations or prohibited representations. The offences and civil penalties in Division 3A refer to these 3 kinds of representations.

42DB Definitions

In this Division:

applicant means an applicant for approval of the use of a restricted representation in an advertisement about therapeutic goods.

approval holder, in relation to a restricted representation, means the person to whom notice of approval of the use of the restricted representation was given.

42DD Restricted representations

For the purposes of this Part, a representation in an advertisement about therapeutic goods that refers to a form of a disease, condition, ailment or defect identified in a part of the Therapeutic Goods Advertising Code as a serious form of a disease, condition, ailment or defect is a restricted representation.

Note: See sections 42DL and 42DLB for offences and a civil penalty for advertising therapeutic goods, where the advertisement contains a restricted representation.

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42DE Applications for approval of use of restricted representation

(1) An application for approval of the use of a restricted representation must be made to the Secretary in accordance with a form approved, in writing, by the Secretary.

(2) An approval of a form may require or permit an application to be given in accordance with specified software requirements:
  (a) on a specified kind of data processing device; or
  (b) by way of a specified kind of electronic transmission.

42DF Approval of use of restricted representation

(1) If an application for approval of the use of a restricted representation is made, the Secretary must approve the use of the restricted representation if the Secretary is satisfied that:
  (a) the representation is accurate and balanced; and
  (b) the representation is not misleading or likely to be misleading.

(2) Otherwise, the Secretary must refuse to approve the use of the restricted representation.

(3) An approval may be subject to conditions imposed by the Secretary.

(4) In deciding whether to approve or refuse to approve the use of a restricted representation, the Secretary must take into consideration:
  (b) any advice of a committee that is established under the regulations and is prescribed by the regulations for the purposes of this paragraph; and
  (c) the public interest criteria mentioned in the part of the Therapeutic Goods Advertising Code dealing with restricted representations.

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42DG Notice of approval or refusal

(1) The Secretary must give written notice to the applicant of the approval of, or of the refusal to approve, the use of a restricted representation.

(2) If written notice is not given to the applicant within the period of 60 days after the day on which the application was made (or within such longer period as the Secretary specifies by written notice to the applicant before the end of that period), the Secretary is taken to have approved the use of the restricted representation at the end of the period.

(3) If an approval is subject to conditions, the conditions must be set out in the notice.

(4) A notice of refusal to approve the use of a restricted representation must:
  (a) give the Secretary's reasons for the refusal; and
  (b) inform the applicant of the applicant's right to have the Secretary's decision reviewed by the Minister under section 60.

42DH Variation of conditions of approval

(1) The Secretary, by written notice to an approval holder, may vary any condition of approval of the use of a restricted representation.

(2) The notice must:
  (a) give the Secretary's reasons for the variation; and
  (b) inform the approval holder of the approval holder's right to have the Secretary's decision reviewed by the Minister under section 60.

42DI Withdrawal of approval

(1) The Secretary, by written notice, may withdraw the approval of the use of a restricted representation if:
  (a) the Secretary is satisfied that:

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(i) information given by the applicant in the application was false or incorrect and the Secretary, or the Minister on review of a decision of the Secretary under section 42DF or 42DH, relied on the information in deciding to approve the use of the representation; or

(ii) the restricted representation has become a prohibited representation; or

(iii) there has been a breach of a condition of approval; or

(b) both:

(i) additional information about the safety or efficacy of the therapeutic goods becomes available; and

(ii) the Secretary is satisfied that, if that information had been available at the time of the approval, the Secretary would not have approved the use of the restricted representation; or

(c) the use of the restricted representation is permitted under subsection 42DK(1).

(2) The notice must:

(a) give the Secretary's reasons for the withdrawal; and

(b) inform the approval holder of the approval holder's right to have the Secretary's decision reviewed by the Minister under section 60.

42DJ Prohibited and required representations

(1) For the purposes of this Part, representations of a kind specified in regulations made for the purposes of this subsection are prohibited representations about therapeutic goods of a kind specified in those regulations.

(2) For the purposes of this Part, representations of a kind specified in regulations made for the purposes of this subsection are required representations about the therapeutic goods of a kind specified in those regulations.

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42DK Permitted use of restricted or prohibited representations

Restricted representations

(1) The Secretary may, by writing, permit the use of specified restricted representations in specified advertisements about specified therapeutic goods.

Prohibited representations

(2) The Secretary may, by writing, permit the use of specified prohibited representations:
  (a) on the label of specified therapeutic goods; or
  (b) on the package in which specified therapeutic goods are contained; or
  (c) on any material included with the package in which specified therapeutic goods are contained;

if the Secretary is satisfied that the representations are necessary for the appropriate use of the goods.

(3) The Secretary may, by writing, permit the use of specified prohibited representations in specified advertisements about specified therapeutic goods if the Secretary is satisfied that the representations are necessary in the interests of public health.

Conditions

(4) A permission under this section may be subject to conditions specified in the permission.

Permission not a legislative instrument

(5) A permission under this section is not a legislative instrument.

Publication

(6) As soon as practicable after giving a permission under this section, the Secretary must cause the permission to be published on the Department's website.

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Division 3A—Advertising offences and civil penalties

42DKB Certain representations not to be advertised

(1) If a representation in an advertisement about therapeutic goods is false or misleading, the Secretary may, by notice given to a person apparently responsible for:

(a) advertising the therapeutic goods; or

(b) causing the advertising of the therapeutic goods;

prevent that person from advertising the therapeutic goods, or causing the advertising of the therapeutic goods, in circumstances where the advertisement contains that representation (whether in express terms or by necessary implication).

Note: See sections 42DLA and 42DLC for criminal offences and a civil penalty for contravening the notice.

(2) A notice under subsection (1) is not a legislative instrument.

Publication

(3) As soon as practicable after giving a notice under subsection (1), the Secretary must cause the notice to be published on the Department's website.

42DL Advertising offences—general

(1) A person commits an offence if:

(a) the person:

(i) advertises, by any means, therapeutic goods; or

(ii) causes the advertising, by any means, of therapeutic goods; and

(b) subsection (5), (6), (7), (8), (9), (10), (11) or (12) applies to the advertisement; and

(c) either:

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(i) the use of the goods in reliance on the advertisement has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods in reliance on the advertisement, if the goods were so used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(2) A person commits an offence if:

(a) the person:

(i) advertises, by any means, therapeutic goods; or

(ii) causes the advertising, by any means, of therapeutic goods; and

(b) subsection (5), (6), (7), (8), (9), (10), (11) or (12) applies to the advertisement.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(3) A person commits an offence if:

(a) the person:

(i) advertises, by any means, therapeutic goods; or

(ii) causes the advertising, by any means, of therapeutic goods; and

(b) subsection (5), (6), (7), (8), (9), (10), (11) or (12) applies to the advertisement.

Penalty: 100 penalty units.

(4) An offence against subsection (3) is an offence of strict liability.

Contravening provisions

(5) This subsection applies to the advertisement if it contains a prohibited representation (whether in express terms or by necessary implication) about the goods and either of the following applies:

(a) no permission under section 42DK is in force in relation to the prohibited representation;

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(b) a permission under section 42DK is in force in relation to the prohibited representation but the use of the prohibited representation is not in accordance with the permission or a condition of the permission.

(6) This subsection applies to the advertisement if it does not contain a required representation about the goods.

(7) This subsection applies to the advertisement if it contains a restricted representation (whether in express terms or by necessary implication) and either of the following applies:

(a) neither an approval under section 42DF nor a permission under section 42DK is in force in relation to the restricted representation;

(b) an approval under section 42DF or a permission under section 42DK is in force in relation to the restricted representation but the use of the restricted representation is not in accordance with the approval or permission or a condition of the approval or permission.

(8) This subsection applies to the advertisement if it contains a reference to this Act, other than in a statement of the registration number, listing number or device number of the goods.

(9) This subsection applies to the advertisement if it contains a statement, pictorial representation or design suggesting or implying the goods have been recommended or approved by or on behalf of a government or government authority (including a foreign government or foreign government authority), other than:

(a) a statement of the availability of the goods as a pharmaceutical benefit; or

(b) a statement, pictorial representation or design authorised or required by a government or government authority (not including a foreign government or foreign government authority); or

(c) a statement, pictorial representation or design prescribed by the regulations for the purposes of this paragraph.

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(10) This subsection applies to the advertisement if it refers to substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

(11) This subsection applies to the advertisement if it refers to a biological, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

(12) This subsection applies to the advertisement if it refers to therapeutic goods that are not entered in the Register and that are prescribed by the regulations for the purposes of this subsection, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

Continuing offences

(13) A person who contravenes subsection (1), (2) or (3) commits a separate offence in respect of each day (including a day of a conviction for the offence or any later day) during which the contravention continues.

(14) The maximum penalty for each day that an offence against subsection (1), (2) or (3) continues is 10% of the maximum pecuniary penalty that can be imposed in respect of that offence.

42DLA Advertising offences—contravening section 42DKB notice

(1) A person commits an offence if:
  (a) the Secretary has given a notice to the person under section 42DKB in relation to therapeutic goods; and
  (b) the person does an act or omits to do an act; and
  (c) the act or omission contravenes the notice; and
  (d) either:

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(i) the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person; and

(e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because of the contravention.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(2) A person commits an offence if:

(a) the Secretary has given a notice to the person under section 42DKB; and

(b) the person does an act or omits to do an act; and

(c) the act or omission contravenes the notice.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(3) A person commits an offence if:

(a) the Secretary has given a notice to the person under section 42DKB; and

(b) the person does an act or omits to do an act; and

(c) the act or omission contravenes the notice.

Penalty: 100 penalty units.

(4) An offence against subsection (3) is an offence of strict liability.

42DLB Civil penalty relating to advertisements—general

(1) A person contravenes this subsection if:

(a) the person:

(i) advertises, by any means, therapeutic goods; or

(ii) causes the advertising, by any means, of therapeutic goods; and

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(b) subsection (2), (3), (4), (5), (6), (7), (8) or (9) applies to the advertisement.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Contravening provisions

(2) This subsection applies to the advertisement if it contains a prohibited representation (whether in express terms or by necessary implication) about the goods and either of the following applies:

(a) no permission under section 42DK is in force in relation to the prohibited representation;

(b) a permission under section 42DK is in force in relation to the prohibited representation but the use of the prohibited representation is not in accordance with the permission or a condition of the permission.

(3) This subsection applies to the advertisement if it does not contain a required representation about the goods.

(4) This subsection applies to the advertisement if it contains a restricted representation (whether in express terms or by necessary implication) and either of the following applies:

(a) neither an approval under section 42DF nor a permission under section 42DK is in force in relation to the restricted representation;

(b) an approval under section 42DF or a permission under section 42DK is in force in relation to the restricted representation but the use of the restricted representation is not in accordance with the approval or permission or a condition of the approval or permission.

(5) This subsection applies to the advertisement if it contains a reference to this Act, other than in a statement of the registration number, listing number or device number of the goods.

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(6) This subsection applies to the advertisement if it contains a statement, pictorial representation or design suggesting or implying the goods have been recommended or approved by or on behalf of a government or government authority (including a foreign government or foreign government authority), other than:

(a) a statement of the availability of the goods as a pharmaceutical benefit; or

(b) a statement, pictorial representation or design authorised or required by a government or government authority (not including a foreign government or foreign government authority); or

(c) a statement, pictorial representation or design prescribed by the regulations for the purposes of this paragraph.

(7) This subsection applies to the advertisement if it refers to substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

(8) This subsection applies to the advertisement if it refers to a biological, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

(9) This subsection applies to the advertisement if it refers to therapeutic goods that are not entered in the Register and that are prescribed by the regulations for the purposes of this subsection, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

Exception

(10) Subsection (1) does not apply if:

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(a) the person is a broadcaster, a datacaster, the SBS or a person of a kind prescribed by the regulations for the purposes of this paragraph; and

(b) as a result of steps taken by the person, it was reasonable for the person to assume that subsections (2) to (9) did not apply to the advertisement.

Continuing contraventions

(10A) A person who contravenes subsection (1) commits a separate contravention of that subsection in respect of each day during which the contravention continues (including the day the order under subsection 42Y(2) is made or any later day).

(10B) The maximum civil penalty for each day that a contravention against subsection (1) continues is 10% of the maximum civil penalty that can be imposed in respect of the contravention.

(11) In this section:

broadcaster has the meaning given by clause 3 of Schedule 2 to the *Broadcasting Services Act 1992*.

datacaster means a person who holds a datacasting licence (within the meaning of the *Broadcasting Services Act 1992*).

SBS has the same meaning as in the *Special Broadcasting Service Act 1991*.

42DLC Civil penalty relating to advertisements—contravening section 42DKB notice

A person contravenes this section if:

(a) the Secretary has given a notice to the person under section 42DKB; and

(b) the person does an act or omits to do an act; and

(c) the act or omission contravenes the notice.

Maximum civil penalty:

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(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

42DM Offences—non-compliance with the Therapeutic Goods Advertising Code

(1) A person commits an offence if:
(a) the person:
(i) advertises, by any means, therapeutic goods; or
(ii) causes the advertising, by any means, of therapeutic goods; and
(b) the advertisement does not comply with the Therapeutic Goods Advertising Code; and
(c) either:
(i) the use of the goods in reliance on the advertisement has resulted in, will result in, or is likely to result in, harm or injury to any person; or
(ii) the use of the goods in reliance on the advertisement, if the goods were so used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(2) A person commits an offence if:
(a) the person:
(i) advertises, by any means, therapeutic goods; or
(ii) causes the advertising, by any means, of therapeutic goods; and
(b) the advertisement does not comply with the Therapeutic Goods Advertising Code.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(3) A person commits an offence if:
(a) the person:
(i) advertises, by any means, therapeutic goods; or

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(ii) causes the advertising, by any means, of therapeutic goods; and

(b) the advertisement does not comply with the Therapeutic Goods Advertising Code.

Penalty: 100 penalty units.

(4) An offence against subsection (3) is an offence of strict liability.

Continuing offences

(5) A person who contravenes subsection (1), (2) or (3) commits a separate offence in respect of each day (including a day of a conviction for the offence or any later day) during which the contravention continues.

(6) The maximum penalty for each day that an offence against subsection (1), (2) or (3) continues is 10% of the maximum pecuniary penalty that can be imposed in respect of that offence.

42DMA Civil penalty—non-compliance with the Therapeutic Goods Advertising Code

(1) A person contravenes this section if:

(a) the person:

(i) advertises, by any means, therapeutic goods; or

(ii) causes the advertising, by any means, of therapeutic goods; and

(b) the advertisement does not comply with the Therapeutic Goods Advertising Code.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Exception

(2) Subsection (1) does not apply if:

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(a) the person is a broadcaster, a datacaster, the SBS or a person of a kind prescribed by the regulations for the purposes of this paragraph; and

(b) as a result of steps taken by the person, it was reasonable for the person to assume that the advertisement complied with the Therapeutic Goods Advertising Code.

Continuing contraventions

(2A) A person who contravenes subsection (1) commits a separate contravention of that subsection in respect of each day during which the contravention continues (including the day the order under subsection 42Y(2) is made or any later day).

(2B) The maximum civil penalty for each day that a contravention against subsection (1) continues is 10% of the maximum civil penalty that can be imposed in respect of the contravention.

(3) In this section:

broadcaster has the meaning given by clause 3 of Schedule 2 to the *Broadcasting Services Act 1992*.

datacaster means a person who holds a datacasting licence (within the meaning of the *Broadcasting Services Act 1992*).

SBS has the same meaning as in the *Special Broadcasting Service Act 1991*.

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Division 4—Generic information about ingredients or components of therapeutic goods

42DN Application of Division

This Division applies to generic information about goods that:

(a) may be used as an ingredient or component in the manufacture of therapeutic goods; and

(b) although not presented for supply as therapeutic goods, come within the meaning of therapeutic goods because they are represented to be:

(i) for therapeutic use; or

(ii) for use as an ingredient or component in the manufacture of other therapeutic goods.

42DO Compliance with the Code

Generic information to which this Division applies must comply with the provisions of the Therapeutic Goods Advertising Code that are prescribed by the regulations for the purposes of this section as if those provisions applied to generic information in the same way as they apply to advertisements.

42DP Offences—dissemination of generic information

(1) A person commits an offence if:

(a) the person disseminates, by any means, generic information about therapeutic goods to the public or a section of the public; and

(b) the dissemination of that generic information does not comply with the provisions of the Therapeutic Goods Advertising Code that are prescribed by regulations for the purposes of section 42DO.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

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(2) A person commits an offence if:

(a) the person disseminates, by any means, generic information about therapeutic goods to the public or a section of the public; and

(b) the dissemination of that generic information does not comply with the provisions of the Therapeutic Goods Advertising Code that are prescribed by regulations for the purposes of section 42DO.

Penalty: 100 penalty units.

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

42DQ Civil penalty for dissemination of generic information

A person contravenes this section if:

(a) the person disseminates, by any means, generic information about therapeutic goods to the public or a section of the public; and

(b) the dissemination of that generic information does not comply with the provisions of the Therapeutic Goods Advertising Code that are prescribed by regulations for the purposes of section 42DO.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

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Division 5—Secretary may require information or documents

42DR Secretary may require information or documents

Advertisements

(1) The Secretary may, by written notice given to a person apparently responsible for advertising therapeutic goods, or for causing the advertising of therapeutic goods, require the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to the advertisement.

Generic information

(2) The Secretary may, by written notice given to a person apparently responsible for disseminating, or for causing the disseminating of, generic information about therapeutic goods to the public or a section of the public, require the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to the dissemination.

Manner of compliance

(3) The person must give the information, or produce the documents, to the Secretary:
  (a) within the period, of not less than 14 days after the day the notice is given, specified in the notice or within such longer period as the Secretary allows; and
  (b) in the form specified in the notice.

Note: Section 42DS contains criminal offences for failing to comply with the notice and for giving false or misleading information or documents and section 42DT contains a civil penalty for giving false or misleading information or documents.

(4) The form may require or permit the information to be given, or the documents to be produced, in accordance with specified software requirements:

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(a) on a specified kind of data processing device; or
(b) by way of a specified kind of electronic transmission.

Notice not a legislative instrument

(5) A notice under subsection (1) or (2) is not a legislative instrument.

42DS Criminal offences for failing to comply with a notice etc.

(1) A person commits an offence if:
(a) the person is given a notice under section 42DR; and
(b) the person fails to comply with the notice.

Penalty: 500 penalty units.

(2) A person commits an offence if:
(a) the person is given a notice under section 42DR; and
(b) the person fails to comply with the notice.

Penalty: 100 penalty units.

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

(4) A person commits an offence if:
(a) the person is given a notice under section 42DR; and
(b) the person gives information or produces a document in compliance or purported compliance with the notice; and
(c) the information or document is false or misleading in a material particular.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(5) A person commits an offence if:
(a) the person is given a notice under section 42DR; and
(b) the person gives information or produces a document in compliance or purported compliance with the notice; and
(c) the information or document is false or misleading in a material particular.

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Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

42DT Civil penalty for giving false or misleading information or document in compliance with a notice

A person contravenes this section if:

(a) the person is given a notice under section 42DR; and

(b) the person gives information or produces a document in compliance or purported compliance with the notice; and

(c) the information or document is false or misleading in a material particular.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

42DU Self-incrimination

(1) A person is not excused from giving information or producing a document under section 42DR on the ground that the information or the production of the document might tend to incriminate the person or expose the person to a penalty.

(2) However, in the case of an individual:

(a) the information given or the document produced; and

(b) giving the information or producing the document; and

(c) any information, document or thing obtained as a direct or indirect consequence of giving the information or producing the document;

are not admissible in evidence against the individual:

(d) in criminal proceedings, except proceedings for an offence against subsection 42DS(4) or (5); or

(e) in civil proceedings, except proceedings under section 42Y for a contravention of section 42DT.

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Division 6—Directions about advertisements or generic information

42DV Directions about advertisements or generic information

Advertisements

(1) If, in relation to the advertising of therapeutic goods, the Secretary is satisfied that there has been a contravention of this Act or the regulations, the Secretary may, in writing, direct a person apparently responsible for advertising the therapeutic goods, or for causing the advertising of the therapeutic goods, to do one or more of the following:
  (a) cease the advertisement;
  (b) make a retraction;
  (c) make a correction;
  (d) recover any advertisement that is still in circulation;
  (e) destroy the advertisement;
  (f) cease making a particular claim or representation made by the advertisement.

Generic information

(2) If, in relation to the dissemination of generic information about therapeutic goods to the public or a section of the public, the Secretary is satisfied that there has been a contravention of this Act or the regulations, the Secretary may, in writing, direct a person apparently responsible for the dissemination, or for causing the dissemination, to do one or more of the following:
  (a) withdraw the generic information;
  (b) make a retraction;
  (c) make a correction;
  (d) recover any generic information that is still in circulation;
  (e) destroy the generic information;

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(f) cease making a particular claim or representation made by the generic information.

Conditions

(3) A direction under subsection (1) or (2) may be subject to conditions specified in the direction.

(4) Without limiting subsection (3), the conditions may relate to one or more of the following:
(a) the period for doing a thing the subject of the direction;
(b) in relation to the making of a retraction or correction, either or both of the following:
(i) the form and manner of the retraction or correction;
(ii) the period for which the retraction or correction must be made publicly available;
(c) the reporting to the Secretary of compliance with the direction.

Direction not a legislative instrument

(5) A direction under subsection (1) or (2) is not a legislative instrument.

Publication

(6) As soon as practicable after giving a direction under subsection (1) or (2), the Secretary must cause the direction to be published on the Department's website.

42DW Offences—contravening direction under section 42DV

(1) A person commits an offence if:
(a) the Secretary has given a direction to the person under subsection 42DV(1) or (2) in relation to therapeutic goods; and
(b) the person does an act or omits to do an act; and

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(c) the act or omission contravenes the direction or a condition of the direction; and

(d) either:

(i) the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person; and

(e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because of the contravention.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(2) A person commits an offence if:

(a) the Secretary has given a direction to the person under subsection 42DV(1) or (2); and

(b) the person does an act or omits to do an act; and

(c) the act or omission contravenes the direction or a condition of the direction.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(3) A person commits an offence if:

(a) the Secretary has given a direction to the person under subsection 42DV(1) or (2); and

(b) the person does an act or omits to do an act; and

(c) the act or omission contravenes the direction or a condition of the direction.

Penalty: 100 penalty units.

(4) An offence against subsection (3) is an offence of strict liability.

42DX Civil penalty for contravening direction under section 42DV

A person contravenes this section if:

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(a) the Secretary has given a direction to the person under subsection 42DV(1) or (2); and
(b) the person does an act or omits to do an act; and
(c) the act or omission contravenes the direction or a condition of the direction.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

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Division 7—Public warning notices

42DY Secretary may issue a public warning notice

(1) The Secretary may issue to the public a written notice containing a warning about therapeutic goods if:

(a) the Secretary reasonably suspects that there has been a contravention of this Act or the regulations in relation to:

(i) the advertising of the therapeutic goods; or

(ii) the dissemination of generic information about the therapeutic goods to the public or a section of the public; and

(b) the Secretary is satisfied that it is in the public interest to issue the notice.

(2) If:

(a) the Secretary gives a person a notice (the ***substantiation notice***) under subsection 42DR(1) or (2); and

(b) the person fails to comply with the substantiation notice; and

(c) the Secretary is satisfied that it is in the public interest to issue a notice under this subsection;

the Secretary may issue to the public a written notice containing a warning that the person has failed to comply with the substantiation notice, and specifying the matter to which the substantiation notice related.

(3) Subsection (2) does not limit subsection (1).

(4) A notice under this section is not a legislative instrument.

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Part 5-1A—Vaping goods

Division 1—Preliminary

42DZA This Part not to apply to certain advertisements for exported goods

This Part does not apply to advertisements that are solely for vaping goods that have been exported, or are intended exclusively for export, if the advertisements are not available to consumers in Australia.

42DZB Definitions

In this Part:

generic information, in relation to vaping goods, includes any statement, pictorial representation or design, however made, about the composition, properties or other characteristics of the vaping goods, but does not include:

(a) an advertisement about the goods; or

(b) generic information included in an advertisement about the goods; or

(c) bona fide news.

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Division 2—General provisions about advertising vaping goods

42DZC Authorised advertisements etc.

Secretary may authorise advertising

(1) The Secretary may, by legislative instrument, authorise the advertising, or a class of advertising, of specified vaping goods or a specified class of vaping goods.

Conditions

(4) An authorisation under this section may be subject to conditions specified in the authorisation.

(5) Without limiting subsection (4), conditions in an authorisation of advertising may relate to any of the following:
  (a) the nature of the audience to which the advertising is targeted;
  (b) the form of the advertising;
  (c) the content of the advertising;
  (d) representations or information on:
    (i) the labels of specified vaping goods or a specified class of vaping goods; or
    (ii) the packages in which specified vaping goods or a specified class of vaping goods are contained; or
    (iii) any material included with the package in which specified vaping goods or a specified class of vaping goods are contained.

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Division 3—Offences and civil penalty provisions

42DZD Offences—no authorisation or conditions of authorisation not complied with

(1) A person commits an offence if:

(a) the person:

(i) advertises, by any means, vaping goods; or

(ii) causes the advertising, by any means, of vaping goods; and

(b) either:

(i) no authorisation under section 42DZC is in force in relation to the advertising; or

(ii) an authorisation under section 42DZC is in force in relation to the advertising, but the advertising does not include representations or information as specified in the authorisation, or the advertising is not otherwise in accordance with the authorisation, or the advertising does not comply with a condition to which the authorisation is subject.

Penalty: Imprisonment for 7 years or 5,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) A person commits an offence of strict liability if:

(a) the person:

(i) advertises, by any means, vaping goods; or

(ii) causes the advertising, by any means, of vaping goods; and

(b) either:

(i) no authorisation under section 42DZC is in force in relation to the advertising; or

(ii) an authorisation under section 42DZC is in force in relation to the advertising, but the advertising does not

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include representations or information as specified in the authorisation, or the advertising is not otherwise in accordance with the authorisation, or the advertising does not comply with a condition to which the authorisation is subject.

Penalty: 200 penalty units.

Continuing offences

(3) A person who contravenes subsection (1) or (2) commits a separate offence in respect of each day (including a day of a conviction for the offence or any later day) during which the contravention continues.

(4) The maximum penalty for each day that an offence against subsection (1) or (2) continues is 10% of the maximum pecuniary penalty that can be imposed in respect of that offence.

42DZE Civil penalty—no authorisation or conditions of authorisation not complied with

(1) A person contravenes this subsection if:

(a) the person:

(i) advertises, by any means, vaping goods; or

(ii) causes the advertising, by any means, of vaping goods; and

(b) either:

(i) no authorisation under section 42DZC is in force in relation to the advertising; or

(ii) an authorisation under section 42DZC is in force in relation to the advertising, but the advertising does not include representations or information as specified in the authorisation, or the advertising is not otherwise in accordance with the authorisation, or the advertising does not comply with a condition to which the authorisation is subject.

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Maximum civil penalty:

(a) for an individual—7,000 penalty units; and

(b) for a body corporate—70,000 penalty units.

Continuing contraventions

(2) A person who contravenes subsection (1) commits a separate contravention of that subsection in respect of each day during which the contravention continues (including the day the order under subsection 42Y(2) is made or any later day).

(3) The maximum civil penalty for each day that a contravention against subsection (1) continues is 10% of the maximum civil penalty that can be imposed in respect of the contravention.

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Division 4—Secretary may require information or documents

42DZF Secretary may require information or documents

Advertisements

(1) The Secretary may, by written notice given to a person apparently responsible for advertising vaping goods, or for causing the advertising of vaping goods, require the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to the advertisement.

Generic information

(2) The Secretary may, by written notice given to a person apparently responsible for disseminating, or for causing the disseminating of, generic information in relation to vaping goods to the public or a section of the public, require the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to the dissemination.

Manner of compliance

(3) The person must give the information, or produce the documents, to the Secretary:
  (a) within the period, of not less than 14 days after the day the notice is given, specified in the notice or within such longer period as the Secretary allows; and
  (b) in the form specified in the notice.

Note: A person may commit an offence under section 42DZG for failing to comply with the notice or giving false or misleading information or documents and may be liable to a civil penalty under section 42DZH for giving false or misleading information or documents.

(4) The form may require or permit the information to be given, or the documents to be produced, in accordance with specified software requirements:

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(a) on a specified kind of data processing device; or
(b) by way of a specified kind of electronic transmission.

Notice not a legislative instrument

(5) A notice under subsection (1) or (2) is not a legislative instrument.

42DZG Offences—failing to comply with a notice etc.

(1) A person commits an offence if:
(a) the person is given a notice under subsection 42DZF(1) or (2); and
(b) the person fails to comply with the notice.

Penalty: 500 penalty units.

(2) A person commits an offence of strict liability if:
(a) the person is given a notice under subsection 42DZF(1) or (2); and
(b) the person fails to comply with the notice.

Penalty: 100 penalty units.

(3) A person commits an offence if:
(a) the person is given a notice under subsection 42DZF(1) or (2); and
(b) the person gives information or produces a document in compliance or purported compliance with the notice; and
(c) the information or document is false or misleading in a material particular.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(4) A person commits an offence of strict liability if:
(a) the person is given a notice under subsection 42DZF(1) or (2); and
(b) the person gives information or produces a document in compliance or purported compliance with the notice; and

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(c) the information or document is false or misleading in a material particular.

Penalty: 100 penalty units.

42DZH Civil penalty—giving false or misleading information or document in compliance with a notice

A person contravenes this section if:

(a) the person is given a notice under subsection 42DZF(1) or (2); and

(b) the person gives information or produces a document in compliance or purported compliance with the notice; and

(c) the information or document is false or misleading in a material particular.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

42DZJ Self-incrimination

(1) A person is not excused from giving information or producing a document under section 42DZF on the ground that the information or the production of the document might tend to incriminate the person or expose the person to a penalty.

(2) However, in the case of an individual:

(a) the information given or the document produced; and

(b) giving the information or producing the document; and

(c) any information, document or thing obtained as a direct or indirect consequence of giving the information or producing the document;

are not admissible in evidence against the individual:

(d) in criminal proceedings, except proceedings for an offence against subsection 42DZG(3) or (4); or

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(e) in civil proceedings, except proceedings under section 42Y for a contravention of section 42DZH.

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Division 5—Directions about advertisements or generic information

42DZK Directions about advertisements or generic information

Advertisements

(1) If, in relation to the advertising of vaping goods, the Secretary is satisfied that there has been a contravention of this Act or the regulations, the Secretary may, in writing, direct a person apparently responsible for advertising the vaping goods, or for causing the advertising of the vaping goods, to do one or more of the following:
   (a) cease the advertisement;
   (b) make a retraction;
   (c) make a correction;
   (d) recover any advertisement that is still in circulation;
   (e) destroy the advertisement;
   (f) cease making a particular claim or representation made by the advertisement.

Generic information

(2) In relation to the dissemination of generic information in relation to vaping goods to the public or a section of the public, the Secretary may, in writing, direct a person apparently responsible for the dissemination, or for causing the dissemination, to do one or more of the following if the Secretary is satisfied that it is in the interests of public health or safety to give the person the direction:
   (a) withdraw the generic information;
   (b) make a retraction;
   (c) make a correction;
   (d) recover any generic information that is still in circulation;
   (e) destroy the generic information;

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(f) cease making a particular claim or representation made by the generic information.

Conditions

(3) A direction under subsection (1) or (2) may be subject to conditions specified in the direction.

(4) Without limiting subsection (3), the conditions may relate to one or more of the following:
(a) the period for doing a thing the subject of the direction;
(b) in relation to the making of a retraction or correction—either or both of the following:
(i) the form and manner of the retraction or correction;
(ii) the period for which the retraction or correction must be made publicly available;
(c) the reporting to the Secretary of compliance with the direction.

Direction not a legislative instrument

(5) A direction under subsection (1) or (2) is not a legislative instrument.

Publication

(6) As soon as practicable after giving a direction under subsection (1) or (2), the Secretary must cause the direction to be published on the Department's website.

42DZL Offences—contravening direction under section 42DZK

(1) A person commits an offence if:
(a) the Secretary has given a direction to the person under subsection 42DZK(1) or (2) in relation to vaping goods; and
(b) the person does an act or omits to do an act; and
(c) the act or omission contravenes the direction or a condition of the direction; and

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(d) either:
  (i) the use of the vaping goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or
  (ii) the use of the vaping goods, if the vaping goods were used, would result in, or would be likely to result in, harm or injury to any person; and
(e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because of the contravention.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (2) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) A person commits an offence if:
(a) the Secretary has given a direction to the person under subsection 42DZK(1) or (2); and
(b) the person does an act or omits to do an act; and
(c) the act or omission contravenes the direction or a condition of the direction.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(3) A person commits an offence of strict liability if:
(a) the Secretary has given a direction to the person under subsection 42DZK(1) or (2); and
(b) the person does an act or omits to do an act; and
(c) the act or omission contravenes the direction or a condition of the direction.

Penalty: 100 penalty units.

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42DZM Civil penalty—contravening direction under section 42DZK

A person contravenes this section if:

(a) the Secretary has given a direction to the person under subsection 42DZK(1) or (2); and

(b) the person does an act or omits to do an act; and

(c) the act or omission contravenes the direction or a condition of the direction.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

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Division 6—Public warning notices

42DZN Secretary may issue a public warning notice

(1) The Secretary may issue to the public a written notice containing a warning about vaping goods if:

(a) the Secretary reasonably suspects that there has been a contravention of this Act or the regulations in relation to:

(i) the advertising of the vaping goods; or

(ii) the dissemination of generic information in relation to the vaping goods to the public or a section of the public; and

(b) the Secretary is satisfied that it is in the public interest to issue the notice.

(2) If:

(a) the Secretary has given a person a notice (the ***substantiation notice***) under subsection 42DZF(1) or (2); and

(b) the person fails to comply with the substantiation notice; and

(c) the Secretary is satisfied that it is in the public interest to issue a notice under this subsection;

the Secretary may issue to the public a written notice containing a warning that the person has failed to comply with the substantiation notice, and specifying the matter to which the substantiation notice related.

(3) Subsection (2) does not limit subsection (1).

(4) A notice under this section is not a legislative instrument.

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Part 5-2—Counterfeit therapeutic goods

42E Offence of dealing with counterfeit therapeutic goods

(1) A person commits an offence if:
  (a) the person intentionally:
    (i) manufactures goods in Australia; or
    (ii) supplies goods in Australia; or
    (iii) imports goods into Australia; or
    (iv) exports goods from Australia; and
  (b) the goods are therapeutic goods; and
  (c) the goods are counterfeit and the person knows that fact or is reckless as to whether that fact exists.

Penalty: 7 years imprisonment or 2,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) Goods are ***counterfeit*** if any of the following contain a false representation of a matter listed in subsection (3):
  (a) the label or presentation of the goods;
  (b) any document or record relating to the goods or their manufacture;
  (c) any advertisement for the goods.

(3) The matters are as follows:
  (a) the identity or name of the goods;
  (b) the formulation, composition or design specification of the goods or of any ingredient or component of them;
  (c) the presence or absence of any ingredient or component of the goods;
  (d) the strength or size of the goods (other than the size of any pack in which the goods are contained);

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(e) the strength or size of any ingredient or component of the goods;
(f) the sponsor, source, manufacturer or place of manufacture of the goods.

(5) To avoid doubt, a term that is defined in subsection 3(1) in relation to therapeutic goods and used in this section in relation to goods has in this section the meaning given by subsection 3(1).

42EA Civil penalty relating to dealing with counterfeit therapeutic goods

A person contravenes this section if:
(a) the person does any of the following:
(i) manufactures goods in Australia;
(ii) supplies goods in Australia;
(iii) imports goods into Australia;
(iv) exports goods from Australia; and
(b) the goods are therapeutic goods; and
(c) the goods are counterfeit.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

42EB Relief from liability for certain contraventions relating to dealing with counterfeit therapeutic goods

(1) If:
(a) proceedings for the contravention of section 42EA (a civil penalty provision) are brought against a person; and
(b) in the proceedings it appears to the Court that the person has, or may have, contravened that section but that:
(i) the person has a reasonable excuse; and
(ii) having regard to all the circumstances of the case, the person ought fairly to be excused for the contravention;

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the Court may relieve the person either wholly or partly from a liability to which the person would otherwise be subject, or that might otherwise be imposed on the person, because of the contravention.

(2) If a person thinks that proceedings for the contravention of section 42EA will or may be begun against them, they may apply to the Court for relief.

(3) On an application under subsection (2), the Court may grant relief under subsection (1) as if proceedings had been begun in the Court.

(4) For the purposes of subsection (2) as applying for the purposes of a case tried by a judge with a jury:
  (a) a reference in that subsection to the Court is a reference to the judge; and
  (b) the relief that may be granted includes withdrawing the case in whole or in part from the jury and directing judgment to be entered for the person on such terms as to costs as the judge thinks appropriate.

Exception

(5) This section does not apply to civil proceedings against a person for manufacturing therapeutic goods in Australia that are counterfeit (see subparagraph 42EA(a)(i)).

42F Customs treatment of counterfeit therapeutic goods

Imported counterfeit therapeutic goods

(1) If the Secretary notifies the Comptroller-General of Customs in writing that the Secretary wishes the *Customs Act 1901* to apply to an import of counterfeit therapeutic goods, that Act has effect as if the goods included in the import were goods described as forfeited to the Crown under section 229 of that Act because they were prohibited imports within the meaning of that Act.

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Exported counterfeit therapeutic goods

(2) If the Secretary notifies the Comptroller-General of Customs in writing that the Secretary wishes the *Customs Act 1901* to apply to an export of counterfeit therapeutic goods, that Act has effect as if the goods included in the export were goods described as forfeited to the Crown under section 229 of that Act because they were prohibited exports within the meaning of that Act.

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Part 5-3—Product tampering

42T Notifying of actual or potential tampering

(1) A person commits an offence if:

(a) the person supplies, manufactures or is a sponsor of, or proposes to supply, manufacture or become a sponsor of, therapeutic goods; and

(b) either:

(i) the person knows that some or all of those therapeutic goods, or any other therapeutic goods, are or have been subject to actual or potential tampering; or

(ii) some or all of those therapeutic goods, or any other therapeutic goods, are or have been subject to actual or potential tampering, and the person is reckless as to that fact; and

(c) the person fails, within 24 hours after becoming aware of, or becoming aware of a substantial risk of, the actual or potential tampering, to notify the Secretary.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) A person commits an offence if:

(a) the person supplies, manufactures or is a sponsor of, or proposes to supply, manufacture or become a sponsor of, therapeutic goods; and

(b) the person receives information or a demand; and

(c) either:

(i) the person knows that the information or demand relates (either expressly or by implication) to actual or potential tampering with some or all of those therapeutic goods, or any other therapeutic goods; or

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(ii) the information or demand relates (either expressly or by implication) to actual or potential tampering with some or all of those therapeutic goods, or any other therapeutic goods, and the person is negligent as to that fact; and

(d) the person fails to notify the Secretary of the information or demand within 24 hours after receiving it.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(3) For the purposes of subparagraph (2)(c)(ii), the person is only taken to be negligent as to the fact that the information or demand is of the kind referred to in that subparagraph if:

(a) the person's acts or omissions involve such a great falling short of the standard of care that a reasonable person would exercise in the circumstances; and

(b) there is such a high risk that the information or demand is of that kind;

that the acts or omissions merit criminal punishment.

(4) For the purposes of this section, it does not matter whether, at the time of receipt of the information or demand:

(a) the person has possession or control of the therapeutic goods to which the information or demand relates; or

(b) the therapeutic goods are in existence.

42U Meaning of *actual or potential tampering* etc.

Actual or potential tampering, in relation to therapeutic goods, means:

(a) tampering with the therapeutic goods; or

(b) causing the therapeutic goods to be tampered with; or

(c) proposing to tamper with the therapeutic goods; or

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(d) proposing to cause the therapeutic goods to be tampered with.

42V Recall of therapeutic goods because of actual or potential tampering

(1) The Secretary may, in writing, impose requirements under this section on a person if:

(a) the person supplies or has supplied therapeutic goods of a particular kind, or a particular batch of therapeutic goods of that kind; and

(b) the Secretary is satisfied that therapeutic goods of that kind, or included in that batch, are, have been or could possibly be, subject to actual or potential tampering.

(2) The requirements may be one or more of the following:

(a) to take specified steps, in the specified manner and within such reasonable period as is specified, to recall therapeutic goods of that kind, or included in that batch, that the person has supplied;

(b) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, that therapeutic goods of that kind, or included in that batch, are, or have been, subject to actual or potential tampering;

(c) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, that therapeutic goods of that kind, or included in that batch, could possibly be subject to actual or potential tampering.

(3) Requirements referred to in paragraph (2)(a) do not apply to therapeutic goods that cannot be recalled because they have been administered to, or applied in the treatment of, a person.

(4) The Secretary must cause to be published in the *Gazette* or on the Department's website, as soon as practicable after imposing such requirements, a notice setting out particulars of the requirements.

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(5) The Secretary may impose requirements under this section whether or not the Secretary has been notified under section 42T.

(6) A person commits an offence if:

(a) the person fails to comply with a requirement under subsection (1) in relation to a supply of therapeutic goods; and

(b) either:

(i) the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person; and

(c) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because the person failed to comply with the requirement.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

Note 1: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (6C) instead: see section 53A.

Note 2: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(6C) A person commits an offence if the person fails to comply with a requirement under subsection (1) in relation to a supply of therapeutic goods.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

(6D) A person commits an offence if the person fails to comply with a requirement under subsection (1) in relation to a supply of therapeutic goods.

Penalty: 100 penalty units.

(6E) An offence against subsection (6D) is an offence of strict liability.

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(7) This section does not prevent the Secretary from taking action under section 29D or 30, Division 6 or 7 of Part 3-2A or Division 1 or 2 of Part 4-6.

42VA Civil penalty relating to the recall of therapeutic goods because of actual or potential tampering

A person contravenes this section if the person fails to comply with a requirement under subsection 42V(1) in relation to a supply of therapeutic goods.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

42VB Relief from liability for contraventions relating to the recall of therapeutic goods because of actual or potential tampering

(1) If:

(a) proceedings for the contravention of section 42VA (a civil penalty provision) are brought against a person; and

(b) in the proceedings it appears to the Court that the person has, or may have, contravened that section but that:

(i) the person has acted honestly; and

(ii) having regard to all the circumstances of the case, the person ought fairly to be excused for the contravention;

the Court may relieve the person either wholly or partly from a liability to which the person would otherwise be subject, or that might otherwise be imposed on the person, because of the contravention.

(2) If a person thinks that proceedings for the contravention of section 42VA will or may be begun against them, they may apply to the Court for relief.

(3) On an application under subsection (2), the Court may grant relief under subsection (1) as if proceedings had been begun in the Court.

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(4) For the purposes of subsection (2) as applying for the purposes of a case tried by a judge with a jury:

(a) a reference in that subsection to the Court is a reference to the judge; and

(b) the relief that may be granted includes withdrawing the case in whole or in part from the jury and directing judgment to be entered for the person on such terms as to costs as the judge thinks appropriate.

42W Supply etc. of therapeutic goods that are subject to recall requirements

(1) A person commits an offence if:

(a) the person supplies therapeutic goods in Australia; and

(b) either:

(i) the person knows that the therapeutic goods are of a kind, or are included in a batch, in respect of which requirements have been imposed under section 42V, on that person or another person, to recall therapeutic goods; or

(ii) the therapeutic goods are of such a kind, or are included in such a batch, and the person is reckless as to that fact; and

(c) the Secretary has not consented in writing to the supply.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) A person commits an offence if:

(a) the person exports therapeutic goods from Australia; and

(b) either:

(i) the person knows that the therapeutic goods are of a kind, or are included in a batch, in respect of which requirements have been imposed under section 42V, on

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that person or another person, to recall therapeutic goods; or

(ii) the therapeutic goods are of such a kind, or are included in such a batch, and the person is reckless as to that fact; and

(c) the Secretary has not consented in writing to the exportation.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(3) The Secretary must not give consent relating to an exportation unless satisfied that there are exceptional circumstances that justify giving the consent.

42X Saving of other laws

This Part is not intended to exclude or limit the operation of any other law of the Commonwealth or any law of a State or Territory.

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Chapter 5A—Enforcement

Part 5A-1—Civil penalties

Division 1—Obtaining an order for a civil penalty

42Y Federal Court may order person to pay pecuniary penalty for contravening civil penalty provision

Application for order

(1) Within 6 years of a person (the ***wrongdoer***) contravening a civil penalty provision, the Secretary may apply on behalf of the Commonwealth to the Federal Court for an order that the wrongdoer pay the Commonwealth a pecuniary penalty.

Court may order wrongdoer to pay pecuniary penalty

(2) If the Court is satisfied that the wrongdoer has contravened a civil penalty provision, the Court may order the wrongdoer to pay to the Commonwealth for each contravention the pecuniary penalty that the Court determines is appropriate (but not more than the maximum amount specified for the provision).

Determining amount of pecuniary penalty

(3) In determining the pecuniary penalty, the Court must have regard to all relevant matters, including:
  (a) the nature and extent of the contravention; and
  (b) the nature and extent of any loss or damage suffered as a result of the contravention; and
  (c) the circumstances in which the contravention took place; and
  (d) whether the person has previously been found by the Court in proceedings under this Act to have engaged in any similar conduct.

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Civil evidence and procedure rules apply

(4) The Court must apply the rules of evidence and procedure for civil matters when hearing and determining an application for an order under this section.

Note: The standard of proof in civil proceedings is the balance of probabilities: see section 140 of the *Evidence Act 1995*.

Conduct contravening more than one civil penalty provision

(5) If conduct constitutes a contravention of 2 or more civil penalty provisions, proceedings may be instituted under this Act against a person in relation to the contravention of any one or more of those provisions. However, the person is not liable to more than one pecuniary penalty under this section in respect of the same conduct.

42YA What is a *civil penalty provision*?

A subsection of this Act (or a section of this Act that is not divided into subsections) is a ***civil penalty provision*** if the words "civil penalty" and one or more amounts in penalty units are set out at the foot of the subsection (or section).

42YC Persons involved in contravening civil penalty provision

(1) A person must not:
  (a) aid, abet, counsel or procure a contravention of a civil penalty provision; or
  (b) induce (by threats, promises or otherwise) a contravention of a civil penalty provision; or
  (c) conspire to contravene a civil penalty provision.

(2) This Act applies to a person who contravenes subsection (1) in relation to a civil penalty provision as if the person had contravened the civil penalty provision.

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42YCA Continuing contraventions of civil penalty provisions

(1) If an act or thing is required under a civil penalty provision to be done:

(a) within a particular period; or

(b) before a particular time;

then the obligation to do that act or thing continues until the act or thing is done (even if the period has expired or the time has passed).

(2) A person who contravenes a civil penalty provision that requires an act or thing to be done:

(a) within a particular period; or

(b) before a particular time;

commits a separate contravention of that provision in respect of each day during which the contravention occurs (including the day the order under subsection 42Y(2) is made or any later day).

42YD Recovery of a pecuniary penalty

If the Federal Court orders a person to pay a pecuniary penalty:

(a) the penalty is payable to the Commonwealth; and

(b) the Commonwealth may enforce the order as if it were a judgment of the Court.

42YE Gathering information for application for pecuniary penalty

(1) This section applies if it appears to the Secretary that a person (the ***wrongdoer***) may have contravened a civil penalty provision.

(2) If the Secretary, on reasonable grounds, suspects that a person other than the wrongdoer can give information relevant to an application for a civil penalty order in relation to the contravention, whether or not such an application has been made, the Secretary may, by writing given to the person, require the person to give all reasonable assistance in connection with such an application.

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(3) Subsection (2) does not apply in relation to a duly qualified legal practitioner who is acting, or has acted, for the wrongdoer.

(4) If a person fails to give assistance as required under subsection (2), the Federal Court may, on the application of the Secretary, order the person to comply with the requirement as specified in the order.

(5) If a person fails to give assistance as required under subsection (2), the person commits an offence against this subsection.

Penalty: 30 penalty units.

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Division 2—Civil penalty proceedings and criminal proceedings

42YF Civil proceedings after criminal proceedings

The Federal Court must not make a pecuniary penalty order against a person for a contravention of a civil penalty provision if the person has been convicted of an offence constituted by conduct that is substantially the same as the conduct constituting the contravention.

42YG Criminal proceedings during civil proceedings

(1) Proceedings for a pecuniary penalty order against a person for a contravention of a civil penalty provision are stayed if:

(a) criminal proceedings are started or have already been started against the person for an offence; and

(b) the offence is constituted by conduct that is substantially the same as the conduct alleged to constitute the contravention.

(2) The proceedings for the order may be resumed if the person is not convicted of the offence. Otherwise, the proceedings for the order are dismissed.

42YH Criminal proceedings after civil proceedings

Criminal proceedings may not be started against a person for conduct that is substantially the same as conduct constituting a contravention of a civil penalty provision if a pecuniary penalty order has been made against the person in respect of that conduct.

42YI Evidence given in proceedings for civil penalty not admissible in criminal proceedings

Evidence of information given or evidence of production of documents by an individual is not admissible in criminal proceedings against the individual if:

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(a) the individual previously gave the evidence or produced the documents in proceedings for a pecuniary penalty order against the individual for a contravention of a civil penalty provision (whether or not the order was made); and

(b) the conduct alleged to constitute the offence is substantially the same as the conduct that was claimed to constitute the contravention.

However, this does not apply to a criminal proceeding in respect of the falsity of the evidence given by the individual in the proceedings for the pecuniary penalty order.

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Part 5A-2—Infringement notices

42YJ Simplified outline of this Part

The Secretary can give a person an infringement notice for a contravention of a provision of this Act or the regulations that is an offence of strict liability or for a contravention of a civil penalty provision.

The person can choose to pay an amount as an alternative to having court proceedings brought against the person for the contravention. If the person does not choose to pay the amount, proceedings can be brought against the person in relation to the contravention.

42YK When an infringement notice may be given

(1) If the Secretary reasonably believes that a person has contravened:
  (a) a provision of this Act or the regulations that is an offence of strict liability; or
  (b) a civil penalty provision;
the Secretary may give to the person an infringement notice for the alleged contravention.

(2) The infringement notice must be given within 12 months after the day on which the contravention is alleged to have taken place.

(3) A single infringement notice must relate only to a single contravention of a single provision unless subsection (4) applies.

(4) The Secretary may give a person a single infringement notice relating to multiple contraventions of a single provision if:
  (a) the provision requires the person to do a thing within a particular period or before a particular time; and
  (b) the person fails or refuses to do that thing within that period or before that time; and

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(c) the failure or refusal occurs on more than 1 day; and
(d) each contravention is constituted by the failure or refusal on one of those days.

Note: For continuing offences, see subsection 4K(2) of the *Crimes Act 1914*. For continuing contraventions of civil penalty provisions, see section 42YCA of this Act.

42YKA Matters to be included in an infringement notice

(1) An infringement notice must:
(a) be identified by a unique number; and
(b) state the day on which it is given; and
(c) state the name of the person to whom the notice is given; and
(d) state the name and contact details of the person who gave the notice; and
(e) give brief details of the alleged contravention, or each alleged contravention, to which the notice relates, including:
(i) the provision that was allegedly contravened; and
(ii) the maximum penalty that a court could impose for each contravention, if the provision were contravened; and
(iii) the time (if known) and day of, and the place of, each alleged contravention; and
(f) state the amount that is payable under the notice; and
(g) give an explanation of how payment of the amount is to be made; and
(h) state that, if the person to whom the notice is given pays the amount within 28 days after the day the notice is given, then (unless the notice is withdrawn):
(i) if the provision is an offence of strict liability—the person will not be liable to be prosecuted in a court for the alleged contravention; or
(ii) if the provision is a civil penalty provision—proceedings seeking an order under subsection 42Y(2) will not be brought in relation to the alleged contravention; and

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(i) state that payment of the amount is not an admission of guilt or liability; and

(j) state that the person may apply to the Secretary to have the period in which to pay the amount extended; and

(k) state that the person may choose not to pay the amount and, if the person does so:

(i) if the provision is an offence of strict liability—the person may be prosecuted in a court for the alleged contravention; or

(ii) if the provision is a civil penalty provision—proceedings seeking an order under subsection 42Y(2) may be brought in relation to the alleged contravention; and

(l) set out how the notice can be withdrawn; and

(m) state that if the notice is withdrawn:

(i) if the provision is an offence of strict liability—the person may be prosecuted in a court for the alleged contravention; or

(ii) if the provision is a civil penalty provision—proceedings seeking an order under subsection 42Y(2) may be brought in relation to the alleged contravention; and

(n) state that the person may make written representations to the Secretary seeking the withdrawal of the notice.

(2) If the notice relates to only one alleged contravention of the provision by the person, the amount to be stated in the notice for the purposes of paragraph (1)(f) is the lesser of:

(a) one-fifth of the maximum penalty that a court could impose on the person for that contravention; and

(b) 12 penalty units where the person is an individual, or 60 penalty units where the person is a body corporate.

(3) If the notice relates to more than one alleged contravention of the provision by the person, the amount to be stated in the notice for the purposes of paragraph (1)(f) is the lesser of:

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(a) one-fifth of the amount worked out by adding together the maximum penalty that a court could impose on the person for each alleged contravention; and

(b) either:

(i) if the person is an individual—the number of penalty units worked out by multiplying the number of alleged contraventions by 12; or

(ii) if the person is a body corporate—the number of penalty units worked out by multiplying the number of alleged contraventions by 60.

Note: Under section 42YK, a single infringement notice may only deal with multiple contraventions if they are contraventions of a single provision continuing over a period.

42YKB Extension of time to pay amount—application by person

(1) A person to whom an infringement notice has been given may apply to the Secretary for an extension of the period (the ***current period***) for paying the amount stated in the notice.

Note: The current period for paying the amount may be the 28-day period referred to in paragraph 42YKA(1)(h) or an extended period under this section or section 42YKBA.

(2) If the application is made before the end of the current period, the Secretary may, in writing, extend that period. The Secretary may do so before or after the end of that period.

(3) For the purposes of this Part, if the Secretary extends the current period, the period within which the amount stated in the notice is to be paid is the extended period.

(4) For the purposes of this Part, if the Secretary does not extend the current period, the period within which the amount stated in the notice is to be paid is the period that ends at the end of the later of the following days:

(a) the day that is the last day of the current period;

(b) the day that is 7 days after the day the person was given notice of the Secretary's decision not to extend.

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(5) The Secretary may give more than one extension under this section in relation to the infringement notice.

42YKBA Extension of time to pay amount—extension by Secretary on own initiative

(1) If the Secretary gives a person an infringement notice, the Secretary may, on the Secretary's own initiative and in writing, extend the period for paying the amount stated in the notice. The Secretary may do so before or after the end of that period.

Note: The period for paying the amount may be the 28-day period referred to in paragraph 42YKA(1)(h) or an extended period under section 42YKB or this section.

(2) For the purposes of this Part, if the Secretary extends that period, the period within which the amount stated in the notice is to be paid is the extended period.

(3) The Secretary must give the person notice of the Secretary's decision.

(4) The Secretary may give more than one extension under this section in relation to the infringement notice.

42YKC Withdrawal of an infringement notice

Representations seeking withdrawal of notice

(1) A person to whom an infringement notice has been given may make written representations to the Secretary seeking the withdrawal of the notice.

Withdrawal of notice

(2) The Secretary may withdraw an infringement notice given to a person (whether or not the person has made written representations seeking the withdrawal).

(3) When deciding whether or not to withdraw an infringement notice (the ***relevant infringement notice***), the Secretary:

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(a) must take into account any written representations seeking the withdrawal that were given by the person to the Secretary; and

(b) may take into account the following:

(i) whether a court has previously imposed a penalty on the person for a contravention of a provision of this Act or the regulations that is an offence of strict liability or for a contravention of a civil penalty provision;

(ii) the circumstances of the alleged contravention;

(iii) whether the person has paid an amount, stated in an earlier infringement notice, for a contravention of a provision of this Act or the regulations that is an offence of strict liability or for a contravention of a civil penalty provision if the contravention is constituted by conduct that is the same, or substantially the same, as the conduct alleged to constitute the contravention in the relevant infringement notice;

(iv) any other matter the Secretary considers relevant.

Notice of withdrawal

(4) Notice of the withdrawal of the infringement notice must be given to the person. The withdrawal notice must state:

(a) the person's name and address; and

(b) the day the infringement notice was given; and

(c) the identifying number of the infringement notice; and

(d) that the infringement notice is withdrawn; and

(e) that:

(i) if the provision is an offence of strict liability—the person may be prosecuted in a court for the alleged contravention; or

(ii) if the provision is a civil penalty provision—proceedings seeking an order under subsection 42Y(2) may be brought in relation to the alleged contravention.

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Refund of amount if infringement notice withdrawn

(5) If:

(a) the Secretary withdraws the infringement notice; and

(b) the person has already paid the amount stated in the notice;

the Commonwealth must refund to the person an amount equal to the amount paid.

42YKD Effect of payment of amount

(1) If the person to whom an infringement notice for an alleged contravention of a provision is given pays the amount stated in the notice before the end of the period within which the amount is to be paid:

(a) any liability of the person for the alleged contravention is discharged; and

(b) if the provision is an offence of strict liability—the person may not be prosecuted in a court for the alleged contravention; and

(c) if the provision is a civil penalty provision—proceedings seeking an order under subsection 42Y(2) may not be brought in relation to the alleged contravention; and

(d) the person is not regarded as having admitted guilt or liability for the alleged contravention; and

(e) if the provision is an offence of strict liability—the person is not regarded as having been convicted of the alleged offence.

(2) Subsection (1) does not apply if the notice has been withdrawn.

42YKE Effect of this Part

This Part does not:

(a) require an infringement notice to be given to a person for an alleged contravention of a provision of this Act or the regulations that is an offence of strict liability or an alleged contravention of a civil penalty provision; or

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(b) affect the liability of a person for an alleged contravention of a provision of this Act or the regulations that is an offence of strict liability or an alleged contravention of a civil penalty provision if:

(i) the person does not comply with an infringement notice given to the person for the contravention; or

(ii) an infringement notice is not given to the person for the contravention; or

(iii) an infringement notice is given to the person for the contravention and is subsequently withdrawn; or

(c) prevent the giving of 2 or more infringement notices to a person for an alleged contravention of a provision of this Act or the regulations that is an offence of strict liability or an alleged contravention of a civil penalty provision; or

(d) limit a court's discretion to determine the amount of a penalty to be imposed on a person who is found to have contravened a provision of this Act or the regulations that is an offence of strict liability or to have contravened a civil penalty provision.

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Part 5A-3—Enforceable undertakings

42YL Enforcement of undertakings

(1) The Secretary may accept a written undertaking given by a person in connection with a matter in relation to which the Secretary has a power or function under this Act or the regulations.

(2) The person may withdraw or vary the undertaking at any time, but only with the consent of the Secretary.

(3) The Secretary must publish details of the undertaking, as in force from time to time, on the internet.

(4) If the Secretary considers that the person who gave the undertaking has breached any of its terms, the Secretary may apply to the Federal Court for an order under subsection (5).

(5) If the Court is satisfied that the person has breached a term of the undertaking, the Court may make all or any of the following orders:

(a) an order directing the person to comply with that term of the undertaking;

(b) an order directing the person to pay to the Commonwealth an amount up to the amount of any financial benefit that the person has obtained directly or indirectly and that is reasonably attributable to the breach;

(c) any order that the Court considers appropriate directing the person to compensate any other person who has suffered loss or damage as a result of the breach;

(d) any other order that the Court considers appropriate.

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Part 5A-4—Injunctions

42YM Simplified outline of this Part

The Secretary can seek injunctions from the Federal Court or Federal Circuit and Family Court of Australia (Division 2) to restrain a person from contravening this Act or the regulations, or to compel compliance with this Act or the regulations.

Interim injunctions are also available.

42YN Grant of injunctions

Restraining injunctions

(1) If a person has engaged, is engaging or is proposing to engage, in conduct in contravention of this Act or the regulations, the Federal Court or Federal Circuit and Family Court of Australia (Division 2) may, on application by the Secretary, grant an injunction:
  (a) restraining the person from engaging in the conduct; and
  (b) if, in the court's opinion, it is desirable to do so—requiring the person to do a thing.

Performance injunctions

(2) If:
  (a) a person has refused or failed, or is refusing or failing, or is proposing to refuse or fail, to do a thing; and
  (b) the refusal or failure was, is or would be a contravention of this Act or the regulations;

the Federal Court or Federal Circuit and Family Court of Australia (Division 2) may, on application by the Secretary, grant an injunction requiring the person to do that thing.

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42YO Interim injunctions

Grant of interim injunctions

(1) Before deciding an application for an injunction under section 42YN, the Federal Court or Federal Circuit and Family Court of Australia (Division 2) may grant an interim injunction:
  (a) restraining a person from engaging in conduct; or
  (b) requiring a person to do a thing.

No undertakings as to damages

(2) The Federal Court or Federal Circuit and Family Court of Australia (Division 2) must not require the Secretary to give an undertaking as to damages as a condition of granting an interim injunction.

42YP Discharging or varying injunctions

The Federal Court or Federal Circuit and Family Court of Australia (Division 2) may discharge or vary an injunction granted by that court under this Part.

42YQ Certain limits on granting injunctions not to apply

Restraining injunctions

(1) The power of the Federal Court or Federal Circuit and Family Court of Australia (Division 2) under this Part to grant an injunction restraining a person from engaging in conduct may be exercised:
  (a) whether or not it appears to the court that the person intends to engage again, or to continue to engage, in conduct of that kind; and
  (b) whether or not the person has previously engaged in conduct of that kind; and
  (c) whether or not there is an imminent danger of substantial damage to any other person if the person engages in conduct of that kind.

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Performance injunctions

(2) The power of the Federal Court or Federal Circuit and Family Court of Australia (Division 2) under this Part to grant an injunction requiring a person to do a thing may be exercised:

(a) whether or not it appears to the court that the person intends to refuse or fail again, or to continue to refuse or fail, to do that thing; and

(b) whether or not the person has previously refused or failed to do that thing; and

(c) whether or not there is an imminent danger of substantial damage to any other person if the person refuses or fails to do that thing.

42YR Other powers of court unaffected

The powers conferred on the Federal Court or Federal Circuit and Family Court of Australia (Division 2) under this Part are in addition to, and not instead of, any other powers of the court, whether conferred by this Act or otherwise.

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Part 5A-5—Enforceable directions

42YS Simplified outline of this Part

If the Secretary believes, on reasonable grounds, that:

(a) a person is not complying with this Act or an instrument made under this Act in relation to particular goods; and

(b) it is in the interests of public health or safety to give the person directions under this Part;

the Secretary may, by written notice, give directions to the person requiring the person to do specified things in relation to the goods within the period specified in the notice and at the person's own cost.

The person may commit an offence or be liable to a civil penalty if the person fails to comply with the notice.

42YT Secretary may give directions if this Act or an instrument is not being complied with

(1) This section applies if the Secretary believes, on reasonable grounds, that:

(a) a person is not complying with this Act or an instrument made under this Act in relation to particular goods; and

(b) it is in the interests of public health or safety to give the person directions under this section.

(2) The Secretary may, by written notice, give directions to the person requiring the person to do any of the following, within the period specified in the notice and at the person's own cost:

(a) relabel, or label, the goods;

(b) repackage the goods;

(c) destroy or otherwise dispose of the goods;

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(d) deliver the goods to a specified person to be destroyed or otherwise disposed of in an appropriate manner;

(e) any other thing prescribed by the regulations in relation to the goods.

Note: For variation and revocation of the directions, see subsection 33(3) of the *Acts Interpretation Act 1901*.

(2A) A notice given under subsection (2) must set out the Secretary's reasons for giving the notice.

(3) A period specified in a notice given under subsection (2) must be reasonable having regard to the circumstances.

Offence

(4) A person commits an offence if:

(a) the person is given a notice under subsection (2); and

(b) the person fails to comply with the notice within the period specified in the notice.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Civil penalty provision

(5) A person contravenes this subsection if:

(a) the person is given a notice under subsection (2); and

(b) the person fails to comply with the notice within the period specified in the notice.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

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Chapter 6—Administration

Part 6-1—Payment of charges

43 By whom charges payable

(1) An annual registration charge, annual listing charge or annual charge for inclusion in the Register is payable by the person in relation to whom the therapeutic goods concerned are registered, listed or included in the Register.

(2) An annual licensing charge is payable by the holder of the licence to which the charge relates.

(3) An annual conformity assessment body determination charge is payable by the Australian corporation that is the subject of the conformity assessment body determination to which the charge relates.

44 Time for payment of charges

Annual registration charge, annual listing charge or annual charge for inclusion in the Register

(1) An annual registration charge, annual listing charge or annual charge for inclusion in the Register for a financial year becomes payable:

(a) if the registration, listing or inclusion in the Register of the therapeutic goods concerned commenced in that financial year—on the day worked out under the regulations; and

(b) in any other case:

(i) on 1 October in that year; or

(ii) if the regulations specify another day for the purposes of this subparagraph—on that other day in that year.

This subsection is subject to subsection (3).

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Annual licensing charge

(2) An annual licensing charge for a financial year becomes payable:

(a) if the licence commenced in that financial year—on the day of that commencement; and

(b) in any other case:

(i) on 1 October in that year; or

(ii) if the regulations specify another day for the purposes of this subparagraph—on that other day in that year.

This subsection is subject to subsection (3).

Annual conformity assessment body determination charge

(2A) An annual conformity assessment body determination charge for a financial year becomes payable:

(a) if the conformity assessment body determination was made in that financial year—on the 28th day after the determination came into force; and

(b) in any other case:

(i) on 1 October in that year; or

(ii) if the regulations specify another day for the purposes of this subparagraph—on that other day in that year.

This subsection is subject to subsection (3).

Charge may become payable on a later day

(3) The Secretary may, by notice in writing given to a person, specify a later day on which a charge referred to in subsection (1), (2) or (2A) becomes payable by the person for a financial year. The notice has effect accordingly.

Interpretation

(4) This section is subject to section 44A.

44A Exemptions from liability to pay charges

(1) The regulations may make provision for and in relation to:

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(a) exempting a person from liability to pay annual registration charge, annual listing charge or annual charge for inclusion in the Register for a financial year (the ***current year***) if the person's turnover of the therapeutic goods concerned for the financial year specified in the regulations is of low value; and

(b) the making of an application for an exemption and requiring payment of that charge for the current year if the application is refused; and

(c) cancelling an exemption and requiring payment of that charge for the current year.

Fees

(2) The regulations may require applications for exemptions to be accompanied by a specified fee. A fee must not be such as to amount to taxation.

Statements prepared by approved persons

(3) The regulations may require a person who is applying for an exemption, or who has been granted an exemption, to provide a statement:

(a) that is prepared by an approved person; and

(b) that specifies whether the person's turnover of the therapeutic goods concerned for the financial year concerned is of low value.

Additional information

(4) The regulations may provide for the obtaining of additional information or documents from applicants for exemptions or persons granted exemptions.

Merits review

(5) The regulations may provide for review by the Administrative Review Tribunal of decisions of the Secretary to refuse applications for exemptions or to cancel exemptions.

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No limit on subsection (1)

(6) Subsections (2) to (5) do not limit subsection (1).

Low value turnover

(7) For the purposes of this section, the regulations may specify when a person's turnover of therapeutic goods for a financial year is of low value. The regulations may specify different rules for different therapeutic goods.

Interpretation

(8) This section does not limit paragraph 63(3)(b) (about the refund, reduction or waiving of fees or charges).

Definitions

(9) In this section:

approved person means a person included in a class of persons specified in regulations made for the purposes of this definition.

turnover has the meaning prescribed by the regulations.

44B Recovery of unpaid charges

An amount of an annual registration charge, an annual listing charge, an annual charge for inclusion in the Register, an annual licensing charge or an annual conformity assessment body determination charge that remains unpaid at the end of the period of 28 days after the day on which the charge becomes payable may be recovered by the Commonwealth as a debt due to the Commonwealth.

Note: Section 44 sets out the day on which a charge becomes payable.

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45 Therapeutic Goods Administration Account

(1) There is continued in existence the Therapeutic Goods Administration Account.

Note: The Account was established by subsection 5(3) of the *Financial Management Legislation Amendment Act 1999*.

(2) The Account is a special account for the purposes of the *Public Governance, Performance and Accountability Act 2013*.

(3) There must be credited to the Account amounts equal to:

(a) amounts received by the Commonwealth by way of annual registration charge, annual listing charge, annual charge for inclusion in the Register, annual licensing charge and annual conformity assessment body determination charge; and

(b) interest received by the Commonwealth from the investment of an amount standing to the credit of the Account; and

(c) money received by the Commonwealth in relation to property paid for after a debit from the Account; and

(d) money received by the Commonwealth for services provided or to be provided, by or on behalf of the Commonwealth, using amounts standing to the credit of the Account (including amounts received by way of fees payable under the regulations); and

(e) donations for the furtherance of a purpose of the Account that are received by the Commonwealth; and

(f) receipts relating to the recovery of debts (other than debts in respect of statutory fines and penalties) by the Commonwealth that are associated with expenditure of an amount standing to the credit of the Account.

Note: An Appropriation Act provides for amounts to be credited to a special account if any of the purposes of the special account is a purpose that is covered by an item in the Appropriation Act.

(4) The purposes of the Account are to make payments:

(a) to further the objects of this Act (as set out in section 4); and

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(b) to enable the Commonwealth to participate in the international harmonisation of regulatory controls on therapeutic goods and other related activities.

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Part 6-1A—Information gathering powers

Division 1—Preliminary

45AA Simplified outline of this Part

The Secretary can gather information or documents that are relevant to a contravention or possible contravention of this Act or the regulations.

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Division 2—Obtaining information or documents

45AB Secretary may require information or documents

(1) The Secretary may, by written notice given to a person, require the person to give to the Secretary any information, or produce to the Secretary any documents, specified in the notice that are relevant to a contravention, or possible contravention, of a provision of this Act or the regulations.

(2) The notice must specify a reasonable period within which the person must comply with the notice. The period must be at least 14 days starting on the day on which the notice is given.

(3) The notice must set out the effect of the following:
  (a) section 45AC (about failure to comply with notice);
  (b) section 45AD (about giving false or misleading information or documents);
  (c) section 137.1 of the *Criminal Code* (about giving false or misleading information);
  (d) section 137.2 of the *Criminal Code* (about producing false or misleading documents).

(4) The notice may require the information to be given, or the documents to be produced, in accordance with specified software requirements:
  (a) on a specified kind of data processing device; or
  (b) by way of a specified kind of electronic transmission.

45AC Offences for failing to comply with notice

Fault-based offence

(1) A person commits an offence if:
  (a) the person is given a notice under section 45AB; and
  (b) the person fails to comply with the notice.

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Penalty: 500 penalty units.

Strict liability offence

(2) A person commits an offence of strict liability if:
(a) the person is given a notice under section 45AB; and
(b) the person fails to comply with the notice.

Penalty: 100 penalty units.

Exception

(3) Subsection (1) or (2) does not apply if the person has a reasonable excuse.

Note: A defendant bears an evidential burden in relation to the matter in subsection (3): see subsection 13.3(3) of the *Criminal Code*.

45AD Offences and civil penalty for giving false or misleading information or documents

Fault-based offence

(1) A person commits an offence if:
(a) the person is given a notice under section 45AB; and
(b) the person gives information, or produces a document, in compliance or purported compliance with the notice; and
(c) the information or document is false or misleading in a material particular.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Strict liability offence

(2) A person commits an offence of strict liability if:
(a) the person is given a notice under section 45AB; and

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(b) the person gives information, or produces a document, in compliance or purported compliance with the notice; and
(c) the information or document is false or misleading in a material particular.

Penalty: 100 penalty units.

Civil penalty provision

(3) A person contravenes this subsection if:
(a) the person is given a notice under section 45AB; and
(b) the person gives information, or produces a document, in compliance or purported compliance with the notice; and
(c) the information or document is false or misleading in a material particular.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

45AE Self-incrimination

(1) An individual is not excused from giving information or producing a document under section 45AB on the ground that giving the information or producing the document might tend to incriminate the individual in relation to an offence.

Note: A body corporate is not entitled to claim the privilege against self-incrimination.

(2) However:
(a) the information given or document produced; and
(b) the giving of the information or the production of the document; and
(c) any information, document or thing obtained as a direct or indirect consequence of the giving of the information or the production of the document;

are not admissible in evidence against the individual in criminal proceedings other than proceedings for an offence against:

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(d) subsection 45AC(1) or (2); or

(e) subsection 45AD(1) or (2); or

(f) section 137.1 or 137.2 of the *Criminal Code* in relation to giving the information or producing the document.

(3) If, at general law, an individual would otherwise be able to claim the privilege against self-exposure to a penalty (other than a penalty for an offence) in relation to giving information or producing a document under section 45AB, the individual is not excused from giving the information or producing the document under that provision on that ground.

Note: A body corporate is not entitled to claim the privilege against self-exposure to a penalty.

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Division 3—Inspecting, copying and retaining documents

45AF Secretary may inspect and copy documents

The Secretary may inspect a document produced under section 45AB and make and retain copies of the whole or a part of the document.

45AG Secretary may retain documents

Retention of documents

(1) The Secretary may take possession of a document produced under section 45AB and retain it for as long as is reasonably necessary.

Certified copy of documents

(2) The person otherwise entitled to possession of a document produced under section 45AB is entitled to be supplied, as soon as practicable, with a copy certified by the Secretary to be a true copy.

(3) The certified copy must be received in all courts and tribunals as evidence as if it were the original.

(4) Until a certified copy is supplied, the Secretary must provide the person otherwise entitled to possession of the document, or a person authorised by that person, reasonable access to the document for the purposes of inspecting and making copies of the whole or a part of the document.

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Part 6-2—Entry, searches and warrants

45A Definitions

In this Part, unless the contrary intention appears:

evidential material means:

(a) in respect of an offence against this Act:

(i) any thing with respect to which the offence has been committed or is suspected, on reasonable grounds, to have been committed; or

(ii) any thing as to which there are reasonable grounds for suspecting that it will afford evidence as to the commission of the offence; or

(iii) any thing as to which there are reasonable grounds for suspecting that it is intended to be used for the purpose of committing the offence; and

(b) in respect of a contravention of a civil penalty provision:

(i) any thing with respect to which the civil penalty provision has been contravened or is suspected, on reasonable grounds, of having been contravened; or

(ii) any thing as to which there are reasonable grounds for suspecting that it will afford evidence as to the contravention of the civil penalty provision; or

(iii) any thing as to which there are reasonable grounds for suspecting that it is intended to be used for the purpose of contravening the civil penalty provision.

occupier, in relation to premises, includes a person present at the premises who is in apparent control of the premises.

person assisting, in relation to an authorised person: see subsection 48AAA(2).

seize includes secure against interference.

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thing includes a substance, and a thing in electronic or magnetic form.

46 Searches to monitor compliance with Act or regulations

(1) Subject to subsections (2) and (3), an authorised person may, for the purpose of finding out whether this Act or the regulations have been complied with:
  (a) enter any premises; and
  (b) exercise the powers set out in subsection 48(1) and section 48BA.

(2) The authorised person must not enter the premises unless:
  (a) the occupier of the premises has consented to the entry; or
  (b) the entry is made under a warrant issued under section 49.

(3) An authorised person is not entitled to exercise any powers under subsection (1) in relation to premises if:
  (a) the occupier of the premises has required the authorised person to produce his or her identity card for inspection by the occupier; and
  (b) the authorised person fails to comply with the requirement.

46A Searches of certain premises to monitor compliance with Act

(1) An authorised person may, subject to subsections (2) and (3), and to the extent that it is reasonably necessary for the purpose of finding out whether this Act or the regulations have been complied with, enter premises to which this section applies and do any of the following:
  (a) search the premises and any thing on the premises;
  (aa) examine or observe any activity conducted on the premises;
  (b) inspect, examine, take measurements of, conduct tests on or take samples of any therapeutic goods or vaping goods on the premises or any thing on the premises that relates to any therapeutic goods or vaping goods;

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(c) make any still or moving image or any recording of the premises or any thing on the premises;
(d) inspect any book, record or document on the premises;
(e) take extracts from or make copies of any such book, record or document.

(2) An authorised person must not, under subsection (1), enter premises that are a residence unless:
(a) the occupier of the premises has consented to the entry; or
(b) the premises are used for commercial purposes in relation to therapeutic goods or vaping goods, in addition to residential purposes.

(3) An authorised person is not entitled to exercise any powers under subsection (1) in relation to premises if:
(a) the occupier of the premises has required the authorised person to produce his or her identity card for inspection by the occupier; and
(b) the authorised person fails to comply with the requirement.

(4) This section applies to:
(a) premises of a person:
(iaa) who is required to comply with a condition of an exemption of vaping goods under section 18 or 41HA; or
(ia) who is required to comply with a condition of an exemption of therapeutic goods under section 18A; or
(i) who has been granted an approval or authority under subsection 19(1) or (5); or
(ii) who has been granted an approval under section 19A; or
(iiaaa) who is required to comply with a condition of an exemption of biologicals under section 32CB; or
(iiaab) who has been granted an approval under subsection 32CK(1) or an authority under subsection 32CM(1); or
(iiaac) who has been granted an approval under subsection 32CO(1), (1A) or (2); or

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(iiaa) who is required to comply with a condition of an exemption of a kind of medical device under section 41GS; or

(iia) who has been granted an approval or authority under subsection 41HB(1) or 41HC(1); or

(iib) who has been granted an approval under subsection 41HD(1), (1A) or (2); or

(iii) in relation to whom therapeutic goods are registered, listed or included in the Register;

being premises connected with:

(iv) the importation, export, manufacture or supply of therapeutic goods; or

(v) the keeping of documents relating to the importation, export, manufacture or supply of therapeutic goods; or

(vi) the keeping of records in compliance with a condition under paragraph 28(5)(c) or (ca) or 32EC(2)(c); and

(b) premises to which the person in relation to whom therapeutic goods are registered, listed or included in the Register, or the sponsor of the goods, must allow access as a condition of the registration, listing or inclusion; and

(c) premises in relation to which a licence has been granted under Part 3-3 for, or a conformity assessment certificate issued under Part 4-4, in relation to the manufacture of therapeutic goods, or premises at which records are kept in relation to such manufacture; and

(d) premises of a person who has been issued with, or who has applied for, an Australian conformity assessment body certificate.

46B Searches and seizures on public health grounds

(1) Subject to subsection (2), if an authorised person has reasonable grounds for suspecting that:

(a) there may be on any premises a particular thing in respect of which this Act or the regulations have not been complied with; and

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(b) it is necessary in the interests of public health to exercise powers under this section in order to avoid an imminent risk of death, serious illness or serious injury;

the authorised person may, to the extent that it is reasonably necessary for the purpose of avoiding an imminent risk of death, serious illness or serious injury, enter the premises and do any of the following:

(c) search the premises for the thing;

(d) if the authorised person finds the thing on the premises—seize it.

(2) An authorised person is not entitled to exercise any powers under subsection (1) in relation to premises if:

(a) the occupier of the premises has required the authorised person to produce his or her identity card for inspection by the occupier; and

(b) the authorised person fails to comply with the requirement.

47 Searches and seizures related to offences and civil penalty provisions

(1) Subject to subsections (2) and (3), if an authorised person has reasonable grounds for suspecting that there may be evidential material in respect of an offence against this Act, in respect of a contravention of a civil penalty provision or in respect of both on any premises, the authorised person may:

(a) enter the premises; and

(b) exercise the powers set out in subsection (4), subsection 48(1) and section 48C; and

(c) if the authorised person finds the thing on the premises—seize it.

(2) The authorised person must not enter the premises unless:

(a) the occupier of the premises has consented to the entry; or

(b) the entry is made under a warrant issued under section 50.

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(3) An authorised person is not entitled to exercise any powers under subsection (1) in relation to premises if:

(a) the occupier of the premises has required the authorised person to produce his or her identity card for inspection by the occupier; and

(b) the authorised person fails to comply with the requirement.

(4) If:

(a) in the course of searching, in accordance with a warrant, for a particular thing, an authorised person finds another thing that the authorised person believes on reasonable grounds to be evidential material in respect of an offence against this Act, in respect of a contravention of a civil penalty provision or in respect of both; and

(b) the authorised person believes, on reasonable grounds, that it is necessary to seize that other thing in order to prevent its concealment, loss or destruction, or its use:

(i) in committing, continuing or repeating an offence against this Act; or

(ii) in committing, continuing or repeating a contravention of a civil penalty provision;

the warrant is taken to authorise the authorised person to seize that other thing.

48 General powers of authorised persons in relation to premises

(1) The powers an authorised person may exercise under paragraphs 46(1)(b) and 47(1)(b) are as follows:

(a) to search the premises and any thing on the premises;

(aa) to examine or observe any activity conducted on the premises;

(b) to inspect, examine, take measurements of, conduct tests on or take samples of any therapeutic goods or vaping goods on the premises or any thing on the premises that relates to any therapeutic goods or vaping goods;

(c) to make any still or moving image or any recording of the premises or any thing on the premises;

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(d) if the authorised person was only authorised to enter the premises because the occupier of the premises consented to the entry—to require the occupier to:
  (i) answer any questions put by the authorised person; and
  (ii) produce any book, record or document requested by the authorised person;
(e) if the authorised person was authorised to enter the premises by a warrant under section 49 or 50—to require any person in or on the premises to:
  (i) answer any questions put by the authorised person; and
  (ii) produce any book, record or document requested by the authorised person;
(f) to inspect any book, record or document on the premises;
(g) to take extracts from or make copies of any such book, record or document;
(h) to take onto the premises such equipment and materials as the authorised person requires for the purpose of exercising powers in relation to the premises.

(3) A person must not refuse or fail to comply with a requirement under paragraph (1)(e).

Penalty: 30 penalty units.

(3A) Subsection (3) does not apply if the person has a reasonable excuse.

Note: The defendant bears an evidential burden in relation to the matter in subsection (3A). See subsection 13.3(3) of the *Criminal Code*.

(4) It is a reasonable excuse for a person to refuse or fail to answer a question or produce a document if answering the question, or producing the document, would tend to incriminate the person.

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48AAA Persons assisting authorised persons

Authorised persons may be assisted by other persons

(1) An authorised person may be assisted by other persons in exercising powers or performing functions or duties under this Part, if that assistance is necessary and reasonable.

(2) A person providing such assistance is a ***person assisting*** an authorised person.

Powers, functions and duties of a person assisting

(3) A person assisting an authorised person:
  (a) may enter premises; and
  (b) may exercise the powers and perform the functions or duties that an authorised person may exercise or perform under this Part; and
  (c) must do so only in accordance with a direction given to the person assisting by the authorised person.

(4) A power exercised by a person assisting an authorised person as mentioned in subsection (3) is taken for all purposes to have been exercised by the authorised person.

(5) A function or duty performed by a person assisting an authorised person as mentioned in subsection (3) is taken for all purposes to have been performed by the authorised person.

(6) If a direction is given under paragraph (3)(c) in writing, the direction is not a legislative instrument.

48A Details of warrant to be given to occupier etc.

(1) If a warrant in relation to premises is being executed and the occupier of the premises or another person who apparently represents the occupier is present at the premises, the authorised person must make available to that person a copy of the warrant.

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(2) The authorised person must identify himself or herself to that person.

(3) The copy of the warrant referred to in subsection (1) need not include the signature of the issuing officer who issued the warrant.

48AA Completing execution of warrant under section 50 after temporary cessation

(1) This section applies if all authorised persons, and all persons assisting the authorised persons, who are executing a warrant under section 50 in relation to premises temporarily cease its execution and leave the premises.

(2) One or more of the authorised persons, and the persons assisting the authorised persons, may complete the execution of the warrant if:

(a) the warrant is still in force; and

(b) the authorised persons, and the persons assisting the authorised persons, are absent from the premises:

(i) for not more than 1 hour; or

(ii) if there is an emergency situation, for not more than 12 hours or such longer period as allowed by an issuing officer under subsection (5); or

(iii) for a longer period if the occupier of the premises consents in writing.

Application for extension in emergency situation

(3) An authorised person, or a person assisting the authorised person, may apply to an issuing officer for an extension of the 12-hour period mentioned in subparagraph (2)(b)(ii) if:

(a) there is an emergency situation; and

(b) the authorised person or person assisting the authorised person believes on reasonable grounds that the authorised person or person assisting the authorised person will not be able to return to the premises within that period.

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(4) If it is practicable to do so, before making the application, the authorised person or person assisting the authorised person must give notice to the occupier of the premises of his or her intention to apply for an extension.

Extension in emergency situation

(5) An issuing officer may extend the period during which the authorised person may be away from the premises if:
  (a) an application is made under subsection (3); and
  (b) the issuing officer is satisfied, by information on oath or affirmation, that there are exceptional circumstances that justify the extension; and
  (c) the extension would not result in the period ending after the warrant ceases to be in force.

48B Announcement before entry

(1) An authorised person must, before entering the premises under a warrant:
  (a) announce that he or she is authorised to enter the premises; and
  (b) give any person at the premises an opportunity to allow entry to the premises.

(2) An authorised person is not required to comply with subsection (1) if he or she believes on reasonable grounds that immediate entry to the premises is required to ensure:
  (a) the safety of a person; or
  (b) that the effective execution of the warrant is not frustrated.

48BA Use of electronic equipment at premises for monitoring compliance with Act or regulations

(1) An authorised person may operate electronic equipment at the premises to see whether information relevant to determining whether this Act or the regulations have been complied with is accessible by doing so.

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(2) If the authorised person, after operating the equipment, finds that information relevant to determining whether this Act or the regulations have been complied with is accessible by doing so, he or she may:

(a) operate electronic equipment on the premises to put the information in documentary form and remove the documents so produced from the premises; or

(b) operate electronic equipment on the premises to transfer the information to a disk, tape or other storage device that:

(i) is brought to the premises for the exercise of the power; or

(ii) is on the premises and the use of which for that purpose has been agreed in writing by the occupier of the premises;

and remove the disk, tape or other storage device from the premises.

(3) An authorised person may operate electronic equipment as mentioned in subsection (1) or (2) only if the authorised person believes on reasonable grounds that the operation of the equipment can be carried out without damage to the equipment.

Note: For compensation for damage to electronic equipment, see section 48D.

(4) If the authorised person believes on reasonable grounds that:

(a) information relevant to determining whether this Act or the regulations have been complied with may be accessible by operating electronic equipment at the premises; and

(b) expert assistance is required to operate the equipment; and

(c) if he or she does not take action under this subsection, the information may be destroyed, altered or otherwise interfered with;

he or she may do whatever is necessary to secure the equipment, whether by locking it up, placing a guard or otherwise.

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(5) The authorised person must give notice to the occupier of the premises of his or her intention to secure equipment and of the fact that the equipment may be secured for up to 24 hours.

(6) The equipment may be secured:
  (a) for a period not exceeding 24 hours; or
  (b) until the equipment has been operated by the expert;
whichever happens first.

(7) The authorised person may apply to an issuing officer for an extension of the 24-hour period if the authorised person believes on reasonable grounds that the equipment needs to be secured for longer than that period.

(8) The authorised person must give notice to the occupier of the premises of his or her intention to apply for an extension, and the occupier is entitled to be heard in relation to the application.

(9) The 24-hour period may be extended more than once.

48C Use of electronic equipment at premises relating to offences and civil penalty provisions

(1) An authorised person may operate electronic equipment at the premises to see whether evidential material in respect of an offence against this Act, in respect of a contravention of a civil penalty provision or in respect of both is accessible by doing so.

(2) If the authorised person, after operating the equipment, finds that evidential material in respect of an offence against this Act, in respect of a contravention of a civil penalty provision or in respect of both is accessible by doing so, he or she may:
  (a) seize the equipment and any disk, tape or other associated device; or
  (b) operate electronic equipment on the premises to put the evidential material in documentary form and remove the documents so produced from the premises; or
  (c) operate electronic equipment on the premises to transfer the evidential material to a disk, tape or other storage device that:

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(i) is brought to the premises for the exercise of the power; or

(ii) is on the premises and the use of which for that purpose has been agreed in writing by the occupier of the premises;

and remove the disk, tape or other storage device from the premises.

(2A) An authorised person may operate electronic equipment as mentioned in subsection (1) or (2) only if the authorised person believes on reasonable grounds that the operation of the equipment can be carried out without damage to the equipment.

Note: For compensation for damage to electronic equipment, see section 48D.

(3) An authorised person may seize equipment under paragraph (2)(a) only if:

(a) it is not practicable to put the material in documentary form as mentioned in paragraph (2)(b) or to transfer the material as mentioned in paragraph (2)(c); or

(b) possession by the occupier of the equipment could constitute an offence.

(4) If the authorised person believes on reasonable grounds that:

(a) evidential material in respect of an offence against this Act, in respect of a contravention of a civil penalty provision or in respect of both may be accessible by operating electronic equipment at the premises; and

(b) expert assistance is required to operate the equipment; and

(c) if he or she does not take action under this subsection, the material may be destroyed, altered or otherwise interfered with;

he or she may do whatever is necessary to secure the equipment, whether by locking it up, placing a guard or otherwise.

(5) The authorised person must give notice to the occupier of the premises of his or her intention to secure equipment and of the fact that the equipment may be secured for up to 24 hours.

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(6) The equipment may be secured:
  (a) for a period not exceeding 24 hours; or
  (b) until the equipment has been operated by the expert;
whichever happens first.

(7) The authorised person may apply to an issuing officer for an extension of the 24-hour period if the authorised person believes on reasonable grounds that the equipment needs to be secured for longer than that period.

(8) The authorised person must give notice to the occupier of the premises of his or her intention to apply for an extension, and the occupier is entitled to be heard in relation to the application.

(9) The 24-hour period may be extended more than once.

48D Compensation for damage to electronic equipment

(1) If:
  (a) damage is caused to equipment as a result of it being operated as mentioned in section 48BA or 48C; and
  (b) the damage was caused as a result of:
    (i) insufficient care being exercised in selecting the person who was to operate the equipment; or
    (ii) insufficient care being exercised by the person operating the equipment;
compensation for the damage is payable to the owner of the equipment.

(2) Compensation is payable out of money appropriated by the Parliament for the purpose.

(3) In determining the amount of compensation payable, regard is to be had to whether the occupier of the premises and his or her employees and agents, if they were available at the time, had provided any warning or guidance as to the operation of the equipment that was appropriate in the circumstances.

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48E Copies of seized things to be provided

(1) Subject to subsection (2), if an authorised person seizes, under a warrant relating to premises:

(a) a document, film, computer file or other thing that can be readily copied; or

(b) a storage device the information in which can be readily copied;

the authorised person must, if requested to do so by the occupier of the premises or another person who apparently represents the occupier and who is present when the warrant is executed, give a copy of the thing or the information to that person as soon as practicable after the seizure.

(2) Subsection (1) does not apply if possession of the document, film, computer file, thing or information by the occupier could constitute an offence against a law of the Commonwealth or contravention of a civil penalty provision.

48F Occupier entitled to be present during search

(1) If a warrant in relation to premises is being executed and the occupier of the premises or another person who apparently represents the occupier is present at the premises, the person is entitled to observe the search being conducted.

(2) The right to observe the search being conducted ceases if the person impedes the search.

(3) This section does not prevent 2 or more areas of the premises being searched at the same time.

48FA Responsibility to provide facilities and assistance

(1) The occupier of premises to which a warrant relates, or another person who apparently represents the occupier, must provide:

(a) an authorised person executing the warrant; and

(b) any person assisting the authorised person;

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with all reasonable facilities and assistance for the effective exercise of the powers of both the authorised person and the person assisting the authorised person.

(2) A person commits an offence if:
(a) the person is subject to subsection (1); and
(b) the person fails to comply with that subsection.

Penalty for contravention of this subsection: 30 penalty units.

48G Receipts for things seized under warrant

(1) If a thing is seized under this Part, the authorised person must provide a receipt for the thing.

(2) If 2 or more things are seized or moved, they may be covered in the one receipt.

48H Retention of seized things

(1) Subject to any contrary order of a court, if an authorised person seizes a thing under this Part, an authorised person must return it if:
(a) the reason for its seizure no longer exists or it is decided that it is not to be used in evidence; or
(b) the period of 120 days after its seizure ends;
whichever first occurs, unless the thing is forfeited or forfeitable to the Commonwealth.

(2) At the end of the 120 days specified in subsection (1), an authorised person must take reasonable steps to return the thing to the person from whom it was seized, unless:
(a) proceedings in respect of which the thing may afford evidence were instituted before the end of the 120 days and have not been completed (including an appeal to a court in relation to those proceedings); or
(b) an authorised person may retain the thing because of an order under section 48J; or

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(c) an authorised person is otherwise authorised (by a law, or an order of a court, of the Commonwealth or of a State or Territory) to retain, destroy or dispose of the thing.

(3) The thing may be returned under subsection (2) either unconditionally or on such terms and conditions as the Secretary sees fit.

Note: This section does not apply in relation to the thing if section 52AAB applies in relation to the thing: see subsection 52AAB(2).

48J Issuing officer may permit a thing to be retained

(1) An authorised person may apply to an issuing officer for an order that he or she may retain the thing for a further period if:

(a) before the end of 120 days after the seizure; or

(b) before the end of a period previously specified in an order of an issuing officer under this section;

proceedings in respect of which the thing may afford evidence have not commenced.

(2) If the issuing officer is satisfied that it is necessary for an authorised person to continue to retain the thing:

(a) for the purposes of an investigation as to whether an offence against this Act has been committed; or

(b) to enable evidence of an offence against this Act to be secured for the purposes of a prosecution; or

(c) for the purposes of an investigation as to whether a civil penalty provision has been contravened; or

(d) to enable evidence of a contravention of a civil penalty provision to be secured for the purposes of civil proceedings;

the issuing officer may order that an authorised person may retain the thing for a period (not being a period exceeding 3 years) specified in the order.

(3) Before making the application, the authorised person must:

(a) take reasonable steps to discover who has an interest in the retention of the thing; and

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(b) if it is practicable to do so, notify each person whom the authorised person believes to have such an interest of the proposed application.

Note: This section does not apply in relation to the thing if section 52AAB applies in relation to the thing: see subsection 52AAB(2).

49 Monitoring warrants

(1) An authorised person may apply to an issuing officer for a warrant under this section in relation to premises.

(2) Subject to subsection (3), the issuing officer may issue the warrant if the issuing officer is satisfied, by information on oath, that it is reasonably necessary that one or more authorised persons should have access to the premises for the purposes of finding out whether this Act or the regulations have been complied with.

(3) The issuing officer must not issue the warrant unless the authorised person or some other person has given to the issuing officer, either orally or by affidavit, such further information (if any) as the issuing officer requires concerning the grounds on which the issue of the warrant is being sought.

(4) The warrant must:
(a) authorise one or more authorised persons (whether or not named in the warrant), with such assistance and by such force as is necessary and reasonable:
(i) to enter the premises; and
(ii) to exercise the powers set out in subsection 48(1) and section 48BA in relation to the premises; and
(b) state whether the entry is authorised to be made at any time of the day or night or during specified hours of the day or night; and
(c) specify the day (not more than 6 months after the issue of the warrant) on which the warrant ceases to have effect; and
(d) state the purpose for which the warrant is issued.

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50 Offence and civil penalty provision related warrants

(1) An authorised person may apply to an issuing officer for a warrant under this section in relation to premises.

(2) Subject to subsection (3), the issuing officer may issue the warrant if the issuing officer is satisfied, by information on oath, that there are reasonable grounds for suspecting that there is, or there may be within the next 72 hours, in or on the premises evidential material in respect of an offence against this Act, in respect of a contravention of a civil penalty provision or in respect of both.

(3) The issuing officer must not issue the warrant unless the authorised person or some other person has given to the issuing officer, either orally or by affidavit, such further information (if any) as the issuing officer requires concerning the grounds on which the issue of the warrant is being sought.

(4) The warrant must:

(a) name one or more authorised persons; and

(b) authorise the persons so named, with such assistance and by such force as is necessary and reasonable:

(i) to enter the premises; and

(ii) to exercise the powers set out in subsections 47(4) and 48(1) and section 48C; and

(iii) to seize the evidential material; and

(c) state whether the entry is authorised to be made at any time of the day or night or during specified hours of the day or night; and

(d) specify the day (not more than one week after the issue of the warrant) on which the warrant ceases to have effect; and

(e) state the purpose for which the warrant is issued.

51 Offence and civil penalty provision related warrants by telephone

(1) If, in an urgent case, an authorised person considers it necessary to do so, the person may apply to an issuing officer by telephone for a warrant under section 50 in relation to premises.

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(2) Before applying for the warrant, the person must prepare an information of the kind mentioned in subsection 50(2) in relation to the premises that sets out the grounds on which the warrant is sought.

(3) If it is necessary to do so, the person may apply for the warrant before the information is sworn.

(4) If the issuing officer is satisfied:

(a) after having considered the terms of the information; and

(b) after having received such further information (if any) as the issuing officer requires concerning the grounds on which the issue of the warrant is being sought;

that there are reasonable grounds for issuing the warrant, the issuing officer may complete and sign the same warrant that the issuing officer would issue under section 50 if the application had been made under that section.

(5) If the issuing officer completes and signs the warrant:

(a) the issuing officer must:

(i) tell the authorised person what the terms of the warrant are; and

(ii) tell the authorised person the day on which and the time at which the warrant was signed; and

(iii) tell the authorised person the day (not more than one week after the issuing officer completes and signs the warrant) on which the warrant ceases to have effect; and

(iv) record on the warrant the reasons for granting the warrant; and

(b) the authorised person must:

(i) complete a form of warrant in the same terms as the warrant completed and signed by the issuing officer; and

(ii) write on the form the name of the issuing officer and the day on which and the time at which the warrant was signed.

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(6) The authorised person must also, not later than the day after the day of expiry or execution of the warrant, whichever is the earlier, send to the issuing officer:
  (a) the form of warrant completed by the person; and
  (b) the information referred to in subsection (2), which must have been duly sworn.

(7) When the issuing officer receives those documents, the issuing officer must:
  (a) attach them to the warrant that the issuing officer completed and signed; and
  (b) deal with them in the way in which the issuing officer would have dealt with the information if the application had been made under section 50.

(8) A form of warrant duly completed under subsection (5) is authority for any entry, search, seizure or other exercise of a power that the warrant signed by the issuing officer authorises.

(9) If:
  (a) it is material, in any proceedings, for a court to be satisfied that an exercise of a power was authorised by this section; and
  (b) the warrant signed by the issuing officer authorising the exercise of the power is not produced in evidence;

the court must assume, unless the contrary is proved, that the exercise of the power was not authorised by such a warrant.

(10) A reference in this Part to a warrant under section 50 includes a reference to a warrant signed by an issuing officer under this section.

51A Inspections for purposes of Mutual Recognition Convention

(1) A person may request the Secretary to arrange for an authorised person to inspect premises, and specified processes being carried out on those premises, for the purposes of paragraph 2 of Article 3 of the Mutual Recognition Convention.

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(2) An authorised person may make an inspection in accordance with arrangements under subsection (1).

51B Offences relating to warrants

(1) A person must not make, in an application for a warrant, a statement that the person knows to be false or misleading in a material particular.

Penalty: Imprisonment for 2 years.

(2) A person must not:

(a) state in a document that purports to be a form of warrant under section 51 the name of an issuing officer unless that issuing officer issued the warrant; or

(b) state on a form of warrant under that section a matter that, to the person's knowledge, departs in a material particular from the form authorised by the issuing officer; or

(c) purport to execute, or present to another person, a document that purports to be a form of warrant under that section that the first-mentioned person knows:

(i) has not been approved by an issuing officer under that section; or

(ii) to depart in a material particular from the terms authorised by an issuing officer under that section; or

(d) give to an issuing officer a form of warrant under that section that is not the form of warrant that the person purported to execute.

Penalty: Imprisonment for 2 years.

51C Issuing officers—personal capacity

Powers conferred personally

(1) A power conferred on an issuing officer by this Part is conferred on the issuing officer:

(a) in a personal capacity; and

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(b) not as a court, or as a member or an officer of a court.

Powers need not be accepted

(2) The issuing officer need not accept the power conferred.

Protection and immunity

(3) An issuing officer exercising a power conferred by this Part has the same protection and immunity as if the issuing officer were exercising the power:

(a) as the court of which the issuing officer is a member or an officer; or

(b) as a member or an officer of the court of which the issuing officer is a member or an officer.

52 Identity cards

(1) The Secretary is to ensure that each authorised person is issued with an identity card that incorporates a recent photograph of the person.

(3) Where a person ceases to be an authorised person, the person must, as soon as practicable after so ceasing, return the person's identity card to the Secretary.

Penalty: 1 penalty unit.

(4) An offence under subsection (3) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

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Part 6-2A—Forfeiture of things seized

52AAA Forfeiture of things seized in certain circumstances

(1) If:

(a) an authorised person seizes a thing under Part 6-2; and

(b) the Secretary believes, on reasonable grounds, that:

(i) the thing has been imported, manufactured or supplied in contravention of this Act or an instrument made under this Act; or

(ii) the thing has been in the possession, custody or control of a person in contravention of this Act or an instrument made under this Act; or

(iii) a requirement under this Act, or an instrument made under this Act, has not been complied with in relation to the thing;

the thing is forfeited to the Commonwealth.

Notice of forfeiture

(2) The Secretary must give a written notice (a ***forfeiture notice***) in accordance with subsection (3) to:

(a) the owner of the thing; or

(b) if the owner cannot be identified after reasonable inquiry—the person who had possession, custody or control of the thing immediately before it was seized.

(3) The forfeiture notice must identify the thing and state the following:

(a) the day the thing was seized;

(b) the provision of Part 6-2 under which the thing was seized and the grounds on which the thing was seized;

(c) that the thing is forfeited to the Commonwealth;

(d) that the owner of the thing, or the person who had possession, custody or control of the thing immediately

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before it was seized, may, within 2 months beginning on the day the forfeiture notice is given, commence proceedings against the Commonwealth in a court of competent jurisdiction for a declaration that the thing is not forfeited to the Commonwealth.

Proceedings may be commenced for declaration that thing is not forfeited to the Commonwealth

(4) The owner of the thing, or the person who had possession, custody or control of the thing immediately before it was seized, may, subject to subsection (5), commence proceedings in a court of competent jurisdiction for a declaration that the thing is not forfeited to the Commonwealth.

(5) Proceedings:

(a) may be commenced under subsection (4) even if the forfeiture notice required to be given under subsection (2) in relation to the thing has not yet been given; and

(b) may only be commenced before the end of the period of 2 months beginning on the day the forfeiture notice is given.

Secretary may retain or dispose of forfeited thing

(6) If:

(a) the owner of the thing, or the person who had possession, custody or control of the thing immediately before it was seized, does not, within the period of 2 months beginning on the day the forfeiture notice was given, commence proceedings against the Commonwealth for a declaration that the thing is not forfeited to the Commonwealth; or

(b) the owner of the thing, or the person who had possession, custody or control of the thing immediately before it was seized, commences such proceedings within that 2 month period, but at the end of the proceedings (including an appeal to a court in relation to the proceedings), the court has not made a declaration that the thing is not forfeited to the Commonwealth;

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then:

(c) the thing is condemned as forfeited to the Commonwealth; and

(d) the Secretary may cause notice of the forfeiture of the thing to be published on the Department's website; and

(e) the Secretary may:

(i) retain the thing for the purpose of proceedings in respect of which the thing may afford evidence; or

(ii) cause the thing to be disposed of in such manner as the Secretary directs.

Note: See also section 54 (offences and forfeiture).

52AAB Return or retention of thing declared not to be forfeited to the Commonwealth

(1) This section applies in relation to a thing if:

(a) the thing was forfeited to the Commonwealth under subsection 52AAA(1); and

(b) a court has made a declaration that the thing is not forfeited to the Commonwealth under that subsection.

(2) Sections 48H and 48J do not apply in relation to the thing.

(3) At the end of 120 days after the declaration referred to in paragraph (1)(b) was made, an authorised person must take reasonable steps to return the thing to the person from whom it was seized unless:

(a) proceedings in respect of which the thing may afford evidence were commenced before the end of the 120 days and have not been completed (including an appeal to a court in relation to those proceedings); or

(b) an authorised person may retain the thing because of an order under subsection (6); or

(c) an authorised person is otherwise authorised (by a law, or an order of a court, of the Commonwealth or of a State or Territory) to retain, destroy or dispose of the thing.

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(4) The thing may be returned under subsection (3) either unconditionally or on such terms and conditions as the Secretary sees fit.

(5) The Secretary may apply to an issuing officer for an order that an authorised person may retain the thing for a further period. The application must be made:

(a) before the end of 120 days after the declaration referred to in paragraph (1)(b) was made; or

(b) if an order has been made under subsection (6)—before the end of the period specified in the most recent order made under that subsection.

(6) If the issuing officer is satisfied that it is necessary for an authorised person to continue to retain the thing:

(a) for the purposes of an investigation as to whether an offence against this Act has been committed; or

(b) to enable evidence of an offence against this Act to be secured for the purposes of a prosecution; or

(c) for the purposes of an investigation as to whether a civil penalty provision has been contravened; or

(d) to enable evidence of a contravention of a civil penalty provision to be secured for the purposes of civil proceedings;

the issuing officer may order that an authorised person may retain the thing for a period (not exceeding 3 years) specified in the order.

(7) Before making an application under subsection (5), the Secretary must:

(a) take reasonable steps to discover who has an interest in the retention of the thing; and

(b) if it is practicable to do so, notify each person who the Secretary believes to have such an interest of the proposed application.

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Part 6-3—Scheduling of substances

52AA Overview

This Part provides the basis for a uniform system in Australia of access controls for goods containing scheduled substances.

The scheduling of substances allows restrictions to be placed on their supply to the public, in the interests of public health and safety. This is aimed at minimising the risks of poisoning from, and the misuse and abuse of, scheduled substances.

52A Definitions

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

current Poisons Standard means:

(a) if no document has been prepared under paragraph 52D(2)(b)—the first Poisons Standard; or

(b) otherwise—the document last prepared under that paragraph (including as amended).

first Poisons Standard means the latest edition at the commencement of this Part of the document known as the *Standard for the Uniform Scheduling of Drugs and Poisons* published by the Australian Health Ministers' Advisory Council.

scheduling, in relation to a substance, means determining the schedule or schedules to the current Poisons Standard in which the name or a description of the substance is to be included.

substance means:

(a) an ingredient, compound, material or preparation which, or the use of which, may cause death, illness or injury to persons or animals; or

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(b) an ingredient, compound, material or preparation specified under subsection (2);

and includes any ingredient, compound, material or preparation referred to in a schedule to the current Poisons Standard (as in force immediately before 1 July 2010).

(2) The Secretary may, by legislative instrument, specify an ingredient, compound, material or preparation for the purposes of paragraph (b) of the definition of ***substance*** in subsection (1).

Note: For specification by class, see subsection 13(3) of the *Legislation Act 2003*.

52B Advisory Committee on Medicines Scheduling

(1) The Advisory Committee on Medicines Scheduling is established by this section.

(2) Subject to subsection (3), the Committee is to be constituted, and to hold meetings, in accordance with the regulations.

(3) The Commonwealth, each State, the Australian Capital Territory and the Northern Territory are each entitled to nominate a member of the Committee in accordance with the regulations.

(4) The functions of the Committee are as follows:

(a) subject to subsection (5), to make recommendations to the Secretary in relation to the classification and scheduling of substances that are, or are included in, therapeutic goods;

(b) to make recommendations to the Secretary in relation to other changes to the current Poisons Standard (other than the schedules);

(c) to reconsider a recommendation made under paragraph (a) or (b) at the request of the Secretary;

(d) subject to subsection (5), to provide advice to the Secretary in relation to the restrictions (including restrictions as to accessibility and availability) to be imposed in respect of particular substances that are, or are included in, therapeutic goods;

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(e) to provide advice to the Secretary in relation to any matter referred to it by the Secretary;

(f) any other functions that are prescribed by the regulations.

(5) Paragraphs (4)(a) and (d) do not apply in relation to substances to the extent that the substances are included in goods other than therapeutic goods.

52C Advisory Committee on Chemicals Scheduling

(1) The Advisory Committee on Chemicals Scheduling is established by this section.

(2) Subject to subsection (3), the Committee is to be constituted, and to hold meetings, in accordance with the regulations.

(3) The Commonwealth, each State, the Australian Capital Territory and the Northern Territory are each entitled to nominate a member of the Committee in accordance with the regulations.

(4) The functions of the Committee are as follows:

(a) subject to subsection (5), to make recommendations to the Secretary in relation to the classification and scheduling of substances;

(b) to make recommendations to the Secretary in relation to other changes to the current Poisons Standard (other than the schedules);

(c) to reconsider a recommendation made under paragraph (a) or (b) at the request of the Secretary;

(d) subject to subsection (5), to provide advice to the Secretary in relation to the restrictions (including restrictions as to accessibility and availability) to be imposed in respect of particular substances;

(e) to provide advice to the Secretary in relation to any matter referred to it by the Secretary;

(f) any other functions that are prescribed by the regulations.

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(5) Paragraphs (4)(a) and (d) do not apply in relation to substances to the extent that the substances are, or are included in, therapeutic goods.

52CA Joint meetings

The Advisory Committee on Medicines Scheduling and the Advisory Committee on Chemicals Scheduling may hold joint meetings in accordance with the regulations.

52D Poisons Standard

(1) On the commencement of this Part, the first Poisons Standard is taken to have been prepared and made available by the then National Drugs and Poisons Schedule Committee.

(2) Subject to this Act and the regulations, the Secretary may:
(a) amend the current Poisons Standard; or
(b) prepare a document (including schedules containing the names or descriptions of substances or classes of substances), in substitution for the current Poisons Standard.

(3) The Secretary may exercise a power under subsection (2) on the Secretary's own initiative or following an application under section 52EAA.

(4A) An instrument made under paragraph (2)(a) or (b) after the commencement of this subsection is a legislative instrument, but section 42 (disallowance) of the *Legislation Act 2003* does not apply to the instrument.

(4B) Despite subsection 14(2) of the *Legislation Act 2003*, an instrument made under paragraph (2)(a) or (b) of this section may make provision in relation to a matter by applying, adopting or incorporating any matter contained in an instrument or other writing as in force or existing from time to time.

(5) In this section:

amend, in relation to the current Poisons Standard, means:

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(a) alter any provision (including a reference to a substance) in the current Poisons Standard; or
(b) omit any provision (including a reference to a substance) from the current Poisons Standard; or
(c) insert any provision (including a reference to a substance) in the current Poisons Standard.

52E Secretary to take certain matters into account in exercising powers

(1) In exercising a power under subsection 52D(2), the Secretary must take the following matters into account (where relevant):
(a) the risks and benefits of the use of a substance;
(b) the purposes for which a substance is to be used and the extent of use of a substance;
(c) the toxicity of a substance;
(d) the dosage, formulation, labelling, packaging and presentation of a substance;
(e) the potential for abuse of a substance;
(f) any other matters that the Secretary considers necessary to protect public health.

(2) In exercising a power under subsection 52D(2), the Secretary must comply with any guidelines of:
(a) the Australian Health Ministers' Advisory Council; and
(b) the subcommittee of the Council known as the National Coordinating Committee on Therapeutic Goods (or any replacement subcommittee);
notified to the Secretary for the purposes of this section.

(3) In exercising a power under subsection 52D(2), the Secretary must have regard to any recommendations or advice of the Advisory Committee on Medicines Scheduling or the Advisory Committee on Chemicals Scheduling.

(4) In exercising a power under subsection 52D(2), the Secretary may seek advice from either or both of the following:

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(a) any committee that the Secretary considers appropriate (whether or not the committee is established under this Act or the regulations);
(b) any person.

(5) Subsections (2) to (4) do not limit the information the Secretary may consider in exercising a power under subsection 52D(2).

52EAA Application for amendment of the Poisons Standard

(1) A person may apply to the Secretary for an amendment of the current Poisons Standard.

(2) An application under subsection (1) must:
(a) be made in accordance with a form approved by the Secretary; and
(b) set out the amendment sought; and
(c) be delivered to an office of the Department specified in the form; and
(d) be accompanied by the prescribed application fee.

Further information

(3) The Secretary may, by notice in writing given to the person, require the person to give to the Secretary, within such reasonable time as is specified in the notice, such further information concerning the application as is specified in the notice.

Applications or information may be given electronically

(4) An approval of a form mentioned in paragraph (2)(a), or a notice mentioned in subsection (3), may require or permit an application or information to be given in accordance with specified software requirements:
(a) on a specified kind of data processing device; or
(b) by way of a specified kind of electronic transmission.

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52F Incorporation of current Poisons Standard

(1) Despite subsection 14(2) of the *Legislation Act 2003*, a legislative instrument, or a notifiable instrument, under this Act may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in the current Poisons Standard as in force or existing from time to time.

(2) Despite subsection 46AA(2) of the *Acts Interpretation Act 1901*, an instrument under this Act (other than a legislative instrument or a notifiable instrument) may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in the current Poisons Standard as in force or existing from time to time.

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Chapter 7—Miscellaneous

52G Exemptions, approvals and authorities to be consistent with prohibitions under Chapter 2A

(1) If there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3), a thing referred to in subsection (3) of this section must not be made or given in relation to therapeutic goods or vaping goods the subject of those prohibitions.

(2) If there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions (the ***first conditions***), a thing referred to in subsection (3) of this section must not be made or given in relation to therapeutic goods or vaping goods the subject of those prohibitions unless the thing is made or given subject to conditions that are consistent with the first conditions.

(3) The things are the following:

(a) an exemption under subsection 18(1) or 18A(1);
(b) an approval under subsection 19(1);
(c) an authority under subsection 19(5);
(d) an authorisation under subsection 19(7A);
(e) an approval under subsection 19A(1), (1A), (2), (2A) or (2B);
(f) an exemption under section 32CA or 32CB;
(g) an approval under subsection 32CK(1);
(h) an authority under subsection 32CM(1);
(i) an authorisation under subsection 32CM(7A);
(j) an approval under subsection 32CO(1), (1A) or (2);
(k) an exemption under section 41GS or 41HA;
(l) an approval under subsection 41HB(1);
(m) an authority under subsection 41HC(1);
(n) an authorisation under subsection 41HC(6);

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(o) an approval under subsection 41HD(1), (1A) or (2);
(oa) an instrument under section 41R;
(ob) a consent under section 41RC;
(p) a variation of a thing mentioned in any of the above paragraphs.

53 Retention of material on withdrawal of application

Where a person withdraws an application for:
(a) registration; or
(b) listing; or
(baa) a recommendation by the Secretary that the Minister vary a section 26BB determination; or
(bab) a recommendation by the Secretary that the Minister vary a determination under section 26BF; or
(ba) inclusion of a biological in the Register; or
(c) a conformity assessment certificate; or
(d) inclusion of a kind of medical device in the Register; or
(e) a licence;
the Department may retain the application and any material submitted in connection with the application.

53A Alternative verdicts for various offences

If a jury acquits a person of an offence against a provision listed in column 2 of an item in the following table, but is satisfied beyond reasonable doubt of facts that prove that the person is guilty of the offence listed in column 3 of that item, the jury may convict the person of the offence listed in column 3 of that item:

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Alternative verdicts for various offences		
Column 1	**Column 2**	**Column 3**
Item	**If a prosecution is for an offence against...**	**the jury may instead convict the person of an offence against...**
1A	subsection 9G(1)	subsection 9G(4)
1	subsection 14(1)	subsection 14(4)
2	subsection 14(6)	subsection 14(9)
3	subsection 14(10)	subsection 14(13)
4	subsection 15(2)	subsection 15(5)
5	subsection 19B(1)	subsection 19B(4)
6	subsection 21A(1)	subsection 21A(4)
7	subsection 21A(5)	subsection 21A(8)
8	subsection 21A(9)	subsection 21A(9A)
8A	subsection 21A(11A)	subsection 21A(11C)
9	subsection 21A(12)	subsection 21A(12A)
9A	subsection 22(2)	subsection 22(3)
9B	subsection 22(6)	subsection 22(7)
10	subsection 22A(1)	subsection 22A(4)
11	subsection 30EC(1)	subsection 30EC(4)
12	subsection 30F(4B)	subsection 30F(5)
13	subsection 31(5A)	subsection 31(6)
13A	subsection 32BA(1)	subsection 32BA(4)
13B	subsection 32BB(1)	subsection 32BB(4)
13C	subsection 32BC(1)	subsection 32BC(4)
13D	subsection 32BD(1)	subsection 32BD(4)
13E	subsection 32BI(1)	subsection 32BI(4)
13EA	subsection 32BJ(2A)	subsection 32BJ(2B)
13EB	subsection 32CJ(6)	subsection 32CJ(7)
13F	subsection 32CN(1)	subsection 32CN(4)
13FA	subsection 32CN(5)	subsection 32CN(7)

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Alternative verdicts for various offences		
Column 1	**Column 2**	**Column 3**
Item	**If a prosecution is for an offence against...**	**the jury may instead convict the person of an offence against...**
13FB	subsection 32CP(1)	subsection 32CP(2)
13G	subsection 32DO(1)	subsection 32DO(4)
13H	subsection 32EF(1)	subsection 32EF(4)
13J	subsection 32HC(1)	subsection 32HC(4)
13K	subsection 32JB(2)	subsection 32JB(5)
14	subsection 35(1)	subsection 35(4)
15	subsection 35(5)	subsection 35(9)
16	subsection 35B(1)	subsection 35B(4)
17	subsection 41EI(1)	subsection 41EI(4)
18	subsection 41FE(1)	subsection 41FE(4)
19	subsection 41JB(4)	subsection 41JB(7)
20	subsection 41KC(1)	subsection 41KC(4)
21	subsection 41MA(1)	subsection 41MA(4)
22	subsection 41MA(5)	subsection 41MA(8)
23	subsection 41MA(9)	subsection 41MA(12)
24	subsection 41MC(2)	subsection 41MC(5)
25	subsection 41ME(1)	subsection 41ME(4)
26	subsection 41ME(5)	subsection 41ME(8)
27	subsection 41MF(1)	subsection 41MF(2)
28	subsection 41MF(3)	subsection 41MF(4)
29	subsection 41MI(1)	subsection 41MI(4)
29A	subsection 41ML(1)	subsection 41ML(2)
30	subsection 41MN(1)	subsection 41MN(4)
31	subsection 41MN(5)	subsection 41MN(8)
31AA	subsection 41MN(9)	subsection 41MN(9A)
31A	subsection 41MN(10)	subsection 41MN(11)

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Alternative verdicts for various offences		
Column 1	**Column 2**	**Column 3**
Item	**If a prosecution is for an offence against...**	**the jury may instead convict the person of an offence against...**
32	subsection 41MO(1)	subsection 41MO(4)
32A	subsection 41MO(4A)	subsection 41MO(4C)
33	subsection 41MO(5)	subsection 41MO(8)
33AA	subsection 41RD(1)	subsection 41RD(2)
33A	subsection 42DL(1)	subsection 42DL(2)
33B	subsection 42DLA(1)	subsection 42DLA(2)
33C	subsection 42DM(1)	subsection 42DM(2)
33D	subsection 42DW(1)	subsection 42DW(2)
33E	subsection 42DZL(1)	subsection 42DZL(2)
34	subsection 42V(6)	subsection 42V(6C)

54 Offences and forfeiture

(3) If a court:

(a) convicts a person of an offence against this Act; or

(aa) makes an order under section 19B of the *Crimes Act 1914* in respect of a person charged with an offence against this Act; or

(b) orders a person to pay a pecuniary penalty for the contravention of a civil penalty provision;

in relation to any therapeutic goods or vaping goods, the court may order that the goods be forfeited to the Commonwealth and, if an order is made, the goods become the property of the Commonwealth.

(4) Where goods are so forfeited, the Secretary may cause notice of the forfeiture to be published in the *Gazette* or on the Department's website.

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(5) Goods forfeited under an order referred to in subsection (3) are to be disposed of in such manner as the Secretary directs.

Note: See also Part 6-2A, which provides for forfeiture of things seized in certain circumstances.

54AA Offences for contravening conditions or requirements imposed under the regulations

(1) If:

(a) a person holds a licence or a permission to import or export therapeutic goods; and

(b) the person engages in conduct; and

(c) the conduct breaches a condition or a requirement to which the licence or permission is subject under the regulations;

the person commits an offence punishable on conviction by a fine of no more than the number of penalty units specified in whichever of subsection (2) or (3) applies.

(1A) In subsection (1):

engage in conduct means:

(a) do an act; or

(b) omit to perform an act.

(2) If:

(a) the condition or requirement relates to the possession, custody, transport, use or disposal of the goods; or

(b) the regulation providing for the condition or requirement states that the purpose of the condition or requirement is to protect the safety of the public;

the number of penalty units for the contravention is 240 penalty units.

(3) If subsection (2) does not apply, the number of penalty units for the contravention is 50 penalty units.

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54AB Criminal offence for damaging etc. documents

(1) A person commits an offence if:

(a) the person damages, destroys, alters, conceals or falsifies a document; and

(b) the document is created, retained or issued for the purposes of this Act, or for purposes that include the purposes of this Act.

Penalty: 7 years imprisonment or 2,000 penalty units, or both.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(2) Strict liability applies to paragraph (1)(b).

Note: For strict liability, see section 6.1 of the *Criminal Code*.

54AC Civil penalty for damaging etc. documents

A person contravenes this section if:

(a) the person damages, destroys, alters, conceals or falsifies a document; and

(b) the document is created, retained or issued for the purposes of this Act, or for purposes that include the purposes of this Act; and

(c) the damage, destruction, alteration, concealment or falsification is likely to interfere with the proper administration of this Act or the regulations.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

54A Time for bringing prosecutions

A prosecution for an offence against this Act may be commenced at any time within 3 years after the commission of the offence.

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54B Personal liability of an executive officer of a body corporate—general

(1) An executive officer of a body corporate commits an offence if:

(a) the body corporate commits an offence against this Act covered by section 54BA; and

(b) the officer knew that the offence would be committed; and

(c) the officer was in a position to influence the conduct of the body in relation to the commission of the offence; and

(d) the officer failed to take all reasonable steps to prevent the commission of the offence.

Note: An offence against this Act includes an offence against the regulations: see subsection 3(7).

(2) The maximum penalty for an offence against subsection (1) is:

(a) the maximum penalty that a court could impose in respect of an individual for the offence committed by the body corporate; or

(b) if the offence committed by the body corporate is an offence against subsection 41MN(10)—imprisonment for 5 years or 4,000 penalty units, or both.

(3) An executive officer of a body corporate contravenes this subsection if:

(a) the body corporate contravenes a civil penalty provision; and

(b) the officer knew that the contravention would occur; and

(c) the officer was in a position to influence the conduct of the body in relation to the contravention; and

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

(4) The maximum civil penalty for a contravention of subsection (3) is:

(a) the maximum civil penalty that a court could impose in respect of an individual for the civil penalty provision contravened by the body corporate; or

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(b) if the civil penalty provision contravened by the body corporate is subsection 41MNA(3)—5,000 penalty units.

(5) In this section:

executive officer of a body corporate means a person, by whatever name called and whether or not a director of the body, who is concerned in, or takes part in, the management of the body.

54BA Personal liability of an executive officer of a body corporate—offences covered

For the purposes of paragraph 54B(1)(a), this section covers offences against:

(a) the provisions of this Act listed in the following table; and

(b) a provision of a regulation prescribed for the purpose of this paragraph; and

(c) section 6 of the *Crimes Act 1914*, or section 11.1, 11.4 or 11.5 of the *Criminal Code*, in relation to an offence mentioned in paragraph (a) or (b) of this subsection; and

(d) section 136.1, 137.1 or 137.2 of the *Criminal Code* in relation to this Act or a regulation.

Corporate offences for which executive officers may be personally liable

Item	Provisions of this Act
1	Subsection 9G(1)
2	Subsection 14(1), (6) or (10)
3	Subsection 15(2)
4	Subsection 19B(1)
4A	Subsection 21A(1) or (5)
5	Subsection 22(2), (6) or (7AB)
6	Subsection 22A(1)
7	Subsection 29A(1)
8	Subsection 29B(3) or (4)
9	Subsection 30EC(1)

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Corporate offences for which executive officers may be personally liable	
Item	**Provisions of this Act**
10	Subsection 30F(4B)
11	Subsection 31(5A)
12	Subsection 31D(1)
13	Subsection 31E(1)
14	Subsection 32BA(1)
15	Subsection 32BB(1)
16	Subsection 32BC(1)
17	Subsection 32BD(1)
17A	Subsection 32BJ(2A)
18	Subsection 32CP(1)
19	Subsection 32CJ(6)
20	Subsection 32DO(1)
21	Subsection 32DQ(1)
22	Subsection 32DR(3) or (4)
23	Subsection 32EF(1)
24	Subsection 32HC(1)
25	Subsection 32JB(2)
26	Subsection 32JI(2)
27	Subsection 35(1) or (5)
27AA	Subsection 35B(1)
27A	Subsection 41AD(1)
27B	Subsection 41AE(1)
28	Subsection 41EI(1)
29	Subsection 41FE(1)
30	Subsection 41JB(4)
31	Subsection 41JH(1)
32	Subsection 41JI(1)
33	Subsection 41KC(1)
34	Subsection 41MA(1), (5) or (9)

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Corporate offences for which executive officers may be personally liable	
Item	**Provisions of this Act**
35	Subsection 41MC(2)
36	Subsection 41ME(1) or (5)
37	Subsection 41MF(1) or (3)
38	Section 41MH
39	Subsection 41MI(1)
39A	Subsection 41ML(1)
40	Subsection 41MN(1), (5), (9) or (10)
41	Subsection 41MNB(1)
42	Subsection 41MP(1)
43	Subsection 41MQ(3) or (4)
43AA	Subsection 41Q(1)
43AB	Subsection 41QA(1)
43AC	Subsection 41QB(1)
43AD	Subsection 41QC(1), (4) or (7)
43AE	Subsection 41QD(1)
43AF	Subsection 41RD(1)
43A	Subsection 42DL(1)
43B	Subsection 42DLA(1)
43C	Subsection 42DM(1)
43D	Subsection 42DW(1)
43E	Subsection 42DZD(1)
43F	Subsection 42DZL(1)
44	Subsection 42E(1)
45	Subsection 42T(1) or (2)
46	Subsection 42V(6)
47	Subsection 42W(1) or (2)
47A	Subsection 45AD(1)
48	Subsection 54AB(1)

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54C Establishing whether an executive officer took reasonable steps to prevent the commission of an offence or the contravention of a civil penalty provision

(1) For the purposes of section 54B, in determining whether an executive officer of a body corporate failed to take all reasonable steps to prevent the commission of the offence or the contravention of a civil penalty provision, a court is to have regard to:

(a) what action (if any) the officer took towards ensuring that the body's employees, agents and contractors have a reasonable knowledge and understanding of the requirements to comply with this Act and the regulations, in so far as those requirements affect the employees, agents or contractors concerned; and

(b) what action (if any) the officer took when he or she became aware that the body was committing an offence against, or otherwise contravening, this Act or the regulations.

(2) This section does not, by implication, limit the generality of section 54B.

(3) In this section, ***executive officer*** has the same meaning as in section 54B.

55 Conduct by directors, employees and agents

(1) Where, in proceedings for an offence against this Act, or for a contravention of a civil penalty provision, it is necessary to establish the state of mind of a body corporate in relation to particular conduct, it is sufficient to show:

(a) that the conduct was engaged in by a director, employee or agent of the body corporate within the scope of his or her actual or apparent authority; and

(b) that the director, employee or agent had the state of mind.

(2) Any conduct engaged in on behalf of a body corporate by a director, employee or agent of the body corporate within the scope of his or her actual or apparent authority is to be taken, for the

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purposes of a prosecution for an offence against this Act, or for a contravention of a civil penalty provision, to have been engaged in also by the body corporate unless the body corporate establishes that the body corporate took reasonable precautions and exercised due diligence to avoid the conduct.

(3) Where, in proceedings for an offence against this Act, or for a contravention of a civil penalty provision, it is necessary to establish the state of mind of a person other than a body corporate in relation to particular conduct, it is sufficient to show that:

(a) the conduct was engaged in by an employee or agent of the person within the scope of his or her actual or apparent authority; and

(b) the employee or agent had the state of mind.

(4) Any conduct engaged in on behalf of a person other than a body corporate (in this subsection called the ***employer***) by an employee or agent of the employer within the scope of his or her actual or apparent authority is to be taken, for the purposes of a prosecution for an offence against this Act, or for a contravention of a civil penalty provision, to have been engaged in also by the employer unless the employer establishes that he or she took reasonable precautions and exercised due diligence to avoid the conduct.

(5) Where:

(a) a person other than a body corporate is convicted of an offence; and

(b) the person would not have been convicted of the offence if subsections (3) and (4) had not been enacted;

the person is not liable to be punished by imprisonment for that offence.

(6) A reference in subsection (1) or (3) to the state of mind of a person includes a reference to:

(a) the knowledge, intention, opinion, belief or purpose of the person; and

(b) the person's reasons for the intention, opinion, belief or purpose.

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(7) A reference in this section to a director of a body corporate includes a reference to a constituent member of a body corporate incorporated for a public purpose by a law of the Commonwealth, of a State or of a Territory.

(8) A reference in this section to engaging in conduct includes a reference to failing or refusing to engage in conduct.

56 Judicial notice

All courts (except in proceedings under Chapter 4) are to take judicial notice of the British Pharmacopoeia, the European Pharmacopoeia, the United States Pharmacopeia-National Formulary, a homoeopathic pharmacopoeia and an anthroposophic pharmacopoeia.

56A Certificates to provide evidence of certain matters

(1) The Secretary or a person authorised in writing by him or her to give certificates under this section may certify in writing that, at a specified time, or at all times during a specified period:

(a) there was no exemption in effect under section 18 or 18A in relation to particular therapeutic goods; or

(aaaa) a person was not exempt under subsection 32CA(1) in relation to a particular biological or there was no exemption under subsection 32CA(2) in relation to a particular biological; or

(aaab) there was no exemption in effect under section 32CB in relation to a particular biological; or

(aaa) there was no exemption in force under section 41GS in relation to a particular kind of medical device; or

(aa) particular medical devices were not exempt devices;

(b) there was no approval under subsection 19(1) or authority under subsection 19(5) granted to a particular person in relation to particular therapeutic goods; or

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(baa) there was no approval under subsection 32CK(1) or authority under subsection 32CM(1) granted to a particular person in relation to a particular biological; or

(ba) there was no approval or authority in effect under section 41HB or subsection 41HC(1) granted to a particular person in relation to particular medical devices;

(bb) there was no approval under subsection 41HD(1), (1A) or (2) granted to a particular person in relation to particular medical devices; or

(c) there was no approval under section 19A granted to a particular person in relation to particular therapeutic goods; or

(ca) there was no approval under subsection 32CO(1), (1A) or (2) granted to a particular person in relation to a particular biological; or

(d) particular therapeutic goods were or were not included in the Register as registered goods; or

(da) particular therapeutic goods were or were not included in the Register as provisionally registered goods; or

(e) particular therapeutic goods were or were not included in the Register as listed goods; or

(eaa) a particular biological was or was not included in the Register; or

(ea) particular medical devices were or were not medical devices of a kind included in the Register; or

(eb) particular medical devices were suspended from the Register; or

(f) particular therapeutic goods were included in the Register subject to conditions including those specified in the certificate; or

(g) the registration, listing or inclusion in the Register of the particular therapeutic goods had been suspended or cancelled; or

(h) there was no declaration under section 7 which applied to particular therapeutic goods; or

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(ha) there was no determination under section 7AA which applied to particular goods; or

(i) a person was or was not the holder of a licence in force under Part 3-3; or

(j) the licence is subject to conditions including those specified in the certificate; or

(k) there was no exemption in effect under subsection 34(1) that applied to particular therapeutic goods or a particular class of therapeutic goods; or

(l) there was no exemption in effect under subsection 34(2) that applied to a particular person in relation to one or more of the following:

(i) the manufacture of particular therapeutic goods;

(ii) a particular step in the manufacture of particular therapeutic goods;

(iii) the manufacture of a particular class of therapeutic goods;

(iv) a particular step in the manufacture of a particular class of therapeutic goods; or

(la) there was no conformity assessment body determination in force in respect of a particular Australian corporation; or

(lb) a conformity assessment body determination was in force in respect of a particular Australian corporation and the determination:

(i) was of general application; or

(ii) was limited to the extent specified in the certificate; or

(m) a conformity assessment certificate has been issued relating to a particular kind of medical device; or

(n) a conformity assessment certificate was subject to conditions including those specified in the certificate under this section; or

(o) a conformity assessment certificate was suspended.

(2) A certificate under subsection (1) may relate to more than one of the matters referred to in paragraphs (1)(a) to (o).

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(3) In proceedings for an offence against this Act or a contravention of a civil penalty provision, a certificate under subsection (1) is prima facie evidence of the matters specified in the certificate.

(4) In proceedings for:

(a) an offence against section 14 or 41MA; or

(b) the contravention of section 14A or 41MAA (civil penalty provisions);

a certificate by the Secretary to the effect that:

(c) the Secretary did not consent to the importation, supply or exportation that is the subject of the proceedings; or

(d) the Secretary consented to that importation, supply or exportation subject to conditions specified in the certificate;

is prima facie evidence of the matters specified in the certificate.

(4A) In proceedings for the contravention of subsection 19D(3) or (4) or 32BF(6) (civil penalty provisions), a certificate by the Secretary, to the effect that the Secretary did not consent to the importation or supply that is the subject of the proceedings, is prima facie evidence of the matters specified in the certificate.

(4B) In proceedings for:

(a) an offence against a provision of section 41QA, 41QB, 41QC or 41QD; or

(b) the contravention of subsection 41QA(3), 41QB(3), 41QC(10) or 41QD(4) (civil penalty provisions);

a certificate by the Secretary to the effect that:

(c) the Secretary did not consent to the manufacture, supply or possession that is the subject of the proceedings; or

(d) the Secretary consented to that manufacture, supply or possession subject to conditions specified in the certificate;

is prima facie evidence of the matters specified in the certificate.

(5) In proceedings for an offence against this Act or a contravention of a civil penalty provision, a document purporting to be a certificate given under this section is, unless the contrary is proved, taken to be such a certificate and to have been duly given.

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57 Delegation

(1) Subject to subsections (2), (6) and (8) to (11), the Minister or the Secretary may, by signed instrument, delegate to:

(a) an officer of the Department; or

(b) an officer of an authority of the Commonwealth that has functions in relation to therapeutic goods; or

(ba) an APS employee in an Agency (within the meaning of the *Public Service Act 1999*) that has functions in relation to therapeutic goods; or

(c) a person occupying or acting in an office, or holding an appointment, declared by the regulations to be an office or appointment the occupant or holder of which may be a delegate under this section; or

(d) a person seconded to the Department from:

(i) an authority of a State or a Territory that has functions relating to therapeutic goods, health or law enforcement; or

(ii) a national regulatory authority of a foreign country that has national responsibility relating to therapeutic goods, health or law enforcement; or

(iii) an international organisation that has a function relating to therapeutic goods, health or law enforcement;

all or any of his or her powers and functions under this Act.

(1A) The Secretary may, by signed instrument, delegate all or any of the Secretary's powers and functions under Chapter 5A (enforcement), section 45AB (Secretary may require information or documents), section 45AF (Secretary may inspect and copy documents), section 45AG (Secretary may retain documents), section 52AAA (forfeiture of things seized) or section 52AAB (return or retention of thing declared not to be forfeited) to an officer of:

(a) a Department of State of a State; or

(b) a Department or administrative unit of the Public Service of a Territory; or

(c) an authority of a State or of a Territory;

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being a Department, unit or authority that has functions relating to therapeutic goods, health or law enforcement. This subsection does not limit subsection (1).

(2) The powers of the Secretary under paragraph 19(1)(a), 32CK(1)(d) or 41HB(1)(d) may be delegated under subsection (1) only to a person referred to in paragraph (1)(a) or (c) who is registered, or eligible for registration, in a State or internal Territory, as a medical or dental practitioner or as a pharmacist.

(3) Subject to the regulations, the Secretary may, in such circumstances as are prescribed, by signed instrument, delegate all or any of his or her powers under paragraph 19(1)(a), 32CK(1)(d) or 41HB(1)(d) to a person who is registered, in a State or internal Territory, as a medical or dental practitioner.

(4) A delegate under subsection (3) is, in the exercise of a delegated power, subject to the directions of:

(a) the Secretary; or

(b) an officer of the Department authorised in writing by the Secretary; or

(c) a person referred to in paragraph (1)(c).

(5) Without limiting the generality of matters that may be dealt with by regulations made for the purposes of subsection (3), the regulations may make provision in relation to the following:

(a) the persons who may be delegates;

(b) the circumstances in which delegates may grant approvals for the purposes of paragraph 19(1)(a), 32CK(1)(d) or 41HB(1)(d);

(c) the conditions to which any approvals granted by delegates are to be subject;

(d) requiring information to be given by delegates to the Secretary.

(5A) The powers of the Secretary under subsection 19(5) may be delegated only to a person referred to in paragraph (1)(a) or (c) of this section who is registered, or eligible for registration, in a State

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or internal Territory as a medical or dental practitioner or as a pharmacist.

(6) The powers of the Secretary under subsection 32CM(1) or 41HC(1) may be delegated only to a person referred to in paragraph (1)(a) or (c) who is registered, or eligible for registration, in a State or internal Territory as a medical or dental practitioner.

(7) The regulations may prescribe the circumstances in which, and the requirements subject to which, delegates may grant authorities under subsection 19(5), 32CM(1) or 41HC(1).

(8) The powers of the Secretary under section 19A or 32CO may be delegated only to a person who holds, occupies or performs the duties of a position in the Department prescribed by the regulations.

(9) The powers of the Secretary under section 41HD may be delegated only to a person who holds, occupies or performs the duties of a position in the Department prescribed by the regulations.

(10) The power of the Minister under subsection 18A(1) or 41P(3) may be delegated only to:

(a) the Secretary; or

(b) an SES employee who holds, or performs the duties of, an SES Band 3 position in the Department; or

(c) a person who is registered, in a State or internal Territory, as a medical practitioner and who holds, or performs the duties of, a position that is equivalent to, or higher than, an SES Band 2 position in the Department.

(10AA) The power of the Minister under subsection 30EK(1) may be delegated only to:

(a) the Secretary; or

(b) an SES employee, or acting SES employee, in the Department; or

(c) a person who is registered, in a State or internal Territory, as a medical practitioner and who holds, or performs the duties

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of, a position that is equivalent to, or higher than, an SES Band 2 position in the Department.

(10A) The power of the Minister under subsection 32CB(1) may be delegated only to:

(a) the Secretary; or

(b) an SES employee who holds, or performs the duties of, an SES Band 3 position in the Department; or

(c) a person who is registered, in a State or internal Territory, as a medical practitioner and who holds, or performs the duties of, a position that is equivalent to, or higher than, an SES Band 2 position in the Department.

(11) The power of the Minister under subsection 41GS(1) may be delegated only to:

(a) the Secretary; or

(b) an SES employee who holds, or performs the duties of, an SES Band 3 position in the Department; or

(c) a person who is registered, in a State or internal Territory, as a medical practitioner and who holds, or performs the duties of, a position that is equivalent to, or higher than, an SES Band 2 position in the Department.

Delegate must comply with directions

(12) In performing any functions or exercising any powers under a delegation under this section, the delegate must comply with any directions of the person who delegated the function or power.

58 Export certifications

(1) The Secretary may issue export certification for goods for therapeutic use in humans, including certifications for the purposes of the World Health Organisation Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

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(2) A State or Territory must not issue export certifications for goods for therapeutic use in humans.

(2A) The Secretary may issue export certification for vaping goods for use in humans that are not goods for which export certification may be issued under subsection (1).

Note: Export certification for vaping goods that are for therapeutic use in humans may be issued under subsection (1).

(2B) A State or Territory must not issue export certifications for vaping goods for which export certification may be issued under subsection (2A).

(3) Such fee as is prescribed is payable in respect of:

(a) an application for a certification under this section; and

(b) where an inspection of a manufacturing site is necessary for the purposes of the issue of a certification under this section—the inspection of that site.

59 Fees

(1) No fees are payable under this Act in respect of an event occurring before 1 July 1990.

(2) Fees prescribed under this Act must not be such as to amount to taxation.

60 Review of decisions

(1) In this section and section 60A:

decision has the same meaning as in the *Administrative Review Tribunal Act 2024*.

initial decision means a decision of the Secretary or of a delegate of the Secretary:

(aa) under subsection 7C(3); or

(ab) under section 9C, 9D or 9F; or

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(b) refusing to grant, or imposing conditions on a grant of, a consent under section 14 or 14A; or

(c) under Part 3-2 (registration and listing of therapeutic goods), other than a decision under paragraph 26BE(4)(a), or a decision under subsection 26BJ(8), to make a recommendation; or

(ca) under Part 3-2A (Biologicals); or

(d) under Part 3-3 (manufacturing of therapeutic goods); or

(e) under Part 4-4 (conformity assessment certificates); or

(f) under Part 4-5 (including medical devices in the Register), other than:

(i) a decision under section 41FH (selecting applications for auditing); or

(ii) a decision about which aspects of the matters referred to in paragraphs 41FI(1)(a) and (b) to consider in auditing an application under Subdivision C of Division 1 of Part 4-5; or

(g) under Part 4-6 (suspension and cancellation from the Register); or

(h) under Part 4-7 (exempting medical devices from inclusion in the Register); or

(j) under Part 4-9 (public notification and recovery of medical devices); or

(k) refusing to grant, or imposing conditions on a grant of, a consent for the purposes of section 41MA or 41MAA (non-compliance with essential principles); or

(ka) refusing to give a consent under subsection 41RC(1), or giving such a consent subject to conditions imposed under subsection 41RC(2); or

(l) under section 42DF, 42DH or 42DI or subsection 42DV(1) or (2); or

(m) under subsection 42DZK(1) or (2); or

(n) to give directions under subsection 42YT(2).

reviewable decision means a decision of the Minister under subsection (3).

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(1AA) A decision under a provision of this Act to give a notice to a person requiring the person to give information, or give or produce documents, to the Secretary is not an initial decision for the purposes of this section.

(1A) For the avoidance of doubt, the following are not initial decisions for the purposes of this section or section 60A:

(aaa) the giving of advice under section 22G;

(aa) a preliminary assessment under section 23B, 26BD, 32DDA or 41FDB;

(a) a proposal to suspend a conformity assessment certificate under section 41EM;

(b) a proposal to revoke a conformity assessment certificate under section 41ET;

(c) a proposal to suspend a kind of medical device from the Register under section 41GA;

(d) a proposal to cancel the entry of a kind of medical device on the Register under section 41GN.

(2) Subject to this section, a person whose interests are affected by an initial decision may, by notice in writing given to the Minister:

(a) if this Act requires the person to be given notice in writing of the decision, or of particulars of the decision—within 90 days after the notice is given to the person; or

(b) otherwise—within 90 days after the earlier of:

(i) notice of the decision, or of particulars of the decision, being published in the *Gazette* or on the Department's website; and

(ii) the decision first coming to the person's notice;

request the Minister to reconsider the decision.

(2A) A request under subsection (2) may be accompanied by information in support of the request.

(2AA) If the Secretary or a delegate of the Secretary makes a decision under subsection 9D(1A) or (1B) to vary an entry in the Register in relation to a medicine, a person is not entitled to request the

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Minister to reconsider the decision unless the person is the person in relation to whom the medicine is registered.

(2AB) If the Secretary or a delegate of the Secretary:

(a) makes a decision under section 22D in relation to an application under section 22C; or

(b) makes a decision under section 22E in relation to an application under subsection 22E(3); or

(d) makes a decision under subsection 25(3) in relation to an application for provisional registration of a medicine;

a person is not entitled to request the Minister to reconsider the decision unless the person made the application.

(2AC) If the Secretary or a delegate of the Secretary makes a decision under section 22F to revoke a provisional determination under section 22D, a person is not entitled to request the Minister to reconsider the decision unless the person made the application for that provisional determination.

(2B) If the Secretary or a delegate of the Secretary decides, under paragraph 26BE(4)(b), to refuse to make a recommendation, a person is not entitled to request the Minister to reconsider the decision unless the person made an application under subsection 26BD(1) for the recommendation.

(2C) If the Secretary or a delegate of the Secretary decides, under subsection 26BJ(8), to refuse to make a recommendation, a person is not entitled to request the Minister to reconsider the decision unless the person made an application under subsection 26BJ(1) for the recommendation.

(2D) If the Secretary or a delegate of the Secretary:

(a) makes a decision under subsection 29(6) or (6A) in relation to an application under subsection 29(4); or

(b) makes a decision under subsection 29(9) to end, or extend, the provisional registration period for a medicine;

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a person is not entitled to request the Minister to reconsider the decision unless the person is the person in relation to whom the medicine is provisionally registered.

(2E) If the Secretary or a delegate of the Secretary makes a decision to give directions under subsection 42YT(2), a person is not entitled to request the Minister to reconsider the decision unless the person is the person to whom the directions were given.

(3) Subject to paragraph 60A(2)(b), the Minister must, as soon as practicable after receiving a request under subsection (2), reconsider the initial decision and, as a result of that reconsideration, may:

(a) confirm the initial decision; or

(b) revoke the initial decision, or revoke that decision and make a decision in substitution for the initial decision.

(3A) Subject to subsection 60A(2), in reconsidering the initial decision:

(a) the Minister must take into account any information referred to in subsection (2A); and

(b) the Minister must not take into account any other information provided by, or on behalf of, the person after the making of the request, other than:

(i) information provided in response to a request from the Minister; or

(ii) information that indicates that the quality, safety or efficacy of therapeutic goods is unacceptable.

(3B) Paragraph (3A)(a) does not limit the information the Minister may take into account in reconsidering the initial decision.

(3C) If, under paragraph (3)(b), the Minister revokes an initial decision and makes a decision in substitution for the initial decision then the substituted decision:

(a) is taken to be a decision of the Secretary (except for the purpose of any review of the substituted decision); and

(b) has effect, or is taken to have had effect, on and from the date determined by the Minister.

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(4) Where a person who has made a request under subsection (2) does not receive notice of the decision of the Minister on reconsideration, or (if applicable) notice that the matter has been remitted under paragraph 60A(2)(b), within 60 days of the making of the request, the Minister is taken to have confirmed under subsection (3) the initial decision.

(5) After reconsideration of an initial decision, the Minister must give the applicant a notice in writing stating the result of the reconsideration and that the applicant may apply for a statement setting out the reasons for the decision on reconsideration in accordance with section 268 of the *Administrative Review Tribunal Act 2024* and may, subject to that Act, make an application to the Administrative Review Tribunal for review of that decision.

(5A) If:

(a) the initial decision is one the particulars of which are required to be published in the *Gazette* or on the Department's website; and

(b) the Minister revokes the initial decision;

the Secretary must, as soon as practicable after the revocation, cause to be published in the *Gazette*, or on the Department's website, a notice setting out particulars of the revocation.

(5B) If:

(a) the initial decision is one the particulars of which are required to be published in the *Gazette* or on the Department's website; and

(b) the Minister revokes the initial decision and makes a decision (the ***substituted decision***) in substitution for the initial decision;

the Secretary must, as soon as practicable after the substituted decision is made, cause to be published in the *Gazette*, or on the Department's website, a notice setting out particulars of the substituted decision.

(6) Where written notice of the making of an initial decision is given to a person whose interests are affected by the decision, the notice

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is to include a statement to the effect that a person whose interests are affected by the decision may:

(a) seek a reconsideration of the decision under this section; and

(b) subject to the *Administrative Review Tribunal Act 2024*, if the person is dissatisfied with the decision upon reconsideration, make an application to the Administrative Review Tribunal for review of that decision.

(7) Any failure to comply with the requirements of subsection (5) or (6) in relation to a decision does not affect the validity of the decision.

(8) An application may be made to the Administrative Review Tribunal for review of a reviewable decision.

60A New information on review—discretion to remit

(1) This section applies only if the Secretary or an authorised delegate makes a decision under section 25, 32DF, 32DG or 41EC in relation to therapeutic goods.

(2) If a person (the ***appellant***) whose interests are affected by the decision requests the Minister to reconsider the decision, and lodges initial new information in support of that request, the Minister must either:

(a) take that information into account when he or she reconsiders the decision; or

(b) remit the matter to an authorised delegate for a fresh decision.

(3) If the appellant applies to the Administrative Review Tribunal for review of the decision on reconsideration, and lodges initial new information or later new information (or both) in support of that application, the Tribunal may, if the Tribunal thinks fit, remit the matter to an authorised delegate for a fresh decision.

(4) If:

(a) the appellant applies to the Administrative Review Tribunal for review of the decision on reconsideration and lodges initial new information in support of that application; and

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(b) the appellant does not lodge later new information in support of that application;

the Tribunal must not remit the matter under subsection (3) if all of the initial new information is information that the Minister took into account under paragraph (2)(a) in making the decision on reconsideration.

(5) If:

(a) the appellant lodges initial new information or later new information (or both) in support of an application to the Administrative Review Tribunal for review of the decision on reconsideration; and

(b) the Tribunal does not remit the matter under subsection (3);

the Tribunal, in reviewing the decision on reconsideration:

(c) may consider initial new information (if any) that the Minister took into account under paragraph (2)(a) in making the decision on reconsideration; and

(d) must not consider any other initial new information, except initial new information that indicates that the quality, safety or efficacy of the therapeutic goods is unacceptable; and

(e) must not consider any later new information, except later new information that indicates that the quality, safety or efficacy of the therapeutic goods is unacceptable.

(6) If:

(aa) the matter relates to a decision under section 25; and

(a) the Minister or the Tribunal remits the matter; and

(b) the appellant has paid, as a further evaluation fee, the evaluation fee that the appellant would have to pay under section 24 on making a new application for registration of the therapeutic goods;

the authorised delegate must make a decision under section 25, taking into account the initial new information or later new information (or both), as the case may be, as if a fresh application for registration had been made.

(6AA) If:

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(a) the matter relates to a decision under section 32DF or 32DG; and
(b) the Minister or the Tribunal remits the matter; and
(c) the appellant has paid, as a further evaluation fee, the evaluation fee that the appellant would have to pay under section 32DI on making a new application for inclusion of the biological in the Register;

the authorised delegate must make a decision whether or not to include the biological in the Register, taking into account the initial new information or later new information (or both), as the case may be, as if a fresh application for inclusion of the biological in the Register had been made.

(6A) If:
(a) the matter relates to a decision under section 41EC; and
(b) the Minister or the Tribunal remits the matter; and
(c) the appellant has paid, as a further conformity assessment fee, the conformity assessment fee that the appellant would have to pay under section 41LA on making a new application for a conformity assessment certificate;

the authorised delegate must make a decision under section 41EC, taking into account the initial new information or later new information (or both), as the case may be, as if a fresh application for a conformity assessment certificate had been made.

(7) To remove any doubt, the authorised delegate's fresh decision is to be treated, for the purposes of subsequent applications of section 60 and this section, as a decision under Part 3-2, 3-2A or 4-4.

(8) In this section:

authorised delegate means a delegate of the Secretary:
(a) exercising a power to decide whether to register therapeutic goods; or
(aa) exercising a power to decide whether to include a biological in the Register; or
(b) exercising a power to decide whether to issue a conformity assessment certificate.

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initial new information means information that:

(a) was in existence at the time the decision referred to in subsection (1) was made; and

(b) was not made available to the Secretary or authorised delegate for the purpose of making that decision; and

(c) is relevant to that decision;

and includes any opinions that are wholly or substantially based on such information (whether the opinions were formed before or after that decision was made).

later new information means information that:

(a) was in existence at the time the decision on reconsideration was made; and

(b) was not made available to the Minister or delegate of the Minister for the purpose of making that decision; and

(c) is relevant to that decision;

and includes any opinions that are wholly or substantially based on such information (whether the opinions were formed before or after that decision was made).

61 Release of information

(1) In this section:

therapeutic goods information means information in relation to therapeutic goods that is held by the Department and relates to the performance of the Department's functions (including functions relating to the EC Mutual Recognition Agreement, the EFTA Mutual Recognition Agreement or the Australia-UK Mutual Recognition Agreement).

vaping goods information means information in relation to vaping goods that is held by the Department and relates to the performance of the Department's functions.

(2) The Secretary may:

(a) release to the World Health Organisation therapeutic goods information relating to:

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(i) notifications concerning therapeutic goods the consumption or supply of which in Australia has been prohibited or severely restricted, or relating to the reasons for that action; or

(ii) the licensing status of Australian manufacturers of therapeutic goods and their compliance with the manufacturing principles; or

(iii) the content of reports to the Department concerning adverse effects of therapeutic goods; or

(iv) the issue of, imposition of conditions on, or revocation of, conformity assessment certificates;

for use in the development of policies relating to the regulation of therapeutic goods or for the provision of information to regulatory authorities of member countries of the World Health Organisation; or

(b) release, in confidence, therapeutic goods information to the World Health Organisation, being information concerning proceedings of committees established under the regulations.

(3) The Secretary may release to an authority of the Commonwealth, a State or a Territory that has functions relating to therapeutic goods, therapeutic goods information relating to:

(a) reported problems and complaints concerning therapeutic goods, the Department's investigation of those problems and complaints and any action that the Department has taken or proposes to take in relation to those problems and complaints; or

(b) reports of inspections conducted under this Act or the regulations; or

(c) decisions to revoke or suspend, or not to issue, licences for the manufacturing of therapeutic goods; or

(d) conditions of licences; or

(e) reports of the testing of samples of therapeutic goods; or

(f) the issue of, imposition of conditions on, or revocation of, conformity assessment certificates;

for use in the performance of those functions.

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(3A) The Secretary may release information obtained in response to a notice under section 31A, 31AA, 31B, 31BA, 32JE, 32JF, 32JG, 32JH, 41AB, 41JCA, 41JD, 41JE or 41JF to:

(a) an authority of the Commonwealth, a State or a Territory that has functions relating to therapeutic goods; and

(b) the body in a State or Territory responsible for the registration of medical practitioners in that State or Territory; and

(c) the body in a State or Territory responsible for the registration of pharmacists in that State or Territory.

(4) The Secretary may release to a national regulatory authority of another country, being an authority that has national responsibility relating to therapeutic goods, therapeutic goods information relating to:

(a) recommendations of advisory committees on therapeutic goods supplied in or proposed for supply in Australia, and any conditions that are or will be applicable to that supply; or

(b) decisions on the registration or listing, or the suspension or cancellation of the registration or listing, of therapeutic goods; or

(baa) decisions on the inclusion of biologicals in the Register, or the suspension or cancellation of the inclusion of biologicals in the Register; or

(ba) decisions on the inclusion of kinds of medical devices in the Register, or the suspension or cancellation of the inclusion of kinds of medical devices in the Register; or

(c) the withdrawal from supply in Australia of therapeutic goods and the reasons for that action; or

(d) the licensing status of Australian manufacturers of therapeutic goods and their compliance with the manufacturing principles; or

(e) proceedings of committees established under the regulations; or

(f) the issue of, imposition of conditions on, or revocation of, conformity assessment certificates;

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for use in the performance of those functions or for furthering international co-operation in the regulation of therapeutic goods.

(4A) The Secretary may release to:

(a) an authority of the Commonwealth, a State or a Territory that has functions relating to therapeutic goods, health or law enforcement; or

(b) a national regulatory authority of another country that has national responsibility relating to therapeutic goods, health or law enforcement; or

(ba) an international organisation that has a function relating to therapeutic goods, health or law enforcement;

therapeutic goods information relating to one or more of the following:

(c) notifications received under section 42T;

(d) action taken by the Secretary under Part 5-3;

(da) action taken by the Secretary under section 30EA (about notification and recall of therapeutic goods);

(db) action taken by the Secretary under section 32HA (about notification and recall of biologicals);

(dc) action taken by the Secretary under section 41KA (about notification and recall of medical devices);

(e) contraventions, or possible contraventions, of Part 5-2 or Part 5-3;

(f) any cases, or possible cases, of actual or potential tampering with therapeutic goods;

(fa) any cases, or possible cases, of counterfeit therapeutic goods;

(g) information relating to an offence committed against this Act, or alleged to have been committed against this Act, involving therapeutic goods;

(h) information relating to the contravention of a civil penalty provision, or the alleged contravention of a civil penalty provision, involving therapeutic goods;

(i) a breach of a requirement of this Act or the regulations.

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(4B) The release of therapeutic goods information mentioned in paragraphs (4A)(g), (h) and (i) is not taken, for the purposes of paragraph 6.2(b) of Australian Privacy Principle 6, to be authorised by this Act.

(5) The Secretary may release to a national regulatory authority of another country, or an international organisation, being another country or an organisation with which the Commonwealth has cooperative arrangements relating to the assessment or regulation of therapeutic goods, the following information the release of which is consistent with those arrangements:

(a) therapeutic goods information;

(b) information relating to Australian conformity assessment bodies and either to conformity assessment body determinations or to certification-related activities of Australian conformity assessment bodies.

(5AA) The Secretary may release to a person, body or authority that is specified, or is of a kind specified, under subsection (5AB) therapeutic goods information of a kind specified under that subsection for a purpose specified under that subsection.

(5AB) For the purpose of subsection (5AA), the Minister may, by legislative instrument, specify one or more of the following:

(a) a person, body or authority;

(b) kinds of persons, bodies or authorities;

(c) kinds of therapeutic goods information;

(d) purposes.

(5A) The Secretary may release to the public therapeutic goods information relating to any decision or action taken under this Act or the regulations.

(5B) The release of therapeutic goods information under subsection (5A) is not taken, for the purposes of paragraph 6.2(b) of Australian Privacy Principle 6, to be authorised by this Act.

(5C) The Secretary may release to the public therapeutic goods information of a kind specified under subsection (5D).

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(5D) The Minister may, by legislative instrument, specify kinds of therapeutic goods information for the purpose of subsection (5C).

(6) The Secretary may release to a person, on application by that person, therapeutic goods information of a kind identified in the regulations relating to:

(a) therapeutic goods included in the Register; or

(b) therapeutic goods in relation to which an application for registration, listing or inclusion in the Register has been made.

(6A) Regulations made for the purposes of subsection (6) may:

(a) relate to therapeutic goods generally or to a class of such goods; and

(b) authorise the release of therapeutic goods information to persons generally or to a class of persons.

(7) The Secretary may release therapeutic goods information:

(a) the release of which is necessary to ensure the safe use of particular therapeutic goods; or

(b) relating to the reasons for the withdrawal of therapeutic goods from supply in Australia.

(7A) The Secretary may release to a person, body or authority that is specified, or is of a kind specified, under subsection (7B) vaping goods information of a kind specified under that subsection for a purpose specified under that subsection.

(7B) For the purposes of subsection (7A), the Minister may, by legislative instrument, specify one or more of the following:

(a) a person, body or authority;

(b) kinds of persons, bodies or authorities;

(c) kinds of vaping goods information;

(d) purposes.

(7C) The Secretary may release to the public vaping goods information of a kind specified under subsection (7D).

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(7D) The Minister may, by legislative instrument, specify kinds of vaping goods information for the purpose of subsection (7C).

(8) Subject to sections 25A and 26AF, therapeutic goods information, or vaping goods information, held by the Department in relation to a matter may:

(a) be used by the Department in the consideration of another matter within its functions relating to therapeutic goods or vaping goods; and

(b) be provided to a committee appointed to advise the Minister or the Secretary on matters relating to therapeutic goods or vaping goods, including a committee of the National Health and Medical Research Council.

Note: The Secretary may also disclose therapeutic goods information held by the Department to the Chief Executive Medicare for the purpose of certain data-matching: see section 132C of the *National Health Act 1953*.

(8A) Regulations prescribing fees in respect of applications for information under the regulations:

(a) may include provision for the payment of deposits on account of such fees; and

(b) may provide for fees that take into account the time spent by officers of the Department in:

(i) searching for or retrieving information; or

(ii) making, or doing anything related to the making of, a decision on an application; and

(c) may provide for fees that take into account the direct costs incurred by the Commonwealth in making available an officer to supervise the inspection by an applicant of any document containing information to which an application relates.

(8C) If, under the regulations, a person is liable to pay a fee in respect of an application for information, the Secretary must notify the person, in writing, accordingly, and must give to the person, together with that notification, a statement setting out the basis on which the amount of that fee is calculated.

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(9) Despite subsection 14(2) of the *Legislation Act 2003*, an instrument under subsection (5AB), (5D), (7B) or (7D) of this section may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

(10) Nothing in this or any other Act requires the Secretary to disclose to any person, court or tribunal information referred to in subsection 25(2E) (including as that subsection applies because of subsection 32DE(2) or 32EB(3)) or 26(2D) if the disclosure would constitute a breach of the Mutual Recognition Convention.

(11) This section (except subsection (10)) has effect subject to the *Freedom of Information Act 1982*.

(12) The subsections of this section permitting the release of information have effect independently of each other.

(13) The Secretary is not required to observe any requirements of the natural justice hearing rule in relation to:

(a) releasing information under subsection (5C) if:

(i) the release of the information is in the interests of public health or safety; or

(ii) the information relates to the safety of one or more therapeutic goods; or

(b) releasing information under any other provision of this section.

(14) Subsection (13) is not to be taken to imply that the natural justice hearing rule applies in relation to any other exercise of power under this Act (including this section) or the regulations.

(15) For the purposes of subparagraph (13)(a)(i), the release of information is not in the interests of public health or safety if the information:

(a) relates to the quality or efficacy of therapeutic goods; and

(b) does not relate to the safety of the therapeutic goods.

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(16) To avoid doubt, this section does not limit any other lawful release, disclosure or use of information held by the Department (including information that has been, or may be, released, disclosed or used under this section).

61A Immunity from civil actions

(1) No civil action, suit or proceeding lies against:

(a) the Commonwealth; or

(b) a protected person;

in respect of loss, damage or injury of any kind suffered by another person as a result of anything done, or omitted to be done, by a protected person in relation to the performance or purported performance, or in relation to the exercise or purported exercise, of a protected person's functions, duties or powers under this Act or the regulations.

(2) Subsection (1) does not apply to an act or omission in bad faith.

(3) A reference in subsection (1) to anything omitted to be done includes a reference to a failure to make a decision.

(4) In this section:

protected person means any of the following:

(a) the Minister;

(b) the Secretary;

(c) a person to whom powers or functions are delegated under subsection 57(1) or (1A);

(d) a member of a committee established under this Act or the regulations;

(e) an authorised person in relation to a provision of this Act (other than this section);

(f) an authorised officer (within the meaning of the regulations);

(g) an authorised person (within the meaning of the regulations);

(ga) a person of a kind prescribed by the regulations;

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(h) a person assisting a person (a ***primary person***) referred to in paragraph (a), (b), (c), (d), (e), (f), (g) or (ga) in relation to the performance or purported performance, or in relation to the exercise or purported exercise, of a primary person's functions, duties or powers under this Act or the regulations.

62 Protection from criminal responsibility

(1) A protected person who, for the purpose of finding out whether this Act or the regulations have been complied with, obtains, possesses or conveys, or facilitates the conveyance of, goods is not criminally responsible for an offence against a law of the Commonwealth, or a State law, relating to the obtaining, possession, conveyance or facilitation of the conveyance of the goods.

(2) If a protected person, in connection with finding out whether this Act or the regulations have been complied with, arranges for another person to convey goods, the other person is not criminally responsible for an offence against a law of the Commonwealth, or a State law, relating to:

(a) the possession of the goods by the other person, to the extent the possession is in connection with that conveyance of the goods; or

(b) that conveyance of the goods.

(3) In this section:

protected person means any of the following:

(a) an APS employee in the Department;

(b) a person of a kind prescribed by the regulations.

63 Regulations

(1) The Governor-General may make regulations, not inconsistent with this Act, prescribing matters:

(a) required or permitted to be prescribed by this Act; or

(b) necessary or convenient to be prescribed for carrying out or giving effect to this Act.

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(2) The regulations may:

(a) make provision in relation to:

(i) the establishment of committees to advise the Minister or the Secretary on matters relating to therapeutic goods; and

(ii) the functions and powers of those committees; and

(iii) the payment of remuneration and allowances to members of those committees; and

(b) prescribe requirements for the storage and transport of therapeutic goods; and

(c) prescribe requirements for the advertising of therapeutic goods; and

(d) provide for the procedures to be followed in the sampling and testing of any of the following:

(i) therapeutic goods;

(ii) vaping goods;

(iii) any kind of goods, for the purpose of ascertaining whether or not they are therapeutic goods or vaping goods; and

(da) provide for the periods within which evaluations under section 25 in relation to specified therapeutic goods or specified classes of such goods are to be completed; and

(daaaa) provide for the periods within which evaluations under section 26AE in relation to specified medicines or specified classes of medicines are to be completed; and

(daaa) provide for the periods within which a decision under paragraph 26BE(4)(a) or (b), in relation to an application under subsection 26BD(1), must be made; and

(daa) provide for the periods within which evaluations under section 32DE in relation to specified biologicals or specified classes of biologicals are to be completed; and

(db) provide for the periods within which decisions under section 41EP to revoke suspensions of conformity assessment certificates are to be made, in cases where applications for revocation have been made under paragraph 41EP(2)(a); and

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(dc) provide for the periods within which decisions on applications for the issuing of conformity assessment certificates under Part 4-4 are to be made if considering the applications involves examining the design of medical devices; and

(dd) provide for the periods within which decisions under section 41GD to revoke suspensions of entries on the Register are to be made, in cases where applications for revocation have been made under paragraph 41GD(2)(a); and

(de) provide for the periods within which the performance of specified functions conferred on the Secretary by this Act is to be completed; and

(df) provide for the periods within which specified decisions under this Act are to be made by the Secretary; and

(e) prescribe requirements for informational material that is included with therapeutic goods; and

(f) make provision for the transfer of registration, listing or inclusion in the Register of therapeutic goods and of licences; and

(g) make provision for the testing of therapeutic goods or vaping goods, the inspection of manufacturing operations or the evaluation of data concerning therapeutic goods or vaping goods by the Department at the request of persons; and

(ga) make provision for the reporting of matters relating to therapeutic goods; and

(h) prescribe fees in respect of matters under this Act or the regulations; and

(j) prescribe penalties not exceeding 10 penalty units for offences against the regulations.

(3) The regulations may:

(a) prescribe different fees under this Act in relation to:

(i) different classes of goods; or

(ii) in the case of fees under Part 3-3—different steps in the manufacture of goods; or

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(b) provide for the refund, reduction or waiving of fees or charges in cases identified in the regulations; or

(c) specify the type of information relating to therapeutic goods manufactured by licence holders that the Secretary may, under subsection 37(2), require to be supplied by the holders of licences at the time of payment of annual licensing charges in respect of the licences.

(3A) The regulations may provide for:

(a) the granting of a licence or permission to import or export therapeutic goods; and

(b) licences or permissions to import or export therapeutic goods to be subject to conditions or requirements; and

(c) the assignment of a licence or permission to import or export therapeutic goods; and

(d) the surrender of a licence or permission to import or export therapeutic goods; and

(e) the revocation of a licence or permission to import or export therapeutic goods.

(4) Despite subsection 14(2) of the *Legislation Act 2003*, the regulations may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

(5) For the purposes of section 2, regulations may be made before the commencement of this Act as if this Act were in force, but do not come into effect on a day earlier than the day on which this Act commences.

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Chapter 8—Repeal and transitional provisions

66 Transitional arrangements for goods required to be registered or listed

(1) This section applies to therapeutic goods in relation to a person if, immediately before the commencement of this Act, the person was supplying goods of that kind in Australia for use in humans.

(2) Where:

(a) this section applies to therapeutic goods in relation to a person; and

(b) the Secretary is not aware of the person having been convicted of an offence against a law of the Commonwealth, of a State or of an internal Territory in respect of goods of that kind during the period of 2 years ending on the commencement of this Act; and

(c) if the goods are imported goods—the Secretary is not aware of the person having, during that period, imported goods of that kind into Australia otherwise than in accordance with regulations in force under the *Customs Act 1901*;

subsections 20(1) and (2) do not apply to goods of that kind in relation to the person during the period of 3 months after that commencement.

(3) Where:

(a) this section applies to therapeutic goods in relation to a person; and

(b) the person makes an application for registration or listing of goods of that kind in accordance with section 23 and within 3 months after the commencement of this Act;

then:

(c) subsection 20(1) does not apply to goods of that kind in relation to the person during the period of 6 months after that

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commencement or before the end of such longer period as the Secretary specifies by notice published in the *Gazette* before the end of that first-mentioned period; and

(d) subsection 20(2) does not apply to goods of that kind in relation to the person during the period of 12 months after that commencement or before the end of such longer period as the Secretary specifies by notice published in the *Gazette* before the end of that first-mentioned period.

(3A) If, on an application under subsection (3), goods have been registered without having been evaluated, the Secretary may, if he or she thinks it appropriate, give the person in relation to whom the goods are registered written notice that the goods are to be evaluated to determine whether they should continue to be registered.

(4) A person who makes an application in accordance with subsection (3) is not required to pay:

(a) any application fee for the registration or listing of the goods to which the application relates; or

(b) in the case of an application for the registration of goods—any fee for the evaluation of the goods for registration;

but where the goods are later evaluated to determine whether the goods should continue to be registered, such fee as is prescribed is payable in respect of that evaluation.

(4A) In relation to an evaluation conducted for the purposes of this section:

(a) section 25 has effect as if:

(i) the person in respect of whom the goods are registered were an applicant for the registration of the goods; and

(ii) the reference in paragraph (1)(b) to an evaluation fee under section 24 were a reference to a fee payable under subsection (4) of this section; and

(b) sections 24A, 24B and 24C have effect as if any reference in those sections to section 24 were a reference to subsection (4) of this section; and

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(c) sections 24D and 24E do not apply.

(4B) If, on an application under subsection (3), goods have been listed without consideration of the matters mentioned in paragraphs 26(1)(c) to (m), the Secretary may, if he or she thinks it appropriate, give the person in relation to whom the goods are listed written notice that the Secretary intends to determine whether the goods should continue to be listed.

(4C) If notice is given under subsection (4B), section 26 applies as if the person in relation to whom the goods are listed were an applicant for the listing of the goods.

(5) Section 21 does not apply, during the period of 15 months after the commencement of this Act or during such longer period as the Secretary specifies by notice published in the *Gazette* before the end of that first-mentioned period, to any goods.

(6) Where a person suffers any kind of loss, damage or injury caused by, or arising out of, the use by the person of therapeutic goods to which this section applies, no liability in respect of that loss, damage or injury attaches to the Commonwealth, the Secretary or any delegate of the Secretary.

67 Transitional provision for therapeutic goods for export only

Section 20 does not apply, during the period of 6 months after the commencement of this Act, to therapeutic goods manufactured in Australia solely for export from Australia.

68 Transitional arrangements for Part 3-3

(1) This section applies to a step in the manufacture of therapeutic goods in relation to a person in relation to premises in Australia if, before the commencement of this Act, the person was carrying out that step in relation to goods of that kind at those premises.

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(2) Where:

(a) this section applies to a step in the manufacture of therapeutic goods in relation to a person in relation to premises; and

(b) the Secretary is not aware of the person having been convicted of an offence against a law of the Commonwealth, of a State or of an internal Territory in respect of goods of that kind during the period of 2 years ending on the commencement of this Act;

subsection 35(1) does not apply the carrying out of that step by the person in relation to goods of that kind at those premises during the period of 4 months after that commencement.

(3) Where:

(a) this section applies to a step in the manufacture of therapeutic goods in relation to a person in relation to premises; and

(b) the person makes an application for a licence to carry out that step in relation to goods of that kind at those premises in accordance with section 37 and within 4 months after the commencement of this Act;

subsection 35(1) does not apply to the carrying out of that step by the person in relation to goods of that kind at those premises until the application is determined.

69 Continuation of standards and requirements

Any standards that were in force immediately before the commencement of this Act under Part 2 of the *Therapeutic Goods Act 1966*, and any requirements that were in force at that time under section 15 of the *Therapeutic Goods Act 1966*, continue in force as if they were standards made under Part 3-1 of this Act.

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Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes
Endnote 2—Abbreviation key
Endnote 3—Legislation history
Endnote 4—Amendment history

Abbreviation key—Endnote 2
The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4
Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Editorial changes
The *Legislation Act 2003* authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

Misdescribed amendments
A misdescribed amendment is an amendment that does not accurately describe how an amendment is to be made. If, despite the misdescription, the amendment

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can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and "(md not incorp)" is added to the amendment history.

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Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

C[x] = Compilation No. x

ch = Chapter(s)

cl = clause(s)

cont. = continued

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

div = Division(s)

ed = editorial change

exp = expires/expired or ceases/ceased to have effect

gaz = gazette

LA = *Legislation Act 2003*

LIA = *Legislative Instruments Act 2003*

(md) = misdescribed amendment can be given effect

(md not incorp) = misdescribed amendment cannot be given effect

mod = modified/modification

No. = Number(s)

Ord = Ordinance

orig = original

p = page(s)

para = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

pt = Part(s)

r = regulation(s)/Court rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s) /rule(s)/subrule(s)/order(s)/suborder(s)

sch = Schedule(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

sub ch = Sub-Chapter(s)

sub div = Subdivision(s)

sub pt = Subpart(s)

underlining = whole or part not commenced or to be commenced

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Therapeutic Goods Act 1989	21, 1990	17 Jan 1990	15 Feb 1991 (s 2)	
Community Services and Health Legislation Amendment Act (No. 2) 1990	141, 1990	28 Dec 1990	Part 8 (s 78–81): 15 Feb 1991 (s 2(6))	—
Community Services and Health Legislation Amendment Act 1991	84, 1991	26 June 1991	s 14: 1 Aug 1991 (s. 2(2) and gaz 1991, No. S207) Remainder: 26 June 1991	s 33–36
Therapeutic Goods Amendment Act 1991	204, 1991	24 Dec 1991	24 Dec 1991 (s 2)	s 4(2), 10(2) and 13(2)
Health, Housing and Community Services Legislation Amendment Act 1992	88, 1992	30 June 1992	s 82–88: 30 Jun 1992 (s (1))	s 83(2)
Health and Community Services Legislation Amendment Act (No. 2) 1993	76, 1993	25 Nov 1993	s 29(h) and 30–32: 14 Feb 1994 (gaz 1994, No GN5) s 29(i), 37(b), 38(b), 47 and 50(1)(d): 2 May 1994 (gaz 1994, No S149) Remainder: 25 Nov 1993	s 33(2), 36(2), 41(2), 49(2), 50(2) and 51(2)
Customs, Excise and Bounty Legislation Amendment Act 1995	85, 1995	1 July 1995	s 12 (items 5, 6): 1 July 1995 (s 2(1)) s 18: 1 Jul 1995 (s 2(1))	s 18
Therapeutic Goods Amendment Act 1996	6, 1996	11 June 1996	11 June 1996 (s 2)	s 84

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Therapeutic Goods Amendment Act 1997	116, 1997	7 July 1997	Schedule 1 (Part 2 (items 2–14)): 1 Jan 1999 (gaz 1998, No S609) Remainder: 7 July 1997	—
as amended by				
Therapeutic Goods Legislation Amendment Act 1999	3, 1999	29 Mar 1999	(No 3, 1999 below)	—
Audit (Transitional and Miscellaneous) Amendment Act 1997	152, 1997	24 Oct 1997	Sch 2 (item 1249): 1 Jan 1998 (gaz 1997, No GN49) (s 2(2))	—
Therapeutic Goods Legislation Amendment Act 1998	34, 1998	17 Apr 1998	17 Apr 1998 (s 2)	—
Therapeutic Goods Legislation Amendment Act 1999	3, 1999	29 Mar 1999	Sch 2: 1 Jan 1999 (gaz 1998, No S609) (s 2(3)) Remainder: 1 Apr 1999 (gaz 1999, No S143)	—
Public Employment (Consequential and Transitional) Amendment Act 1999	146, 1999	11 Nov 1999	Sch 1 (items 936–938): 5 Dec 1999 (gaz 1999, No S584) (s 2(1))	—
Therapeutic Goods Amendment Act 2000	12, 2000	31 Mar 2000	31 Mar 2000 (s 2)	—
Therapeutic Goods Amendment Act (No. 2) 2000	56, 2000	30 May 2000	30 May 2000 (s 2)	Sch 1 (item 5)
Therapeutic Goods Amendment Act (No. 3) 2000	120, 2000	12 Sept 2000	Sch1: 10 Oct 2000 Remainder: 12 Sept 2000	Sch 1 (items 4, 6, 8, 10, 17)

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Gene Technology (Consequential Amendments) Act 2000	170, 2000	21 Dec 2000	22 June 2001 (s 2)	—
Therapeutic Goods Amendment Act 2001	14, 2001	22 Mar 2001	22 Sept 2001	Sch 1 (item 36)
Australia New Zealand Food Authority Amendment Act 2001	81, 2001	10 July 2001	s 2(6): 10 Jul 2001 (s 2(1)(a)) Sch 3 (item 8): 1 July 2002 (s 2(2), (5) and gaz 2002, No GN30)	s 2(6)
Health and Aged Care Legislation Amendment (Application of Criminal Code) Act 2001	111, 2001	17 Sept 2001	17 Sept 2001 (s 2)	s. 4
Therapeutic Goods Amendment Act (No. 1) 2002	23, 2002	4 Apr 2002	4 Apr 2002 (s 2)	—
Therapeutic Goods Amendment (Medical Devices) Act 2002	24, 2002	4 Apr 2002	Sch 1: 4 Oct 2002 (s 2(1) item 2) Sch 2: (s 2(1) item 5) (Sch 2 (item 8) rep No 140, 2007 (s 2)) Remainder: 4 Apr 2002	Sch 1 (items 38, 46, 55) s 2(1) (item 3) (rep by No 140, 2007, Sch 1 (item 7))
as amended by				
Therapeutic Goods and Other Legislation Amendment Act 2002	56, 2002	3 July 2002	Sch 3 (item 22): (No 56, 2002 below)	—
Therapeutic Goods Amendment Act (No. 1) 2006	39, 2006	3 May 2006	Sch 1 (item 158): 4 Oct 2007 (s 2(1) item 5)	—
Therapeutic Goods Amendment Act 2007	140, 2007	14 Sept 2007	Sch 1 (items 7, 8): 3 Oct 2007	—

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Therapeutic Goods and Other Legislation Amendment Act 2002	56, 2002	3 July 2002	Sch 1 (items 1–5), Sch 3 (items 1–3, 6–21) and Sch 4 (item 2): 3 July 2002 (s 2(1) items 1, 3, 8) Sch 1 (items 6, 7), Sch 3 (item 4) and Sch 4 (item 1): 4 Oct 2002 (s 2(1) items 2, 4, 7) Sch 3 (item 5): never commenced (s 2(1) item 5)	Sch 3 (items 20, 21)
Therapeutic Goods Amendment Act (No. 1) 2003	39, 2003	27 May 2003	Sch 1 (items 1–19) and Sch 2: 27 Nov 2003 (s 2(1) items 2, 6) Sch 1 (items 41, 55, 60): 27 May 2003 (s 2(1) item 3) Sch 1 (item 79): 17 Sept 2001 (s 2(1) item 4)	Sch 1 (items 41, 55, 60)
US Free Trade Agreement Implementation Act 2004	120, 2004	16 Aug 2004	Sch 7: 1 Jan 2005	Sch 7 (item 7)
Financial Framework Legislation Amendment Act 2005	8, 2005	22 Feb 2005	s 4 and Sch 1 (items 493, 496): 22 Feb 2005	s 4 and Sch 1 (item 496)
Therapeutic Goods Amendment Act (No. 2) 2006	2, 2006	1 Mar 2006	Sch 1: 3 Apr 2006 (s 2(1) item 2) Remainder: 1 Mar 2006	Sch 1 (item 15)

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Act 2006	5, 2006	3 Mar 2006	3 Mar 2006 (s 2)	s. 3
Therapeutic Goods Amendment Act (No. 1) 2006	39, 2006	3 May 2006	Sch 1 (items 1–117, 119–157): 31 May 2006 Sch 1 (item 118): 27 Nov 2003 Remainder: 3 May 2006	s 2(1) (item 5) (rep by 140, 2007, Sch. 1 (item 4))
as amended by				
Therapeutic Goods Amendment Act 2007	140, 2007	14 Sept 2007	Sch 1 (items 4–6): 3 Oct 2007	—
National Health and Medical Research Council Amendment Act 2006	50, 2006	9 June 2006	Sch 1: 1 July 2006 Remainder: 9 June 2006	—
Therapeutic Goods Amendment Act (No. 3) 2006	96, 2006	5 Sept 2006	5 Sept 2006 (s 2)	—
Therapeutic Goods Amendment Act 2007	140, 2007	14 Sept 2007	3 Oct 2007 (s 2)	—
Therapeutic Goods Amendment (Poisons Standard) Act 2008	9, 2008	20 Mar 2008	20 Mar 2008 (s 2)	—
Statute Law Revision Act 2008	73, 2008	3 July 2008	Sch 1 (item 47): 17 Sep 2001 (s 2(1) item 31)	—
Therapeutic Goods Legislation Amendment (Annual Charges) Act 2008	96, 2008	3 Oct 2008	Sch 1 (items 1–3): 1 Jan 2009 (s 2(1) item 2)	Sch. 1 (item 3)

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Therapeutic Goods Amendment (Medical Devices and Other Measures) Act 2009	38, 2009	17 June 2009	Sch 1, 2 and 5–7: 18 June 2009 (s 2(1) items 2, 5) Sch 3: 1 Dec 2009 (s 2(1) item 3) Sch 4: 1 July 2009 (s 2(1) item 4) Remainder: 17 June 2009 (s 2(1) item 1)	Sch 2 (item 4), Sch 3 (item 23), Sch 4 (item 20), Sch 5 (item 3) and Sch 6 (item 12)
Therapeutic Goods Amendment (2009 Measures No. 1) Act 2009	76, 2009	27 Aug 2009	Sch 1, 3, 6 and Sch 7 (items 1–28): 28 Aug 2009 (s 2(1) items 2, 4, 7, 8) Sch 2: 25 Feb 2010 (s 2(1) item 3) Sch 4: 1 July 2011 (s 2(1) item 5) Sch 5: 8 Feb 2010 (s 2(1) item 6)) Sch 7 (items 29–58): 25 Jan 2010 (s 2(1) item 9) Remainder: 27 Aug 2009 (s 2(1) item 1)	Sch 1 (item 7), Sch 2 (items 25, 26), Sch 3 (item 16), Sch 5 (item 5), Sch 6 (item 14) and Sch 7 (items 26–28, 56–59)
Therapeutic Goods Amendment (2009 Measures No. 2) Act 2009	96, 2009	29 Sept 2009	Sch 1: 1 July 2010 (s 2(1) item 2) Sch 2 and Sch 3 (items 1–7): 30 Sept 2009 (s 2(1) items 3, 4) Sch 3 (items 8–10): 29 Mar 2010 Remainder: 29 Sept 2009	Sch. 1 (item 13), Sch. 2 (item 4) and Sch. 3 (items 7, 10)

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Statute Law Revision Act 2010	8, 2010	1 Mar 2010	Sch 5 (items 124, 137): 1 Mar 2010(s 2(1) items 31, 38)	—
Therapeutic Goods Amendment (2009 Measures No. 3) Act 2010	54, 2010	31 May 2010	Sch 1: 31 May 2011 (s 2(1) item 2) Sch 2–6: 1 June 2010 (s 2(1) item 3) Remainder: 31 May 2010 (s 2(1) item 1)	Sch 1 (items 58–60), Sch. 2 (items 15, 16), Sch 3 (item 3), Sch 4 (item 6), Sch 5 (item 2) and Sch 6 (item 20)
Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010	141, 2010	15 Dec 2010	Sch 1 and Sch 2 (items 7A–21): 16 Dec 2010 (s 2(1) items 2, 4) Sch 1A and Sch 2 (items 1A–7): 12 Jan 2011 (s 2(1) items 2A, 3) Sch 2 (items 22, 23): 31 May 2011 (s 2(1) item 5*)* Remainder: 15 Dec 2010 (s 2(1) item 1)	Sch 1A (item 10) and Sch 2 (items 7, 21)
Statute Law Revision Act 2011	5, 2011	22 Mar 2011	Schedule 7 (item 140): 19 Apr 2011 (s 2(1) item 18)	—
Acts Interpretation Amendment Act 2011	46, 2011	27 June 2011	Sch 2 (items 1150–1156) and Sch 3 (items 10, 11): 27 Dec 2011	Sch. 3 (items 10, 11)
Therapeutic Goods Amendment (2011 Measures No. 1) Act 2011	77, 2011	25 July 2011	26 July 2011 (s 2)	Sch. 1 (items 6–8)

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Statute Law Revision Act 2012	136, 2012	22 Sept 2012	Sch 6 (items 85–88): 22 Sept 2012	—
Personal Liability for Corporate Fault Reform Act 2012	180, 2012	10 Dec 2012	Sch 5 and Sch 7: 11 Dec 2012 (s 2)	Sch 7
Privacy Amendment (Enhancing Privacy Protection) Act 2012	197, 2012	12 Dec 2012	Sch 5 (item 98) and Sch 6 (items 15–19): 12 Mar 2014 (s 2(1) items 3, 19) Sch 6 (item 1): 12 Dec 2012 (s 2(1) item 16)	Sch 6 (items 1, 15–19)
Therapeutic Goods Amendment (2013 Measures No. 1) Act 2014	4, 2014	28 Feb 2014	28 Feb 2014	Sch 1 (items 23–25), Sch 2 (item 16), Sch 3 (item 8), Sch 4 (item 4), Sch 5 (items 11, 12), Sch 6 (item 14), Sch 7 (item 5), Sch 8 (item 2), Sch 9 (item 2), Sch 10 (item 2), Sch 11 (item 3), Sch 12 (item 2), Sch 13 (items 6, 7), Sch 14 (item 3), Sch 15 (item 4) and Sch 16 (item 6)
Statute Law Revision Act (No. 1) 2014	31, 2014	27 May 2014	Sch 8 (items 44, 45): 24 June 2014	—

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Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Public Governance, Performance and Accountability (Consequential and Transitional Provisions) Act 2014	62, 2014	30 June 2014	Sch 12 (items 230, 231) and Sch 14: 1 July 2014 (s 2(1) items 6, 14)	Sch 14
as amended by				
Public Governance and Resources Legislation Amendment Act (No. 1) 2015	36, 2015	13 Apr 2015	Sch 2 (item 7) and Sch 7: 14 Apr 2015 (s 2)	Sch 7
as amended by				
Acts and Instruments (Framework Reform) (Consequential Provisions) Act 2015	126, 2015	10 Sept 2015	Sch 1 (item 486): 5 Mar 2016 (s 2(1) item 2)	—
Acts and Instruments (Framework Reform) (Consequential Provisions) Act 2015	126, 2015	10 Sept 2015	Sch 1 (item 495): 5 Mar 2016 (s 2(1) item 2)	—
Statute Law Revision Act (No. 1) 2015	5, 2015	25 Feb 2015	Sch 3 (items 195–199): 25 Mar 2015 (s 2(1) item 10)	—

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Customs and Other Legislation Amendment (Australian Border Force) Act 2015	41, 2015	20 May 2015	Sch 6 (items 190–197) and Sch 9: 1 July 2015 (s 2(1) items 2, 7)	Sch 6 (item 197) and Sch 9
as amended by				
Australian Border Force Amendment (Protected Information) Act 2017	115, 2017	30 Oct 2017	Sch 1 (item 26): 1 July 2015 (s 2(1) item 2)	—
Acts and Instruments (Framework Reform) (Consequential Provisions) Act 2015	126, 2015	10 Sept 2015	Sch 1 (items 643–651): 5 Mar 2016 (s 2(1) item 2)	—
Statute Law Revision Act (No. 1) 2016	4, 2016	11 Feb 2016	Sch 4 (items 1, 316–320): 10 Mar 2016 (s 2(1) item 6)	—
Narcotic Drugs Amendment Act 2016	12, 2016	29 Feb 2016	Sch 5 (item 1): 29 Oct 2016 (s 2(1) item 4)	—
Narcotic Drugs Legislation Amendment Act 2016	76, 2016	23 Nov 2016	Sch 2 (items 47, 48): 23 Nov 2016 (s 2(1) item 3)	—
Therapeutic Goods Amendment (2016 Measures No. 1) Act 2017	47, 2017	19 June 2017	Sch 1 and 9: 1 July 2017 (s 2(1) items 2, 4) Sch 2, Sch 3 (items 2–37), Sch 4–8, Sch 10–12: 20 June 2017 (s 2(1) items 3, 5)	Sch 5 (item 4), Sch 9 (item 3), Sch 10 (item 63), Sch 11 (item 2) and Sch 12 (item 58)

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018	7, 2018	5 Mar 2018	Sch 1–5, Sch 6 (items 1–51) and Sch 7–9: 6 Mar 2018 (s 2(1) items 2–5, 7–9) Sch 6 (items 59–65): 1 July 2020 (s 2(1) item 6)	Sch 2 (items 21–23), Sch 4 (30, 50, 70), Sch 5 (item 66), Sch 6 (items 48–51, 65), Sch 7 (items 330–342), Sch 8 (item 6) and Sch 9 (items 39–41)
Therapeutic Goods Amendment (2018 Measures No. 1) Act 2018	104, 2018	21 Sept 2018	Sch 1: 1 Jan 2019 (s 2(1) item 2) Sch 2 (items 1–13): 22 Sept 2018 (s 2(1) item 3) Sch 2 (items 14, 15): 19 Oct 2018 (s 2(1) item 4)	Sch 1 (item 4) and Sch 2 (items 13, 15)
Health Legislation Amendment (Data-matching and Other Matters) Act 2019	121, 2019	12 Dec 2019	Sch 1 (item 9): 13 Dec 2019 (s 2(1) item 1)	—
Therapeutic Goods Amendment (2020 Measures No. 1) Act 2020	75, 2020	25 June 2020	Sch 1 (items 1–18): 25 Aug 2020 (s 2(1) item 2) Sch 1 (items 19–25), Sch 5–9 and Sch 10 (items 2–49): 26 June 2020 (s 2(1) items 3, 5) Sch 2–4: 23 July 2020 (s 2(1) item 4)	Sch 1 (items 21, 23), Sch 3 (item 10), Sch 4 (item 16), Sch 5 (item 4), Sch 6 (item 4), Sch 7 (item 2), Sch 8 (item 11), Sch 9 (item 6) and Sch 10 (items 24, 47)
National Emergency Declaration (Consequential Amendments) Act 2020	129, 2020	15 Dec 2020	Sch 1 (items 57–73): 16 Dec 2020 (s 2(1) item 2)	Sch 1 (item 73)

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Endnote 3—Legislation history

Act	Number and year	Assent	Commencement	Application, saving and transitional provisions
Therapeutic Goods Amendment (2020 Measures No. 2) Act 2021	8, 2021	19 Feb 2021	Sch 1–4 and 7–10: 20 Feb 2021 (s 2(1) items 2, 4) Sch 5 and 6: 19 Apr 2021 (s 2(1) item 3)	Sch 3 (item 2), Sch 4 (items 27–30), Sch 5 (item 4), Sch 6 (item 8), Sch 7 (item 3), Sch 8 (item 2), Sch 9 (item 5) and Sch 10 (item 9)
Federal Circuit and Family Court of Australia (Consequential Amendments and Transitional Provisions) Act 2021	13, 2021	1 Mar 2021	Sch 2 (items 773–775): 1 Sept 2021 (s 2(1) item 5)	—

Act (Register ID)	Number and year	Assent	Commencement	Application, saving and transitional provisions
Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023 (C2023A00010)	10, 2023	21 Mar 2023	sch 1: 21 Mar 2025 (s 2(1) item 2) sch 2: 21 June 2023 (s 2(1) item 3) sch 3-10, 12: 22 Mar 2023 (s 2(1) items 4, 6) sch 11: 21 Sept 2023 (s 2(1) item 5)	sch 1 (item 5), sch 3 (item 3), sch 4 (item 3), sch 5 (item 4), sch 6 (item 3), sch 7 (item 6), sch 8 (item 2), sch 9 (item 8), sch 10 (item 2), sch 11 (item 11), sch 12 (item 32)

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Act (Register ID)	Number and year	Assent	Commencement	Application, saving and transitional provisions
Administrative Review Tribunal (Consequential and Transitional Provisions No. 2) Act 2024 (C2024A00039)	39, 2024	31 May 2024	sch 9 (items 151-159): 14 Oct 2024 (s 2(1) item 2)	—
Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024 (C2024A00050)	50, 2024	27 June 2024	sch 1: 1 July 2024 (s 2(1) items 2-2C) sch 4 (items 1-4, 18-20): 1 Oct 2024 (s 2(1) item 5)	sch 1 (items 26, 49, 55, 95, 97, 117), sch 4 (items 18-20)
Health Legislation Amendment (Improved Medicare Integrity and Other Measures) Act 2025 (C2025A00038)	38, 2025	4 Sept 2025	sch 2: 5 Sept 2025 (s 2(1) item 6)	sch 2 (items 27, 38, 44, 50, 81, 84, 94)

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Endnote 4—Amendment history

Provision affected	How affected
Chapter 1	
Part 1 heading	rep. No. 24, 2002
Chapter 1 heading	ad. No. 24, 2002
s 3	am No 141, 1990; No 84, 1991; No 88, 1992; No 76, 1993; No 6, 1996; No 116, 1997; No 34, 1998; No 3, 1999; No 12, 2000; No 56, 2000; No 120, 2000; No 170, 2000; No 14, 2001; No 81, 2001; No 111, 2001; No 24, 2002 (as am by No 56, 2002); No 56, 2002; No 39, 2003; No 5, 2006; No 39, 2006; No 50, 2006; No 9, 2008; No 38, 2009; No 76, 2009; No 96, 2009; No 54, 2010; No 141, 2010; No 5, 2011; No 4, 2014; No 31, 2014; No 41, 2015; No 47, 2017; No 7, 2018; No 104, 2018; No 75, 2020; No 129, 2020; No 8, 2021; No 13, 2021; No 10, 2023; No 50, 2024; No 38, 2025
s 3AA	ad. No. 76, 2009
	am No 126, 2015
s 3AB	ad No 76, 2009
	am No 126, 2015
s. 3A	ad. No. 116, 1997
	am. No. 12, 2000; No 4, 2014
s. 3B	ad. No. 56, 2002
	am No 4, 2014
s 3C	ad No 38, 2009
	am No 126, 2015; No 10, 2023
s 4	rs No 204, 1991; No 76, 1993; No 3, 1999
	am No 24, 2002; No 8, 2021; No 50, 2024
s. 5	am. No. 39, 2006
s 5A	ad No 111, 2001
	rs No 39, 2006
	am No 7, 2018; No 50, 2024
s 6	am No 76, 1993; No 10, 2023
s. 6AA	ad. No. 6, 1996

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Provision affected	How affected
	am. No. 111, 2001
	rep. No. 5, 2006
s. 6AB	ad. No. 6, 1996
	rep. No. 5, 2006
s. 6A	ad. No. 76, 1993
	am. No. 146, 1999; No. 24, 2002
	rep. No. 56, 2002
s 6AAA	ad. No. 56, 2002
s 6AAB	ad. No. 56, 2002
s 6AAC	ad. No. 56, 2002
s 6AAD	ad. No. 56, 2002
s. 6AAE	ad. No. 56, 2002
	am. No. 56, 2002; No. 54, 2010; No 7, 2018
s 6B	ad No 76, 1993
	am No 39, 2024
s 6C	ad No 76, 1993
s 7	am No 76, 1993; No 24, 2002; No 141, 2010; No 4, 2014; No 8, 2021; No 10, 2023; No 38, 2025
s 7AAA	ad No 50, 2024
s 7AA	ad No 4, 2014
	am No 126, 2015
s 7A	ad No 76, 1993
	am No 50, 2024
s 7B	ad No 76, 1993
	am No 24, 2002; No 54, 2010; No 4, 2014; No 75, 2020
s. 7C	ad. No. 76, 2009
s. 7D	ad. No. 141, 2010
s 8	am No 84, 1991; No 6, 1996; No 111, 2001; No 38, 2009; No 4, 2014; No 50, 2024
s 9	am No 54, 2010; No 10, 2023

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Endnote 4—Amendment history

Provision affected	How affected
Chapter 2	
Chapter 2	ad. No. 24, 2002
s 9A	ad No 24, 2002
	am No 56, 2002; No 54, 2010; No 4, 2014; No 7, 2018; No 10, 2023
s 9B	ad No 24, 2002
	am No 140, 2007
	rep No 75, 2020
s. 9C	ad. No. 24, 2002
	am. No. 38, 2009
s. 9D	ad. No. 24, 2002
	am No 54, 2010; No 141, 2010; No 77, 2011; No 47, 2017; No 7, 2018; No 104, 2018
s. 9E	ad. No. 24, 2002
s 9F	ad No 4, 2014
s 9G	ad No 4, 2014
	am No 7, 2018
s 9H	ad No 4, 2014
Chapter 2A	
Chapter 2A	ad No 8, 2021
Chapter 2A heading	am No 38, 2025
s 9J	ad No 8, 2021
	am No 38, 2025
s 9K	ad No 8, 2021
	am No 38, 2025
s 9L	ad No 8, 2021
	am No 38, 2025
s 9M	ad No 8, 2021
s 9N	ad No 8, 2021
Chapter 3	
Part 2 heading	rep No 24, 2002

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Endnote 4—Amendment history

Provision affected	How affected
Chapter 3 heading	ad No 24, 2002
Chapter 3	am No 140, 2007; No 75, 2020
Part 3-1	
Part 3-1 heading	ad. No. 24, 2002
s. 10	am. No. 24, 2002; Nos. 38 and 76, 2009; No 46, 2011; No 126, 2015; No 47, 2017; No 104, 2018
s 10A	ad No 24, 2002
	rep No 75, 2020
s 11	rep No 76, 2009
s 12	rep No 76, 2009
s 13	rs No 38, 2009
	am No 4, 2014
s. 13A	ad. No. 76, 2009
s 14	am No 85, 1995; No 6, 1996; No 39, 2003
	rs No 39, 2006
	am No 38, 2009; No 54, 2010; No 180, 2012; No 4, 2014; No 7, 2018; No 38, 2025
s 14A	ad No 39, 2006
	am No 54, 2010; No 4, 2014; No 38, 2025
s 14B	ad No 39, 2006
	am No 41, 2015; No 7, 2018; No 50, 2024
s. 15	am. No. 6, 1996; No. 111, 2001
	rs. No. 39, 2006
	am. No. 38, 2009; No 180, 2012; No 7, 2018
s. 15AA	ad. No. 39, 2006
s. 15AB	ad. No. 54, 2010
Part 3-2	
Part 3 heading	rep. No. 24, 2002
Part 3-2 heading	ad. No. 24, 2002
Division 1	
s 15A	ad No 24, 2002

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Endnote 4—Amendment history

Provision affected	How affected
	rs No 75, 2020
s 15B	ad No 54, 2010
s 16	am No 141, 1990; No 84, 1991; No 76, 1993; No 14, 2001; No 24, 2002; No 75, 2020
s. 17	am. No. 84, 1991; No. 3, 1999; No. 56, 2002
	rep. No. 24, 2002
s. 18	rs. No. 204, 1991
	am. No. 120, 2000
s 18A	ad No 23, 2002
	am No 39, 2006; No 38, 2009; No 54, 2010; No 129, 2020
s 19	am No 204, 1991; No 6, 1996; No 120, 2000; No 54, 2010; No 12, 2016; No 76, 2016; No 47, 2017; No 7, 2018; No 104, 2018; No 75, 2020; No 50, 2024; No 38, 2025
s 19A	ad No 6, 1996
	am No 76, 2009; No 4, 2014; No 47, 2017; No 7, 2018; No 75, 2020; No 10, 2023; No 38, 2025
s. 19B	ad. No. 39, 2006
	am. No. 38, 2009; No. 180, 2012; No 41, 2015; No 7, 2018
s 19C	ad. No. 39, 2006
s 19D	ad No 39, 2006
	am No 41, 2015; No 75, 2020; No 8, 2021
s. 20	am. No. 204, 1991; No. 85, 1995; No. 6, 1996; No. 56, 2000; No. 111, 2001; No. 23, 2002; No. 39, 2003; No. 39, 2006; No. 38, 2009; No 4, 2016; No 7, 2018
s. 20A	ad. No. 39, 2006
s. 21	am. No. 204, 1991; No. 6, 1996; No. 111, 2001; No. 23, 2002; No. 38, 2009; No 75, 2020
s. 21A	ad. No. 39, 2006
	am. No. 38, 2009; No 180, 2012; No 47, 2017; No 7, 2018
s. 21B	ad. No. 39, 2006
	am No 7, 2018

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Provision affected	How affected
s 22	am No 204, 1991; No 6, 1996; No 120, 2000; No 14, 2001; No 111, 2001; No 23, 2002; No 39, 2003; No 39, 2006; No 180, 2012; No 38, 2009; No 96, 2009; No 4, 2016; No 7, 2018; No 75, 2020; No 50, 2024
s 22AA	ad No 39, 2006
	am No 50, 2024
s. 22A	ad. No. 204, 1991
	am. No. 6, 1996; No. 111, 2001; No. 39, 2003
	rs. No. 39, 2006
	am. No. 38, 2009; No 180, 2012; No 7, 2018
s. 22B	ad. No. 39, 2006
Division 1A	
Division 1A	ad No 7, 2018
s 22C	ad No 7, 2018
s 22D	ad No 7, 2018
s 22E	ad No 7, 2018
s 22F	ad No 7, 2018
Division 1B	
Division 1B	ad No 75, 2020
s 22G	ad No 75, 2020
Division 2	
s. 23	am. No. 84, 1991; No. 76, 1993; No. 141, 2010
	rs No 7, 2018
s 23AA	ad No 6, 1996
	rep No 5, 2006
	ad No 7, 2018
	am No 75, 2020
s 23A	ad No 7, 2018
	am No 75, 2020
s 23B	ad No 7, 2018
	am No 8, 2021

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Endnote 4—Amendment history

Provision affected	How affected
s 23C	ad No 7, 2018
	am No 75, 2020; No 8, 2021
s. 24	am. Nos. 84 and 204, 1991; No. 77, 2011; No 7, 2018
s. 24A	ad. No. 84, 1991
	am. No. 204, 1991; No. 77, 2011
s. 24B	ad. No. 84, 1991
	am. No. 24, 2002
s. 24C	ad. No. 84, 1991
s. 24D	ad. No. 204, 1991
	am. No. 56, 2002; No. 76, 2009; No. 77, 2011; No 4, 2014
s. 24E	ad. No. 88, 1992
s 25	am No 84, 1991; No 204, 1991; No 76, 1993; No 6, 1996; No 116, 1997; No 34, 1998; No 12, 2000; No 24, 2002; No 56, 2002; No 39, 2003; No 120, 2004; No 2, 2006; No 54, 2010; No 141, 2010; No 4, 2014; No 7, 2018; No 75, 2020; No 8, 2021; No 50, 2024
s 25AAA	ad No 47, 2017
	am No 104, 2018
s. 25AA	ad. No. 141, 2010
	am No 4, 2014; No 7, 2018
s 25AB	ad No 4, 2014
	am No 7, 2018; No 75, 2020
s 25AC	ad No 4, 2014
	am No 7, 2018
s 25A	ad No 34, 1998
	am No 54, 2010; No 75, 2020
s 25B	ad No 116, 1997 (as am by No 3, 1999)
	am No 56, 2002; No 7, 2018
	rep No 75, 2020

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Endnote 4—Amendment history

Provision affected	How affected
s 26	am No 76, 1993; No 6, 1996; No 116, 1997; No 12, 2000; No 14, 2001; No 24, 2002; No 56, 2002; No 39, 2003; No 120, 2004; No 2, 2006; No 76, 2009; No 54, 2010; No 141, 2010; No 4, 2014; No 7, 2018; No 75, 2020; No 8, 2021
s 26AA	ad No 116, 1997
	am No 56, 2002; No 7, 2018
	rep No 75, 2020
s. 26A	ad. No. 6, 1996
	am. No. 116, 1997; No. 12, 2000; No. 14, 2001; Nos. 24 and 56, 2002; No. 39, 2003; No. 120, 2004; No. 2, 2006; No. 76, 2009; Nos. 54 and 141, 2010; No 4, 2014; No 7, 2018
s 26AB	ad No 7, 2018
s 26AC	ad No 7, 2018
s 26AD	ad No 7, 2018
s 26AE	ad No 7, 2018
	am No 75, 2020
s 26AF	ad No 75, 2020
	am No 8, 2021
s. 26B	ad. No. 120, 2004
	am. No. 2, 2006; No. 38, 2009; No 4, 2016
s. 26BA	ad. No. 2, 2006
	am No 4, 2014; No 7, 2018
s. 26BB	ad. No. 76, 2009
	rs. No. 141, 2010
	am No 126, 2015; No 7, 2018
s. 26BC	ad No 76, 2009
	am No 141, 2010
s 26BD	ad No 76, 2009
	am No 141, 2010
	rep No 47, 2017
	ad No 75, 2020
s 26BDA	ad No 75, 2020

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Endnote 4—Amendment history

Provision affected	How affected
	am No 8, 2021
s 26BE	ad No 76, 2009
	rep No 141, 2010
	ad No 47, 2017
	am No 7, 2018; No 75, 2020; No 8, 2021
s 26BF	ad No 7, 2018
	am No 10, 2023
s 26BG	ad No 7, 2018
s 26BH	ad No 7, 2018
s 26BJ	ad No 7, 2018
s. 26C	ad. No. 120, 2004
	am. No. 38, 2009
s. 26D	ad. No. 120, 2004
s. 27	rs. No. 84, 1991
s 28	am No 84, 1991; No 76, 1993; No 3, 1999; No 14, 2001; No 39, 2003; No 76, 2009; No 54, 2010; No 4, 2014; No 47, 2017
	ed C67
	am No 7, 2018; No 75, 2020; No 10, 2023
s. 28A	ad. No. 76, 2009
	am No 7, 2018
s 29	am No 76, 2009; No 7, 2018; No 75, 2020
s. 29A	ad. No. 88, 1992
	am. No. 6, 1996; No. 39, 2003; No. 39, 2006; No 38, 2009; No 180, 2012
s. 29AA	ad. No. 39, 2006
s. 29B	ad. No. 88, 1992
	am. No. 6, 1996; No. 111, 2001; No. 39, 2003; No. 39, 2006; No. 38, 2009; No 180, 2012
s. 29C	ad. No. 39, 2006
s. 29D	ad. No. 76, 2009
	am No 4, 2014; No 7, 2018

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Provision affected	How affected
s. 29E	ad. No. 76, 2009
	am No 4, 2014
s. 29F	ad. No. 76, 2009
	am No 4, 2014
s. 29G	ad. No. 76, 2009
s 30	am No 88, 1992; No 6, 1996; No 34, 1998; No 56, 2000; No 14, 2001; No 111, 2001; No 39, 2003; No 39, 2006; No 76, 2009; No 141, 2010; No 4, 2014; No 47, 2017; No 7, 2018; No 75, 2020; No 8, 2021; No 50, 2024; No 38, 2025
s. 30A	ad. No. 6, 1996
	am. No. 111, 2001; No. 23, 2002
	rep. No. 39, 2003
	ad. No. 76, 2009
s 30AA	ad No 47, 2017
s. 30B	ad. No. 116, 1997
	rep. No. 39, 2003
	ad No 4, 2014
s. 30C	ad. No. 170, 2000
	am. No. 96, 2009; No 7, 2018
s. 30D	ad. No. 170, 2000
	am. No. 96, 2009
s. 30E	ad. No. 170, 2000
Division 2A	
Division 2A heading	rs No 47, 2017
Division 2A	ad. No. 39, 2003
s 30EA	ad No 39, 2003
	am No 39, 2006; No 76, 2009; No 54, 2010; No 4, 2014; No 47, 2017; No 7, 2018; No 8, 2021
s. 30EB	ad. No. 39, 2003
	am No 4, 2014
s. 30EC	ad. No. 39, 2003
	rs. No. 39, 2006

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Endnote 4—Amendment history

Provision affected	How affected
	am. No. 38, 2009; No 180, 2012; No 7, 2018
s. 30ECA	ad. No. 39, 2006
s. 30ED	ad. No. 39, 2003
	am. No. 76, 2009
s 30EE	ad No 47, 2017
Division 2B	
Division 2B	ad No 104, 2018
s 30EF	ad No 104, 2018
	am No 10, 2023
s 30EFA	ad No 10, 2023
s 30EG	ad No 104, 2018
s 30EH	ad No 104, 2018
s 30EI	ad No 104, 2018
s 30EIA	ad No 10, 2023
s 30EJ	ad No 104, 2018
Division 2C	
Division 2C	ad No 8, 2021
s 30EK	ad No 8, 2021
	am No 50, 2024
s 30EL	ad No 8, 2021
	am No 50, 2024
Division 3	
s. 30F	ad. No. 23, 2002
	am. No. 39, 2006; No. 38, 2009; No 180, 2012; No 126, 2015; No 47, 2017; No 7, 2018
s. 30FA	ad. No. 39, 2006
s. 30G	ad. No. 23, 2002
s. 30H	ad. No. 23, 2002
	am. No. 38, 2009

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Provision affected	How affected
s 31	am No 84, 1991; No 76, 1993; No 6, 1996; No 34, 1998; No 14, 2001; No 111, 2001; No 39, 2003; No 39, 2006; No 38, 2009; No 54, 2010; No 141, 2010; No 77, 2011; No 180, 2012; No 4, 2014; No 47, 2017; No 7, 2018; No 104, 2018; No 8, 2021; No 50, 2024
s. 31AAA	ad. No. 39, 2006
	am No 4, 2014
s. 31A	ad. No. 120, 2000
	am. No. 39, 2006
s. 31AA	ad. No. 23, 2002
	am. No. 39, 2006
s. 31B	ad. No. 120, 2000
	am. No. 39, 2006; No 47, 2017
s 31BA	ad No 47, 2017
	am No 10, 2023
s. 31C	ad. No. 120, 2000
	am. No. 23, 2002
	rs. No. 39, 2006
	am. No. 38, 2009; No 47, 2017; No 7, 2018
s. 31D	ad. No. 120, 2000
	am. No. 23, 2002; No. 39, 2006; No. 38, 2009; No 180, 2012; No 4, 2016; No 47, 2017; No 7, 2018
s. 31E	ad. No. 120, 2000
	am. No. 39, 2006; No. 38, 2009; No 180, 2012; No 4, 2016; No 47, 2017; No 7, 2018
s. 31F	ad. No. 120, 2000
	am. No. 39, 2006; No 47, 2017; No 7, 2018
Part 3-2A	
Part 3-2A	ad. No. 54, 2010
Division 1	
s. 32	am. Nos. 84 and 204, 1991; No. 76, 1993; No. 6, 1996
	rep. No. 24, 2002
	ad. No. 54, 2010

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Endnote 4—Amendment history

Provision affected	How affected
	am No 47, 2017
s. 32A	ad. No. 54, 2010
	am No 126, 2015
s 32AA	ad. No. 54, 2010
	am No 7, 2018
s 32AB	ad. No. 54, 2010
Division 2	
s. 32B	ad. No. 54, 2010
s. 32BA	ad. No. 54, 2010
	am No. 180, 2012; No 47, 2017; No 7, 2018
s. 32BB	ad. No. 54, 2010
	am No. 180, 2012; No 7, 2018
s 32BBA	ad No 7, 2018
s. 32BC	ad. No. 54, 2010
	am No. 180, 2012; No 7, 2018
s. 32BD	ad. No. 54, 2010
	am No. 180, 2012; No 47, 2017; No 7, 2018
s. 32BE	ad. No. 54, 2010
s 32BF	ad No 54, 2010
	am No 47, 2017; No 7, 2018; No 10, 2023; No 38, 2025
s. 32BG	ad. No. 54, 2010
	am No 7, 2018
s. 32BH	ad. No. 54, 2010
	am No 47, 2017; No 7, 2018
s. 32BI	ad. No. 54, 2010
	am No 47, 2017; No 7, 2018
s 32BJ	ad No 54, 2010
	am No 47, 2017; No 7, 2018; No 75, 2020
s. 32BK	ad. No. 54, 2010
	am No 47, 2017; No 7, 2018
s 32BL	ad No 7, 2018

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Provision affected	How affected
Division 3	
Subdivision A	
s. 32C	ad. No. 54, 2010
Subdivision B	
s 32CA	ad No 54, 2010
	am No 126, 2015; No 38, 2025
Subdivision C	
s 32CB	ad No 54, 2010
	am No 46, 2011; No 129, 2020
s 32CC	ad No 54, 2010
	am No 38, 2025
s 32CD	ad No 54, 2010
	am No 46, 2011
s. 32CE	ad. No. 54, 2010
s 32CF	ad No 54, 2010
	am No 129, 2020
s. 32CG	ad. No. 54, 2010
s 32CH	ad No 54, 2010
	am No 180, 2012
	rep No 38, 2025
s 32CI	ad No 54, 2010
	rep No 38, 2025
s. 32CJ	ad. No. 54, 2010
	am No. 180, 2012; No 47, 2017; No 7, 2018
Subdivision D	
Subdivision D heading	rs No 47, 2017
s 32CK	ad No 54, 2010
	am No 7, 2018; No 75, 2020; No 38, 2025
s 32CL	ad No 54, 2010
	am No 38, 2025
s 32CM	ad No 54, 2010

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Endnote 4—Amendment history

Provision affected	How affected
	am No 47, 2017; No 7, 2018; No 104, 2018; No 75, 2020; No 10, 2023; No 50, 2024; No 38, 2025
s 32CN	ad No 54, 2010
	am No 47, 2017; No 7, 2018; No 38, 2025
Subdivision E	
s 32CO	ad No 54, 2010
	am No 47, 2017; No 7, 2018; No 38, 2025
Subdivision F	
Subdivision F	ad No 38, 2025
s 32CP	ad No 38, 2025
s 32CQ	ad No 38, 2025
Division 4	
Subdivision A	
s 32D	ad No 54, 2010
	rs No 10, 2023
Subdivision B	
s 32DA	ad No 54, 2010
	am No 4, 2014; No 8, 2021
s. 32DB	ad. No. 54, 2010
s. 32DC	ad. No. 54, 2010
Subdivision BA	
Subdivision BA	ad No 10, 2023
s 32DCA	ad No 10, 2023
s 32DCB	ad No 10, 2023
s 32DCC	ad No 10, 2023
Subdivision C	
Subdivision C heading	rs No 10, 2023
s 32DD	ad No 54, 2010
	am No 7, 2018; No 10, 2023
s 32DDA	ad No 7, 2018
	am No 8, 2021

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Provision affected	How affected
s 32DE	ad No 54, 2010
	am No 4, 2014; No 7, 2018
	ed C69
	am No 8, 2021
s 32DEA	ad No 47, 2017
	am No 104, 2018
s. 32DF	ad. No. 54, 2010
	am No 7, 2018
s. 32DG	ad. No. 54, 2010
	am No 7, 2018
s. 32DH	ad. No. 54, 2010
	am No 7, 2018
s. 32DI	ad. No. 54, 2010
	am No 7, 2018
s. 32DJ	ad. No. 54, 2010
s. 32DK	ad. No. 54, 2010
s. 32DL	ad. No. 54, 2010
s. 32DM	ad. No. 54, 2010
Subdivision D	
s. 32DN	ad. No. 54, 2010
Subdivision E	
s. 32DO	ad. No. 54, 2010
	am No. 180, 2012; No 7, 2018
s. 32DP	ad. No. 54, 2010
s. 32DQ	ad. No. 54, 2010
	am No 180, 2012
s. 32DR	ad. No. 54, 2010
	am No 180, 2012
Subdivision F	
s 32DS	ad. No. 54, 2010
s 32DT	ad. No. 54, 2010

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Endnote 4—Amendment history

Provision affected	How affected
s 32DU	ad. No. 54, 2010
Division 5	
s. 32E	ad. No. 54, 2010
s 32EA	ad No 54, 2010
	am No 7, 2018; No 10, 2023
s. 32EB	ad. No. 54, 2010
s. 32EC	ad. No. 54, 2010
	am No 7, 2018
s. 32ED	ad. No. 54, 2010
s. 32EE	ad. No. 54, 2010
	am No 4, 2014
s. 32EF	ad. No. 54, 2010
	am No. 180, 2012; No 7, 2018
s. 32EG	ad. No. 54, 2010
Division 6	
s. 32F	ad. No. 54, 2010
s. 32FA	ad. No. 54, 2010
	am No 4, 2014; No 7, 2018
s. 32FB	ad. No. 54, 2010
	am No 4, 2014
s. 32FC	ad. No. 54, 2010
	am No 4, 2014
s. 32FD	ad. No. 54, 2010
Division 7	
s. 32G	ad. No. 54, 2010
s 32GA	ad No 54, 2010
	am No 4, 2014; No 7, 2018; No 8, 2021; No 10, 2023
s 32GB	ad No 54, 2010
	am No 4, 2014; No 10, 2023
s. 32GC	ad. No. 54, 2010
	am No 4, 2014; No 7, 2018

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Provision affected	How affected
s. 32GD	ad. No. 54, 2010
s 32GDA	ad No 47, 2017
s. 32GE	ad. No. 54, 2010
	am No 4, 2014
s. 32GF	ad. No. 54, 2010
Division 8	
Division 8 heading	rs No 47, 2017
s. 32H	ad. No. 54, 2010
	am No 47, 2017
s 32HA	ad No 54, 2010
	am No 4, 2014; No 47, 2017; No 7, 2018; No 8, 2021
s. 32HB	ad. No. 54, 2010
	am No 4, 2014
s. 32HC	ad. No. 54, 2010
	am No. 180, 2012; No 7, 2018
s. 32HD	ad. No. 54, 2010
s. 32HE	ad. No. 54, 2010
s 32HF	ad No 47, 2017
Division 9	
Subdivision A	
s. 32J	ad. No. 54, 2010
Subdivision B	
s 32JA	ad No 54, 2010
	am No 4, 2014; No 8, 2021
s. 32JB	ad. No. 54, 2010
	am No 180, 2012; No 4, 2014; No 7, 2018
s. 32JC	ad. No. 54, 2010
s. 32JD	ad. No. 54, 2010
	am No 7, 2018
Subdivision C	
s. 32JE	ad. No. 54, 2010

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Endnote 4—Amendment history

Provision affected	How affected
s. 32JF	ad. No. 54, 2010
s. 32JG	ad. No. 54, 2010
	am No 47, 2017
s. 32JH	ad. No. 54, 2010
	am No 47, 2017
s. 32JI	ad. No. 54, 2010
	am No 180, 2012; No 7, 2018
s. 32JJ	ad. No. 54, 2010
s. 32JK	ad. No. 54, 2010
	am No 7, 2018
Subdivision D	
s 32JL	ad No. 54, 2010
s 32JM	ad No. 54, 2010
s. 33	rep No. 24, 2002
Part 3-3	
Part 4 heading	rep. No. 24, 2002
Part 3-3 heading	ad. No. 24, 2002
s 33A	ad No 24, 2002
	rs No 75, 2020
s. 33B	ad. No. 54, 2010
s. 35	am. No. 6, 1996; No. 111, 2001; No. 23, 2002; No. 39, 2003
	rs. No. 39, 2006
	am. No. 38, 2009; No. 54, 2010; No. 180, 2012; No 7, 2018
s. 35A	ad. No. 39, 2006
	am. No. 54, 2010
s. 35B	ad. No. 39, 2006
	am. No. 38, 2009; No 7, 2018
s. 35C	ad. No. 39, 2006
s 36	am No 76, 2009; No 47, 2017; No 10, 2023
s 37	am No 76, 1993; No 56, 2002; No 96, 2006; No 76, 2009; No 8, 2021

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Provision affected	How affected
s 38	am No 76, 1993; No 34, 1998; No 39, 2003; No 39, 2006; No 38, 2009; No 76, 2009; No 46, 2011; No 4, 2014; No 8, 2021
s 38A	ad No. 76, 2009
s 38B	ad No. 76, 2009
s. 39	am. No. 23, 2002; No. 54, 2010
s. 40	am. No. 76, 1993; No. 56, 2002; No. 39, 2003; Nos. 38 and 76, 2009; No. 54, 2010; No. 4, 2014
s 40A	ad No 76, 2009
s 40B	ad No 76, 2009
	am No 46, 2011; No 7, 2018
s 41	am No 34, 1998; No 23, 2002; No 39, 2003; No 39, 2006; No 38, 2009; No 76, 2009; No 54, 2010; No 4, 2014; No 8, 2021
s 41AAAA	ad No 4, 2014
s. 41AA	ad. No. 38, 2009
s 41AB	ad No 47, 2017
s 41AC	ad No 47, 2017
s 41AD	ad No 47, 2017
s 41AE	ad No 47, 2017
s 41AF	ad No 47, 2017
s 41AG	ad No 47, 2017
s. 41AAA	ad. No. 76, 2009
s 41A (prev s 42)	am No 76, 1993 renum No 24, 2002
	am No 76, 2009
Chapter 4	
Chapter 4	ad No 24, 2002
	am No 140, 2007; No 75, 2020
Part 4-1	
Division 1	
s. 41B	ad. No. 24, 2002
	am. No. 39, 2006
s. 41BA	ad. No. 24, 2002

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Endnote 4—Amendment history

Provision affected	How affected
	am No 7, 2018
s. 41BB	ad. No. 24, 2002
	am. No. 38, 2009; No 47, 2017; No 7, 2018
s. 41BC	ad. No. 24, 2002
	am. No. 39, 2006
Division 2	
s 41BD	ad No 24, 2002
	am No 76, 2009; No 4, 2014; No 75, 2020; No 10, 2023
	ed C82
s. 41BE	ad. No. 24, 2002
	am. No. 76, 2009
s. 41BEA	ad. No. 96, 2009
s 41BF	ad No 24, 2002
	rs No 75, 2020
s 41BG	ad No 24, 2002
	am No 76, 2009; No 50, 2024
s 41BH	ad No 24, 2002
s 41BI	ad No 24, 2002
s 41BIA	ad No 7, 2018
s 41BIB	ad No 7, 2018
Division 3	
s 41BJ	ad No 24, 2002
	rep No 75, 2020
s. 41BJA	ad. No. 54, 2010
s. 41BK	ad. No. 24, 2002
Part 4-2	
s 41C	ad No 24, 2002
	am No 39, 2006; No 8, 2021
Division 1	
s 41CA	ad No 24, 2002
	am No 8, 2021

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Provision affected	How affected
Division 2	
s 41CB	ad No 24, 2002
	am No 76, 2009; No 126, 2015; No 75, 2020
s. 41CC	ad. No. 24, 2002
	am. No. 38, 2009; No. 46, 2011; No 4, 2014
s. 41CD	ad. No. 24, 2002
Division 3	
Division 3	ad No 8, 2021
s 41CE	ad No 8, 2021
Part 4-3	
s. 41D	ad No 24, 2002
	am No 39, 2006
Division 1	
s 41DA	ad. No. 24, 2002
s 41DB	ad. No. 24, 2002
Division 2	
s 41DC	ad No 24, 2002
	am No 76, 2009; No 126, 2015; No 75, 2020
s. 41DD	ad. No. 24, 2002
	am. No. 46, 2011; No 4, 2014
s. 41DE	ad. No. 24, 2002
Part 4-4	
s. 41E	ad. No. 24, 2002
	am No 7, 2018
Division 1	
s 41EA	ad No 24, 2002
s 41EB	ad No 24, 2002
	am No. 39, 2006
s. 41EC	ad. No. 24, 2002
	am. No. 39, 2003; No. 39, 2006; No. 38, 2009; No 7, 2018
s 41ECA	ad No 47, 2017

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Endnote 4—Amendment history

Provision affected	How affected
	am No 104, 2018
s. 41ED	ad. No. 24, 2002
	am. No. 54, 2010
s 41EE	ad. No. 24, 2002
	am No 7, 2018
s 41EF	ad. No. 24, 2002
	am No 7, 2018
s. 41EG	ad. No. 24, 2002
	am. No. 38, 2009; No. 141, 2010; No 7, 2018
s. 41EH	ad. No. 24, 2002
s. 41EI	ad. No. 24, 2002
	rs. No. 39, 2006
	am. No. 38, 2009; No 180, 2012; No 7, 2018
s. 41EIA	ad. No. 39, 2006
Division 2	
Division 2 heading	am No. 39, 2006
Division 2	am No 7, 2018
s. 41EJ	ad. No. 24, 2002
	am. Nos. 38 and 76, 2009
s. 41EK	ad. No. 24, 2002
s. 41EL	ad. No. 24, 2002
	am No 4, 2014
Division 3	
Division 3	am No 7, 2018
s 41EM	ad. No. 24, 2002
s 41EN	ad No. 24, 2002
s 41EO	ad No. 24, 2002
s 41EP	ad No. 24, 2002
s 41EQ	ad No. 24, 2002
Division 4	
Division 4	am No 7, 2018

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Provision affected	How affected
s. 41ER	ad. No. 24, 2002
s. 41ES	ad. No. 24, 2002
	am No 4, 2014
s. 41ET	ad. No. 24, 2002
	am. No. 39, 2003; No. 39, 2006; No. 38, 2009; No 7, 2018
s. 41EU	ad. No. 24, 2002
s. 41EV	ad. No. 24, 2002
	am No 4, 2014
s. 41EW	ad. No. 24, 2002
Part 4–4A	
Part 4–4A	ad No 47, 2017
s 41EWA	ad No 47, 2017
	am No 7, 2018
s 41EWB	ad No 7, 2018
s 41EWC	ad No 7, 2018
s 41EWD	ad No 7, 2018
Part 4-5	
s. 41F	ad. No. 24, 2002
	am No 7, 2018
Division 1	
s. 41FA	ad. No. 24, 2002
	am No 39, 2006; No 7, 2018
s. 41FB	ad. No. 24, 2002
	rep No 7, 2018
Subdivision A	
s. 41FC	ad. No. 24, 2002
	am No 39, 2006
	rs No 7, 2018
s 41FD	ad No 24, 2002
	am No 39, 2003; No 96, 2009; No 4, 2014; No 7, 2018; No 8, 2021; No 50, 2024

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Endnote 4—Amendment history

Provision affected	How affected
s 41FDA	ad No 7, 2018
	am No 75, 2020
s 41FDB	ad No 7, 2018
s. 41FE	ad. No. 24, 2002
	am. No. 39, 2003
	rs. No. 39, 2006
	am. No. 38, 2009; No 180, 2012; No 7, 2018
s. 41FEA	ad. No. 39, 2006
Subdivision B	
s. 41FF	ad. No. 24, 2002
	am. No. 96, 2009; No 7, 2018
s. 41FG	ad. No. 24, 2002
	rs No 7, 2018
Subdivision C	
s. 41FH	ad. No. 24, 2002
	am No 4, 2014; No 7, 2018
s. 41FI	ad. No. 24, 2002
	am No 7, 2018
s 41FIA	ad No 47, 2017
	rs No 7, 2018
s. 41FJ	ad. No. 24, 2002
s. 41FK	ad. No. 24, 2002
	am. No. 141, 2010; No 4, 2014; No 7, 2018
Subdivision D	
s 41FKA	ad No 47, 2017
	am No 104, 2018
s 41FL	ad No 24, 2002
s 41FM	ad No 24, 2002
	am No 7, 2018
Division 2	
Division 2 heading	rs. No. 39, 2006

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Provision affected	How affected
Division 2	am No 7, 2018
s 41FN	ad No 24, 2002
	am No 39, 2006; No 76, 2009; No 47, 2017; No 7, 2018; No 104, 2018; No 10, 2023
s. 41FO	ad. No. 24, 2002
s. 41FP	ad. No. 24, 2002
	am No 4, 2014
Part 4-6	
Division 1	
Subdivision A	
s. 41G	ad. No. 24, 2002
	am No 7, 2018
s. 41GA	ad. No. 24, 2002
	am No 4, 2014; No 7, 2018
s. 41GB	ad. No. 24, 2002
s. 41GC	ad. No. 24, 2002
	am No 4, 2014
s. 41GD	ad. No. 24, 2002
	am No 4, 2014
s. 41GE	ad. No. 24, 2002
Subdivision B	
Subdivision B heading	rs No 7, 2018
s. 41GF	ad. No. 24, 2002
	am No 4, 2014; No 7, 2018
s 41GFA	ad No 7, 2018
s. 41GG	ad. No. 24, 2002
	am No 7, 2018
s. 41GH	ad. No. 24, 2002
	am No 4, 2014; No 7, 2018
Subdivision C	
s. 41GI	ad. No. 24, 2002

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Endnote 4—Amendment history

Provision affected	How affected
	am No 39, 2006
s. 41GJ	ad. No. 24, 2002
Division 2	
s 41GK	ad No 24, 2002
	am No 8, 2021
s 41GL	ad No 24, 2002
	am No 39, 2003; No 4, 2014; No 7, 2018; No 75, 2020; No 50, 2024
s 41GLA	ad No 4, 2014
s 41GLB	ad No 47, 2017
s. 41GM	ad. No. 24, 2002
	am No 4, 2014
s 41GN	ad No 24, 2002
	am No 39, 2006; No 7, 2018; No 50, 2024
s. 41GO	ad. No. 24, 2002
s. 41GP	ad. No. 24, 2002
	am No 4, 2014
s. 41GQ	ad. No. 24, 2002
Part 4-6A	
Part 4-6A	ad. No. 38, 2009
s 41GR	ad No 38, 2009
	am No 47, 2017
s 41GS	ad No 38, 2009
	am No 129, 2020
s 41GT	ad No 38, 2009
	am No 8, 2021
s 41GU	ad No 38, 2009
s 41GV	ad No 38, 2009
s 41GW	ad No 38, 2009
	am No 129, 2020
s 41GX	ad. No. 38, 2009

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Provision affected	How affected
	rep. No. 54, 2010
s. 41GY	ad. No. 38, 2009
Part 4-7	
Part 4-7 heading	rs. No. 38, 2009
s 41H	ad No 24, 2002
	am No 38, 2009; No 141, 2010; No 47, 2017; No 38, 2025
s 41HA	ad No 24, 2002
	am No 39, 2006; No 50, 2024
s 41HB	ad No 24, 2002
	am No 39, 2006; No 7, 2018; No 75, 2020; No 8, 2021; No 50, 2024
s 41HC	ad No 24, 2002
	am No 54, 2010; No 47, 2017; No 7, 2018; No 104, 2018; No 75, 2020; No 50, 2024
s 41HD	ad No 141, 2010
	am No 126, 2015; No 47, 2017; No 7, 2018; No 50, 2024; No 38, 2025
Part 4-8	
s. 41J	ad. No. 24, 2002
	am No. 39, 2006; No 7, 2018
Division 1	
s 41JA	ad No 24, 2002
	am No 39, 2003; No 38, 2009; No 76, 2009; No 4, 2014; No 7, 2018; No 8, 2021; No 50, 2024
s. 41JB	ad. No. 24, 2002
	am. No. 39, 2006; No. 38, 2009; No 180, 2012; No 4, 2014; No 7, 2018
s. 41JBA	ad. No. 39, 2006
s. 41JC	ad. No. 24, 2002
	am. No. 39, 2006; No 7, 2018
Division 2	
s. 41JCA	ad. No. 38, 2009

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Provision affected	How affected
s 41JD	ad. No. 24, 2002
	am. No. 39, 2006
s 41JE	ad. No. 24, 2002
	am. No. 39, 2006
s 41JF	ad. No. 24, 2002
	am. No. 39, 2006; No 47, 2017
s. 41JFA	ad. No. 141, 2010
	am No 47, 2017
s. 41JG	ad. No. 24, 2002
	rs. No. 39, 2006
	am. No. 38, 2009; No. 141, 2010; No 7, 2018
s. 41JH	ad. No. 24, 2002
	am. No. 39, 2006; No. 38, 2009; No. 141, 2010; No 180, 2012; No 4, 2016; No 7, 2018
s. 41JI	ad. No. 24, 2002
	am. No. 39, 2006; No. 38, 2009; No. 141, 2010; No 180, 2012; No 4, 2016; No 7, 2018
s. 41JJ	ad. No. 24, 2002
	am. No. 39, 2006; No. 38, 2009; No. 141, 2010
Part 4-8A	
Part 4-8A	ad No 10, 2023
Division 1	
s 41JK	ad No 10, 2023
s 41JL	ad No 10, 2023
Division 2	
s 41JM	ad No 10, 2023
Part 4-9	
Part 4-9 heading	rs No 47, 2017
s. 41K	ad. No. 24, 2002
	am No 47, 2017
s 41KA	ad No 24, 2002

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Provision affected	How affected
	am No 38, 2009; No 54, 2010; No 141, 2010; No 47, 2017; No 7, 2018; No 8, 2021
s. 41KB	ad. No. 24, 2002
	am No 4, 2014
s. 41KC	ad. No. 24, 2002
	rs. No. 39, 2006
	am. No. 38, 2009; No 180, 2012; No 7, 2018
s. 41KCA	ad. No. 39, 2006
s. 41KD	ad. No. 24, 2002
s 41KE	ad No 47, 2017
Part 4-10	
s. 41L	ad. No. 24, 2002
s 41LA	ad No 24, 2002
s 41LB	ad No 24, 2002
s 41LC	ad No 24, 2002
s 41LD	ad No 24, 2002
s 41LE	ad No 24, 2002
Part 4-11	
Part 4-11 heading	rs. No. 39, 2006
s. 41M	ad. No. 24, 2002
	am. No. 39, 2006; No. 38, 2009; No 7, 2018
Division 1	
s. 41MA	ad. No. 24, 2002
	am. No. 39, 2003
	rs. No. 39, 2006
	am. No. 38, 2009; No 180, 2012; No 7, 2018
s. 41MAA	ad. No. 39, 2006
	am. No. 38, 2009; No 7, 2018
s 41MAB	ad No 38, 2025
s. 41MB	ad. No. 24, 2002
	am. No. 39, 2006

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Endnote 4—Amendment history

Provision affected	How affected
s. 41MC	ad. No. 24, 2002
	rs. No. 39, 2006
	am. No. 38, 2009; No 180, 2012; No 7, 2018
s. 41MCA	ad. No. 39, 2006
s. 41MD	ad. No. 24, 2002
	am. No. 39, 2006; No 41, 2015; No 7, 2018
Division 2	
s. 41ME	ad. No. 24, 2002
	am. No. 39, 2003
	rs. No. 39, 2006
	am. No. 38, 2009; No 180, 2012; No 7, 2018
s. 41MEA	ad. No. 39, 2006
	am. No. 38, 2009
s. 41MF	ad. No. 24, 2002
	am. No. 39, 2003
	rs. No. 39, 2006
	am. No. 38, 2009; No 180, 2012; No 7, 2018
s. 41MG	ad. No. 24, 2002
	am. No. 39, 2006; No 7, 2018
s. 41MH	ad. No. 24, 2002
	am No. 39, 2003; No 39, 2006; No. 38, 2009; No 180, 2012; No 4, 2016; No 7, 2018
s 41MHA	ad No 39, 2006
	am No 7, 2018
Division 3	
s. 41MI	ad. No. 24, 2002
	am. No. 39, 2003
	rs. No. 39, 2006
	am. No. 38, 2009; No. 141, 2010; No 180, 2012; No 47, 2017; No 7, 2018
s. 41MIA	ad. No. 39, 2006

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Provision affected	How affected
s. 41MIB	ad. No. 39, 2006
	am. No. 38, 2009; No. 141, 2010; No 47, 2017
s. 41MJ	ad. No. 24, 2002
	am. No. 39, 2006; No 41, 2015; No 7, 2018
s. 41MK	ad. No. 24, 2002
	am. No. 38, 2009; No. 141, 2010; No 4, 2016; No 47, 2017
s. 41ML	ad. No. 24, 2002
	am. No. 39, 2006; No. 38, 2009
	rs. No. 96, 2009; No 7, 2018
s. 41MLA	ad. No. 39, 2006
	am. No. 141, 2010; No 47, 2017
s 41MLB	ad No 7, 2018
s 41MM	ad No 24, 2002
	am No 38, 2009; No 4, 2016
	rs No 7, 2018
	rep No 75, 2020
s 41MN	ad No 24, 2002
	rs No 39, 2006
	am No 38, 2009; No 141, 2010; No 180, 2012; No 47, 2017; No 7, 2018; No 50, 2024
s 41MNA	ad No 39, 2006
	am No 7, 2018; No 50, 2024
Division 3A	
Division 3A	ad. No. 38, 2009
s. 41MNB	ad. No. 38, 2009
	am No 180, 2012
s. 41MNC	ad. No. 38, 2009
s. 41MND	ad. No. 38, 2009
Division 4	
Division 4 heading	rs. No. 39, 2006
s. 41MO	ad. No. 24, 2002

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Endnote 4—Amendment history

Provision affected	How affected
	rs. No. 39, 2006
	am. No. 38, 2009; No 47, 2017; No 7, 2018
s. 41MP	ad. No. 24, 2002
	am. No. 39, 2006; No. 38, 2009; No 180, 2012; No 4, 2016; No 47, 2017; No 7, 2018
s 41MPA	ad. No. 39, 2006
	am No 47, 2017; No 7, 2018
s 41MPB	ad. No. 39, 2006
s. 41MQ	ad. No. 24, 2002
	am. No. 39, 2006; No. 38, 2009; No 180, 2012; No 4, 2016
s. 41MR	ad. No. 39, 2006
Chapter 4A	
Chapter 4A	ad No 50, 2024
Part 4A-1	
Division 1	
s 41N	ad No 50, 2024
s 41NA	ad No 50, 2024
Division 2	
s 41P	ad No 50, 2024
Part 4A-2	
Division 1	
s 41Q	ad No 50, 2024
s 41QA	ad No 50, 2024
s 41QB	ad No 50, 2024
	am No 50, 2024; No 38, 2025
s 41QC	ad No 50, 2024
	am No 50, 2024; No 38, 2025
s 41QD	ad No 50, 2024
	am No 50, 2024; No 38, 2025
Division 2	
s 41QE	ad No 50, 2024

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Provision affected	How affected
Part 4A-3	
Division 1	
s 41R	ad No 50, 2024
s 41RA	ad No 50, 2024
Division 2	
s 41RB	ad No 50, 2024
	am No 38, 2025
s 41RC	ad No 50, 2024
	am No 38, 2025
s 41RD	ad No 50, 2024
Chapter 5	
Part 4A heading	rep. No. 24, 2002
Chapter 5 heading	ad. No. 24, 2002
Part 4A	ad. No. 3, 1999
Part 5-1	
Part 5-1 heading	ad. No. 24, 2002
	rs. No. 39, 2003
Division 1	
Division 1 of	ad. No. 39, 2003
s 42AA	ad No 39, 2003
	am No 76, 2009; No 10, 2023
s. 42AB	ad. No. 39, 2003
s. 42AC	ad. No. 39, 2003
	am. No. 38, 2009; No 7, 2018
s 42AD	ad No 50, 2024
	am No 38, 2025
s. 42A	ad. No. 3, 1999
	rep. No. 39, 2003
s 42B	ad No 3, 1999
	am No 39, 2003; No 38, 2009; No 7, 2018; No 10, 2023
s. 42BAA	ad. No. 76, 2009

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Endnote 4—Amendment history

Provision affected	How affected
	am No 104, 2018
Division 2	rep No 7, 2018
Division 2 heading	ad No 39, 2003
	rep No 7, 2018
s 42BA	ad No 39, 2003
	rep No 7, 2018
s 42C	ad No 3, 1999
	rs No 39, 2003
	am No 39, 2006; No 4, 2016
	rep No 7, 2018
s 42D	ad No 3, 1999
	rep No 39, 2003
Division 3	
Division 3	ad. No. 39, 2003
s 42DA	ad No 39, 2003
	rs No 38, 2009; No 7, 2018
s. 42DB	ad. No. 39, 2003
s. 42DC	ad. No. 39, 2003
	rep. No. 38, 2009
s. 42DD	ad. No. 39, 2003
	am. Nos. 38 and 76, 2009; No 7, 2018
s 42DE	ad No 39, 2003
	rs No 104, 2018
s 42DF	ad No 39, 2003
	am No 76, 2009; No 7, 2018
s 42DG	ad. No 39, 2003
s 42DH	ad. No 39, 2003
s 42DI	ad No 39, 2003
	am No 7, 2018; No 10, 2023
s 42DK	ad No 39, 2003
	am No 8, 2010

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Provision affected	How affected
	rs No 7, 2018
Division 3A	
Division 3A heading	ad No 38, 2009
	rs No 7, 2018
s 42DKA	ad No 38, 2009
	rep No 7, 2018
s 42DKB	ad. No. 38, 2009
	am No 7, 2018
s. 42DL	ad. No. 39, 2003
	am. No. 38, 2009; No. 54, 2010; No 4, 2014
	rs No 7, 2018
s 42DLA	ad No 7, 2018
s 42DLB	ad No 7, 2018
	am No 50, 2024
s 42DLC	ad No 7, 2018
s. 42DM	ad. No. 39, 2003
	am No 4, 2016
	rs No 7, 2018
s 42DMA	ad No 7, 2018
	am No 50, 2024
Division 4	
Division 4	ad. No. 39, 2003
s 42DN	ad. No. 39, 2003
s 42DO	ad. No. 39, 2003
	am No 7, 2018
s 42DP	ad. No. 39, 2003
	am No 4, 2016
	rs No 7, 2018
s 42DQ	ad No 7, 2018
Division 5	
Division 5	ad No 7, 2018

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Endnote 4—Amendment history

Provision affected	How affected
s 42DR	ad No 7, 2018
s 42DS	ad No 7, 2018
s 42DT	ad No 7, 2018
s 42DU	ad No 7, 2018
Division 6	
Division 6	ad No 7, 2018
s 42DV	ad No 7, 2018
s 42DW	ad No 7, 2018
s 42DX	ad No 7, 2018
Division 7	
Division 7	ad No 7, 2018
s 42DY	ad No 7, 2018
Part 5-1A	
Part 5-1A	ad No 50, 2024
Division 1	
s 42DZA	ad No 50, 2024
s 42DZB	ad No 50, 2024
Division 2	
s 42DZC	ad No 50, 2024
Division 3	
s 42DZD	ad No 50, 2024
s 42DZE	ad No 50, 2024
Division 4	
s 42DZF	ad No 50, 2024
s 42DZG	ad No 50, 2024
s 42DZH	ad No 50, 2024
s 42DZJ	ad No 50, 2024
Division 5	
s 42DZK	ad No 50, 2024
	am No 38, 2025
s 42DZL	ad No 50, 2024

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Provision affected	How affected
s 42DZM	ad No 50, 2024
Division 6	
s 42DZN	ad No 50, 2024
Part 5-2	
Part 4B heading	rep. No. 24, 2002
Part 5-2 heading	ad. No. 24, 2002
Part 4B	ad. No. 56, 2000
s. 42E	ad. No. 56, 2000
	am. No. 39, 2003; No. 39, 2006; No. 38, 2009; No 180, 2012; No 4, 2016
s 42EA	ad. No. 39, 2006
s 42EB	ad. No. 39, 2006
s. 42F	ad. No. 56, 2000
	am No 41, 2015
Part 5-3	
Part 4C heading	rep. No. 24, 2002
Part 5-3 heading	ad. No. 24, 2002
Part 4C	ad. No. 120, 2000
s. 42T	ad. No. 120, 2000
	am. No. 39, 2006; No. 38, 2009; No 180, 2012; No 4, 2016; No 47, 2017
s. 42U	ad. No. 120, 2000
s. 42V	ad. No. 120, 2000
	am. No. 24, 2002; No. 39, 2006; No. 38, 2009; No. 54, 2010; No 180, 2012; No 4, 2014; No 47, 2017; No 7, 2018
s 42VA	ad. No. 39, 2006
	am No 47, 2017
s 42VB	ad. No. 39, 2006
	am No 47, 2017
s. 42W	ad. No. 120, 2000
	am. No. 39, 2006; No. 38, 2009; No 180, 2012; No 4, 2016; No 47, 2017

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Endnote 4—Amendment history

Provision affected	How affected
s. 42X	ad. No. 120, 2000
Chapter 5A	
Chapter 5A	ad. No. 39, 2006
Part 5A-1	
Division 1	
s. 42Y	ad. No. 39, 2006
s. 42YA	ad. No. 39, 2006
s. 42YB	ad. No. 39, 2006
	rep No 31, 2014
s. 42YC	ad. No. 39, 2006
s 42YCA	ad No 7, 2018
s. 42YD	ad. No. 39, 2006
s. 42YE	ad. No. 39, 2006
	am. No. 38, 2009
Division 2	
s 42YF	ad. No. 39, 2006
s 42YG	ad. No. 39, 2006
s 42YH	ad. No. 39, 2006
s 42YI	ad. No. 39, 2006
Part 5A-2	
Part 5A–2	rs No 7, 2018
s 42YJ	ad. No. 39, 2006
	rs No 7, 2018
s 42YK	ad. No. 39, 2006
	rs No 7, 2018
s 42YKA	ad No 7, 2018
s 42YKB	ad No 7, 2018
	rs No 10, 2023
s 42YKBA	ad No 10, 2023
s 42YKC	ad No 7, 2018
s 42YKD	ad No 7, 2018

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Provision affected	How affected
	am No 10, 2023
s 42YKE	ad No 7, 2018
Part 5A-3	
s. 42YL	ad. No. 39, 2006
	am. No. 8, 2010
Part 5A-4	
Part 5A–4	ad No 7, 2018
s 42YM	ad No 7, 2018
	am No 13, 2021
s 42YN	ad No 7, 2018
	am No 13, 2021
s 42YO	ad No 7, 2018
	am No 13, 2021
s 42YP	ad No 7, 2018
	am No 13, 2021
s 42YQ	ad No 7, 2018
	am No 13, 2021
s 42YR	ad No 7, 2018
	am No 13, 2021
Part 5A-5	
Part 5A-5	ad No 50, 2024
s 42YS	ad No 50, 2024
	am No 38, 2025
s 42YT	ad No 50, 2024
	am No 38, 2025
Chapter 6	
Part 5 heading	rep. No. 24, 2002
Chapter 6 heading	ad. No. 24, 2002
Part 6-1	
Part 6-1 heading	ad. No. 24, 2002
s. 43	am. No. 24, 2002; No 7, 2018

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Endnote 4—Amendment history

Provision affected	How affected
s. 44	am. No. 84, 1991; No. 24, 2002
	rs. No. 96, 2008
	am No 7, 2018
s 44A	ad No 96, 2008
	am No 39, 2024
s. 44B	ad. No. 54, 2010
	am No 7, 2018
s. 45	rs. No. 152, 1997
	am. No. 24, 2002
	rs. No. 8, 2005
	am No 62, 2014; No 7, 2018
Part 6-1A	
Part 6-1A	ad No 10, 2023
Division 1	
s 45AA	ad No 10, 2023
Division 2	
s 45AB	ad No 10, 2023
s 45AC	ad No 10, 2023
s 45AD	ad No 10, 2023
s 45AE	ad No 10, 2023
Division 3	
s 45AF	ad No 10, 2023
s 45AG	ad No 10, 2023
Part 6-2	
Part 6 heading	rep. No. 6, 1996
Part 5A heading	ad. No. 6, 1996
	rep. No. 24, 2002
Part 6-2 heading	ad. No. 24, 2002
s 45A	ad No 6, 1996
	am No 39, 2006; No 38, 2025
s. 46	rs. No. 6, 1996

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Endnote 4—Amendment history

Provision affected	How affected
	am No 7, 2018
s 46A	ad No 6, 1996
	am No 23, 2002; No 24, 2002; No 38, 2009; No 76, 2009; No 54, 2010; No 141, 2010; No 47, 2017; No 7, 2018; No 75, 2020; No 50, 2024
s. 46B	ad No 6, 1996
s. 47	am. No. 76, 1993
	rs. No. 6, 1996
	am. No. 39, 2006; No 7, 2018
s 48	am No 6, 1996; No 111, 2001; No 38, 2009; No 76, 2009; No 7, 2018; No 50, 2024
s 48AAA	ad No 38, 2025
s 48A	ad No 6, 1996
	am No 50, 2024
s 48AA	ad No 7, 2018
	am No 50, 2024; No 38, 2025
s 48B	ad. No. 6, 1996
s 48BA	ad No 7, 2018
	am No 50, 2024
s 48C	ad No 6, 1996
	am No 39, 2006; No 7, 2018; No 50, 2024
s. 48D	ad. No. 6, 1996
	am No 7, 2018
s. 48E	ad. No. 6, 1996
	am. No. 39, 2006; No 7, 2018
s 48F	ad No 6, 1996
s 48FA	ad No 7, 2018
	am No 38, 2025
s 48G	ad No 6, 1996
s 48H	ad No 6, 1996
	am No 10, 2023; No 50, 2024

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Endnote 4—Amendment history

Provision affected	How affected
s 48J	ad No 6, 1996
	am No 39, 2006; No 10, 2023; No 50, 2024
s 49	am No 6, 1996; No 7, 2018; No 50, 2024
s 50	am No 6, 1996; No 39, 2006; No 7, 2018; No 50, 2024
s 51	am No 6, 1996; No 39, 2006; No 50, 2024
s. 51A	ad. No. 76, 1993
	am No 7, 2018
s 51B	ad No 6, 1996
	am No 38, 2009; No 50, 2024
s 51C	ad No 50, 2024
s. 52	am. No. 6, 1996; No. 111, 2001; No. 38, 2009
Part 6-2A	
Part 6-2A	ad No 50, 2024
s 52AAA	ad No 50, 2024
	am No 38, 2025
s 52AAB	ad No 50, 2024
Part 6-3	
Part 5B heading	rep. No. 24, 2002
Part 6-3 heading	ad. No. 24, 2002
	rs. No. 96, 2009
Part 5B	ad. No. 3, 1999
s. 52AA	ad. No. 96, 2009
s. 52A	ad. No. 3, 1999
	am. No. 96, 2009; No 126, 2015
s 52B	ad. No. 3, 1999
	rs. No. 96, 2009
s 52C	ad. No. 3, 1999
	rs. No. 96, 2009
s. 52CA	ad. No. 96, 2009
s. 52D	ad. No. 3, 1999
	am. No. 9, 2008; No. 96, 2009; No 126, 2015

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Provision affected	How affected
s. 52E	ad. No. 3, 1999
	rs. No. 96, 2009
s. 52EAA	ad. No. 96, 2009
s 52EA	ad. No. 9, 2008
	rep No 126, 2015
s 52EB	ad No 9, 2008
	rep No 75, 2020
s 52EC	ad No 96, 2009
	rep No 8, 2021
Part 5C heading	rep. No. 24, 2002
Part 6-4 heading	ad. No. 24, 2002
	rep. No. 76, 2009
Part 5C	ad. No. 3, 1999
Part 6-4	rep. No. 76, 2009
s 52F	ad No 3, 1999
	rep No 76, 2009
	ad No 8, 2021
Chapter 7	
Part 6 heading	ad. No. 6, 1996
	rep. No. 24, 2002
Chapter 7 heading	ad. No. 24, 2002
s 52G	ad No 3, 1999
	rep No 76, 2009
	ad No 8, 2021
	am No 10, 2023; No 38, 2025
s 53	rs No 24, 2002
	am No 54, 2010; No 8, 2021
s 53A	ad No 39, 2006
	am No 54, 2010; No 4, 2014; No 47, 2017; No 7, 2018; No 50, 2024; No 38, 2025

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Endnote 4—Amendment history

Provision affected	How affected
s 54	am No 204, 1991; No 76, 1993; No 6, 1996; No 24, 2002; No 39, 2006; No 4, 2014; No 7, 2018; No 50, 2024; No 38, 2025
s. 54AA	ad. No. 3, 1999
	am. No. 111, 2001; No. 39, 2003; No. 73, 2008; No 4, 2016
s. 54AB	ad. No. 39, 2003
	am. No. 39, 2006; No. 38, 2009; No 180, 2012; No 4, 2016
s. 54A	ad No 6, 1996
s. 54B	ad. No. 39, 2006
	am. No. 180, 2012; No 7, 2018
s 54BA	ad No 180, 2012
	am No 47, 2017; No 7, 2018; No 10, 2023; No 50, 2024; No 38, 2025
s. 54C	ad. No. 39, 2006
s 55	am No 6, 1996; No 39, 2006; No 5, 2015
s. 56	am. No. 24, 2002; Nos. 38 and 76, 2009
s 56A	ad No 6, 1996
	am No 24, 2002; No 39, 2006; No 38, 2009; No 76, 2009; No 54, 2010; No 141, 2010; No 4, 2014; No 47, 2017; No 7, 2018; No 8, 2021; No 10, 2023; No 50, 2024
s 57	am No 84, 1991; No 204, 1991; No 88, 1992; No 6, 1996; No 146, 1999; No 23, 2002; No 24, 2002; No 5, 2006; No 38, 2009; No 96, 2009; No 54, 2010; No 141, 2010; No 47, 2017; No 8, 2021; No 10, 2023; No 50, 2024; No 38, 2025
s 58	am No 76, 1993; No 76, 2009; No 50, 2024
s. 59	am. No. 54, 2010
s 60	am No 6, 1996; No 24, 2002; No 39, 2003; No 39, 2006; No 76, 2009; No 54, 2010; No 141, 2010; No 4, 2014; No 47, 2017; No 7, 2018; No 75, 2020; No 8, 2021; No 10, 2023; No 39, 2024; No 50, 2024; No 38, 2025
s 60A	ad No 6, 1996
	am No 24, 2002; No 54, 2010; No 39, 2024

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Provision affected	How affected
s 61	am No 84, 1991; No 88, 1992; No 76, 1993; No 116, 1997; No 34, 1998; No 12, 2000; No 120, 2000; No 24, 2002; No 39, 2006; No 38, 2009; No 76, 2009; No 54, 2010; No 197, 2012; No 47, 2017; No 7, 2018; No 121, 2019; No 75, 2020; No 10, 2023; No 50, 2024; No 38, 2025
s 61A	ad No 54, 2010
	am No 50, 2024
s 62	rep No 136, 2012
	ad No 8, 2021
	am No 50, 2024
s 63	am No 204, 1991; No 76, 1993; No 6, 1996; No 34, 1998; No 24, 2002; No 54, 2010; No 47, 2017; No 7, 2018; No 8, 2021; No 10, 2023; No 50, 2024; No 38, 2025
Chapter 8	
Part 7 heading	rep. No. 24, 2002
Chapter 8 heading	ad. No. 24, 2002
s. 64	rep. No. 136, 2012
s. 65	rep. No. 136, 2012
s. 66	am. No. 76, 1993
s. 69	am. No. 24, 2002; No. 136, 2012
Schedule	am. No. 141, 1990
	rep. No. 136, 2012

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