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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 13 December 2019 (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. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

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.

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. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

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If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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An Act relating to therapeutic goods

Chapter 1—Preliminary

1 Short title

This Act may be cited as the *Therapeutic Goods Act 1989*.

2 Commencement

This Act commences on the day after the day on which a House of the Parliament approves regulations made under this Act in the same form as approved by the other House, provided that:

(a) not more than 90 days have elapsed; and

(b) the places of Senators have not become vacant under section 13 of the Constitution; and

(c) a dissolution or expiration of the House of Representatives has not occurred;

between the approval of one House and the approval of the other House.

3 Interpretation

(1) In this Act, unless the contrary intention appears:

accessory, in relation to a medical device covered by paragraph 41BD(1)(a), (aa) or (ab), means a thing that the manufacturer of the thing specifically intended to be used together with the device to enable the device to be used as the manufacturer of the device intended.

actual or potential tampering has the meaning given by section 42U.

advertise, in relation to therapeutic goods, includes make any statement, pictorial representation or design that is intended,

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whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design:

(a) is on the label of the goods; or

(b) is on the package in which the goods are contained; or

(c) is on any material included with the package in which the goods are contained.

anthroposophic pharmacopoeia means:

(a) a publication specified under paragraph 3AB(3)(a), as that publication is in force from time to time; or

(b) a part of a publication specified under paragraph 3AB(3)(b), as that part is in force from time to time.

anthroposophic preparation has the meaning given by subsection 3AB(1).

anthroposophic standard has the meaning given by subsection 3AB(2).

application audit assessment fee means a fee payable under subsection 41LA(3).

assessment fee means:

(a) a conformity assessment fee; or

(b) an application audit assessment fee;

payable under Part 4-10.

Australian conformity assessment body means an Australian corporation that is the subject of a conformity assessment body determination made under the regulations.

Australian conformity assessment body certificate means a certificate that is issued by an Australian conformity assessment body and that is of a kind mentioned in section 41FIA.

Australian corporation means a corporation that is registered under Part 2A.2 of the *Corporations Act 2001*.

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authorised person means:

(a) in relation to any provision of this Act or the regulations, a person authorised by the Secretary to exercise powers under that provision; or

(b) in relation to a provision of Part 6-2, a member of the Australian Federal Police, or a Customs officer exercising powers in a Customs place (within the meaning of section 183UA of the *Customs Act 1901*).

batch means a quantity of a product that is:

(a) uniform in composition, method of manufacture and probability of chemical or microbial contamination; and

(b) made in one cycle of manufacture and, in the case of a product that is sterilised or freeze dried, sterilised or freeze dried in one cycle.

bioburden, in relation to therapeutic goods, means the quantity and characteristics of microorganisms present in the goods or to which the goods may be exposed in a manufacturing environment.

biological has the meaning given by section 32A.

biological number of a biological means:

(a) the number assigned to the biological under subsection 32DB(2), 32DF(2) or 32DN(5); or

(b) if, in accordance with regulations made for the purposes of paragraph 9A(4)(ca), a different number is assigned to the biological—that different number.

British Pharmacopoeia means the edition of the publication of that name, including any additions or amendments, that was in effect for the purposes of this Act immediately before the commencement of Schedule 4 to the *Therapeutic Goods Amendment (Medical Devices and Other Measures) Act 2009* and, if additions or amendments of that publication are made after that commencement, or new editions of that publication are published after that commencement, includes those additions or amendments, or those new editions, from the effective date published by the British Pharmacopoeia Commission or any replacement body.

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certification-related activities, when used in relation to an Australian conformity assessment body, means activities that consist of, or relate to, the issue of certificates as mentioned in section 41FIA.

civil penalty provision has the meaning given by section 42YA.

Class 1 biological means a biological included in a class of biologicals that is:

(a) a class prescribed by the regulations for the purposes of section 32AA; and

(b) a class referred to in those regulations as Class 1 biologicals.

Commonwealth authority includes:

(a) a body corporate, or an unincorporated body, established for a public purpose by or under an Act; and

(b) a tribunal or authority established by or in accordance with an Act.

Commonwealth officer includes:

(a) a Minister; and

(b) a person holding:

(i) an office established by or under an Act; or

(ii) an appointment made under an Act; or

(iii) an appointment made by the Governor-General or a Minister but not under an Act; and

(c) a person who is a member or officer of a Commonwealth authority; and

(d) a person who is in the service or employment of the Commonwealth, or of a Commonwealth authority, or is employed or engaged under an Act or regulations made under an Act.

composite pack has the meaning given by subsection 7B(2).

Comptroller-General of Customs means the person who is the Comptroller-General of Customs in accordance with subsection 11(3) or 14(2) of the *Australian Border Force Act 2015*.

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conformity assessment body determination has the meaning given by section 41EWA.

conformity assessment certificate means a certificate issued under section 41EE.

conformity assessment document means:

(a) a conformity assessment certificate; or

(b) an Australian conformity assessment body certificate; or

(c) an overseas regulator conformity assessment document.

conformity assessment fee means a fee payable under subsection 41LA(1).

conformity assessment procedures has the meaning given by section 41DA.

conformity assessment standard means a conformity assessment standard specified in an order under section 41DC.

container, in relation to therapeutic goods, means the vessel, bottle, tube, ampoule, syringe, vial, sachet, strip pack, blister pack, wrapper, cover or other similar article that immediately covers the goods, but does not include an article intended for ingestion.

corporation means a body corporate that is:

(a) a foreign corporation; or

(b) a trading corporation formed within the limits of the Commonwealth or a financial corporation so formed.

corresponding State law means a State law declared by the regulations to correspond to this Act or the regulations, including such a law as amended from time to time.

counterfeit has the meaning given by section 42E.

current Poisons Standard has the meaning given by section 52A.

Customs officer means an officer of Customs within the meaning of the *Customs Act 1901*.

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data processing device means any article or material (for example, a disc) from which information is capable of being reproduced with or without the aid of any other article or device.

default standard means any of the following:

(a) a standard referred to in paragraph (b) of the definition of ***standard*** in this subsection;

(b) a standard referred to in paragraph (c) of that definition;

(c) a standard referred to in paragraph (d) of that definition.

device number, in relation to a medical device, means any combination of numbers, symbols and letters assigned to the device under section 41FL.

directions for use, in relation to therapeutic goods, includes information on:

(a) appropriate doses of the goods; and

(b) the method of administration or use of the goods; and

(c) the frequency and duration of treatment for each indication of the goods; and

(d) the use of the goods by persons of particular ages or by persons having particular medical conditions.

EC/EFTA attestation of conformity means an attestation of conformity (within the meaning of the EC Mutual Recognition Agreement or the EFTA Mutual Recognition Agreement) issued by an EC/EFTA conformity assessment body that is approved by the Secretary in writing.

EC/EFTA conformity assessment body means a Conformity Assessment Body designated in one of the following Sectoral Annexes to the EC Mutual Recognition Agreement or the EFTA Mutual Recognition Agreement:

(a) Sectoral Annex (Medical Devices);

(b) Sectoral Annex (Medicinal Products GMP Inspection and Batch Certification).

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EC Mutual Recognition Agreement means the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between Australia and the European Community, as in force from time to time.

EFTA Mutual Recognition Agreement means the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between Australia and the European Free Trade Association, as in force from time to time.

essential principles has the meaning given by section 41CA.

ethics committee means a committee:

(a) constituted and operating as an ethics committee in accordance with guidelines issued by the CEO of the National Health and Medical Research Council as in force from time to time; and

(b) which has notified its existence to the Australian Health Ethics Committee established under the *National Health and Medical Research Council Act 1992*.

European Pharmacopoeia means the English edition of the publication of that name, including any additions or amendments, that was in effect immediately before the commencement of this definition and, if additions or amendments of that publication are made after that commencement, or new editions of that publication are published after that commencement, includes those additions or amendments, or those new editions, from the effective date published by the Council of Europe or any replacement body.

exempt device means a medical device that is of a kind that is exempted from Division 3 of Part 4-11 by the regulations.

exempt goods, in relation to a provision of Part 3-2, means therapeutic goods that are exempted from the operation of that Part (except section 31A and sections 31C to 31F) by the regulations.

exempt goods, in relation to a provision of Part 3-3, means therapeutic goods that are exempted from the operation of that Part by the regulations.

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exempt person, in relation to therapeutic goods, means a person exempted from the operation of Part 3-3 in relation to those goods by the regulations.

export only medicine means a medicine that:

(a) is manufactured in Australia for export only, or imported into Australia for export only; and

(b) is listable goods only because it is so manufactured or imported (and not for any other reason).

Federal Circuit Court means the Federal Circuit Court of Australia.

Federal Court means the Federal Court of Australia.

financial corporation means a financial corporation within the meaning of paragraph 51(xx) of the Constitution.

first Poisons Standard has the meaning given by section 52A.

foreign corporation means a foreign corporation within the meaning of paragraph 51(xx) of the Constitution.

gazetted kits group means a group of kits identified in an order in force under subsection 16(3A).

gazetted therapeutic devices group has the meaning given by subsection 16(3).

gazetted therapeutic goods group has the meaning given by subsection 16(2).

Gene Technology Regulator has the same meaning as in the *Gene Technology Act 2000*.

genetically modified organism has the same meaning as in the *Gene Technology Act 2000*.

GM product has the same meaning as in the *Gene Technology Act 2000*.

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grouped therapeutic goods means therapeutic goods included in:

(a) a gazetted therapeutic goods group; or

(b) a gazetted therapeutic devices group; or

(c) a gazetted kits group.

health practitioner means a person who, under a law of a State or internal Territory, is registered or licensed to practice in any of the following health professions:

(a) Aboriginal and Torres Strait Islander health practice;

(b) dental (not including the professions of dental therapist, dental hygienist, dental prosthetist or oral health therapist);

(c) medical;

(d) medical radiation practice;

(e) nursing;

(f) midwifery;

(g) occupational therapy;

(h) optometry;

(i) pharmacy;

(j) physiotherapy;

(k) podiatry;

(l) psychology.

homoeopathic pharmacopoeia means:

(a) a publication specified under paragraph 3AA(3)(a), as that publication is in force from time to time; or

(b) a part of a publication specified under paragraph 3AA(3)(b), as that part is in force from time to time.

homoeopathic preparation has the meaning given by subsection 3AA(1).

homoeopathic standard has the meaning given by subsection 3AA(2).

included in the Register:

(a) in relation to a biological—means included in the Register under Part 3-2A; and

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(b) in relation to a medical device to which Chapter 4 applies—means included in the Register under Chapter 4.

Note: Section 41BJ deals with the application of Chapter 4 to medical devices.

indications, in relation to therapeutic goods, means the specific therapeutic uses of the goods.

international instrument means:

(a) any treaty, convention, protocol, agreement or other instrument that is binding in international law; and

(b) a part of such a treaty, convention, protocol, agreement or other instrument.

kind, in relation to a medical device, has the meaning given by section 41BE.

label, in relation to therapeutic goods, means a display of printed information:

(a) on or attached to the goods; or

(b) on or attached to a container or primary pack in which the goods are supplied; or

(c) supplied with such a container or pack.

licence means a licence under Part 3-3.

listable devices means therapeutic devices that are required to be included in the part of the Register for listed goods.

listable goods means therapeutic goods that are required:

(a) under the regulations; or

(b) by a notice published in the *Gazette* or on the Department's website under subsection 9A(5);

to be included in the part of the Register relating to listed goods.

listed goods means therapeutic goods that are included in the Part of the Register for goods known as listed goods.

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listing number, in relation to listed goods, means any combination of numbers, symbols and letters assigned to the goods under section 27.

major interest holder of a body corporate means a person who:

(a) is in a position to cast, or control the casting of, more than one-fifth of the maximum number of votes that might be cast at a general meeting of the body corporate; or

(b) holds more than one-fifth of the issued share capital of the body corporate (excluding any part of that issued share capital that carries no right to participate beyond a specified amount in a distribution of either profits or capital).

manufacture, in relation to therapeutic goods that are not medical devices, means:

(a) to produce the goods; or

(b) to engage in any part of the process of producing the goods or of bringing the goods to their final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing for supply of the goods or of any component or ingredient of the goods as part of that process.

manufacturer, of a medical device, has the meaning given by section 41BG.

manufacturing principles means the principles for the time being having effect under section 36.

manufacturing site means premises:

(a) that are for use in the manufacture of a particular kind of therapeutic goods; and

(b) at which the same persons have control of the management of the production of the goods and the procedures for quality control.

manufacturing site authorisation means an authorisation referred to in subsection 38(2B) or 40B(4).

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medical device has the meaning given by section 41BD.

medical device classification means a classification specified in the regulations made for the purposes of section 41DB.

medical device standard, in relation to a kind of medical device, means a medical device standard, specified in an order under section 41CB, that is applicable to that kind of medical device.

medicine means:

(a) therapeutic goods (other than biologicals) that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human; and

(b) any other therapeutic goods declared by the Secretary, for the purpose of the definition of ***therapeutic device***, not to be therapeutic devices.

member of EFTA means a country declared by the Minister under section 3A to be a member of the European Free Trade Association.

member of the European Community means a country declared by the Minister under section 3A to be a member of the European Community.

mother substance means any of the following:

(a) an animal;

(b) a plant;

(c) an alga;

(d) a fungus;

(e) a micro-organism;

(f) a mineral;

(g) a mineral compound;

(h) a chemical;

(i) a product obtained from any of the things mentioned in paragraphs (a) to (h).

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Mutual Recognition Convention means the Convention for the Mutual Recognition of Inspections in respect of the Manufacture of Pharmaceutical Products done at Geneva on 8 October 1970.

non-EC/EFTA attestation of conformity, for a non-EC/EFTA MRA, means an attestation of conformity issued, after the non-EC/EFTA MRA has come into force, by a conformity assessment body that is designated in the non-EC/EFTA MRA and approved by the Secretary in writing for the non-EC/EFTA MRA.

non-EC/EFTA MRA means an international instrument that Australia is bound by, or is a party to, if:

(a) a purpose of the instrument is the recognition of attestations of conformity; and

(b) the instrument satisfies the requirements (if any) set out in regulations made for the purposes of this paragraph;

but does not include:

(c) the EC Mutual Recognition Agreement; or

(d) the EFTA Mutual Recognition Agreement.

oath includes affirmation.

overseas regulator has the meaning given by section 41BIB.

overseas regulator conformity assessment document means a certificate or other document that is issued by an overseas regulator after that regulator is satisfied that requirements, comparable to the conformity assessment procedures, have been applied to a medical device by the manufacturer of the device.

passed preliminary assessment:

(a) when used in relation to a section 23 application for registration—has the meaning given by subsection 23B(3); and

(b) when used in relation to a section 23 application for listing under section 26AE—has the meaning given by subsection 23B(3); and

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(c) when used in relation to a section 32DD application—has the meaning given by subsection 32DDA(3); and
(d) when used in relation to a section 41FC application—has the meaning given by subsection 41FDB(3).

poison means an ingredient, compound, material or preparation which, or the use of which, may cause death, illness or injury and includes any ingredient, compound, material or preparation referred to in a schedule to the current Poisons Standard.

premises includes:
(a) a structure, building, aircraft, vehicle or vessel; and
(b) a place (whether enclosed or built upon or not); and
(c) a part of a thing referred to in paragraph (a) or (b).

presentation, in relation to therapeutic goods, means the way in which the goods are presented for supply, and includes matters relating to the name of the goods, the labelling and packaging of the goods and any advertising or other informational material associated with the goods.

primary pack, in relation to therapeutic goods, means the complete pack in which the goods, or the goods and their container, are to be supplied to consumers.

product information, in relation to therapeutic goods, means information relating to the safe and effective use of the goods, including information regarding the usefulness and limitations of the goods.

protected information, in relation to therapeutic goods, has the meaning given by section 25A.

quality, in relation to therapeutic goods, includes the composition, strength, potency, stability, sterility, purity, bioburden, design, construction and performance characteristics of the goods.

refurbishment has the meaning given by the regulations.

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Register means the Australian Register of Therapeutic Goods maintained under section 9A.

registered goods means:

(a) therapeutic goods included in the part of the Register for goods known as registered goods; or

(b) therapeutic goods included in the part of the Register for goods known as provisionally registered goods.

Note: Subsection (8) provides that a reference in this Act to therapeutic goods that are registered, or to the registration of therapeutic goods, includes a reference to a medicine that is provisionally registered under section 29.

registration number, in relation to registered goods, means any combination of numbers, symbols and letters assigned to the goods under section 27.

related body corporate has the same meaning as in the *Corporations Act 2001*.

reportable medicine has the meaning given by section 30EH.

restricted medicine means:

(a) a medicine specified in an instrument under subsection (2A); or

(b) a medicine included in a class of medicine specified in an instrument under subsection (2B).

scheduling has the meaning given by section 52A.

Secretary means the Secretary of the Department.

shortage of a medicine in Australia has the meaning given by section 30EI.

sponsor, in relation to therapeutic goods, means:

(a) a person who exports, or arranges the exportation of, the goods from Australia; or

(b) a person who imports, or arranges the importation of, the goods into Australia; or

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(c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere);

but does not include a person who:

(d) exports, imports or manufactures the goods; or

(e) arranges the exportation, importation or manufacture of the goods;

on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.

standard, in relation to therapeutic goods, means any of the following:

(a) a standard that is constituted by the matters specified in an order under section 10 that is applicable to the goods;

(b) if the goods are the subject of one or more monographs (other than a monograph exempt under subsection 3C(1)) in the British Pharmacopoeia—a standard that is constituted by the statements (other than statements exempt under subsection 3C(2)) in those monographs, as interpreted in accordance with the General Notices section of the British Pharmacopoeia;

(c) if the goods are the subject of one or more monographs (other than a monograph exempt under subsection 3C(1)) in the European Pharmacopoeia—a standard that is constituted by the statements (other than statements exempt under subsection 3C(2)) in those monographs, as interpreted in accordance with the General Notices section of the European Pharmacopoeia;

(d) if the goods are the subject of one or more monographs (other than a monograph exempt under subsection 3C(1)) in the United States Pharmacopeia-National Formulary—a standard that is constituted by the statements (other than statements exempt under subsection 3C(2)) in those monographs, as interpreted in accordance with the General Notices section of the United States Pharmacopeia-National Formulary;

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(e) a homoeopathic standard;
(f) an anthroposophic standard.

Note: See also section 13.

State includes the Australian Capital Territory and the Northern Territory.

State law means a law of a State, of the Australian Capital Territory or of the Northern Territory.

supply includes:

(a) supply by way of sale, exchange, gift, lease, loan, hire or hire-purchase; and
(b) supply, whether free of charge or otherwise, by way of sample or advertisement; and
(c) supply, whether free of charge or otherwise, in the course of testing the safety or efficacy of therapeutic goods in persons; and
(d) supply by way of administration to, or application in the treatment of, a person.

system or procedure pack has the meaning given by section 41BF.

tamper: therapeutic goods are tampered with if:

(a) they are interfered with in a way that affects, or could affect, the quality, safety or efficacy of the goods; and
(b) the interference has the potential to cause, or is done for the purpose of causing, injury or harm to any person.

therapeutic device means therapeutic goods (other than biologicals) consisting of an instrument, apparatus, appliance, material or other article (whether for use alone or in combination), together with any accessories or software required for its proper functioning, which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means though it may be assisted in its function by such means, but the expression does not include therapeutic goods declared by the

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Secretary, by order published in the *Gazette* or on the Department's website, not to be therapeutic devices.

therapeutic goods means goods:

(a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:
  (i) for therapeutic use; or
  (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or
  (iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or

(b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);

and includes biologicals, medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:

(c) goods declared not to be therapeutic goods under an order in force under section 7; or

(d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or

(e) goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a standard (within the meaning of subsection 4(1) of the *Food Standards Australia New Zealand Act 1991*); or

(f) goods (other than goods declared to be therapeutic goods under an order in force under section 7) which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented; or

(g) goods covered by a determination under subsection 7AA(1) (excluded goods); or

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(h) goods covered by a determination under subsection 7AA(2) (excluded goods), if the goods are used, advertised, or presented for supply in the way specified in the determination.

Therapeutic Goods Advertising Code means the code in force under section 42BAA.

therapeutic use means use in or in connection with:

(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or

(b) influencing, inhibiting or modifying a physiological process in persons; or

(c) testing the susceptibility of persons to a disease or ailment; or

(d) influencing, controlling or preventing conception in persons; or

(e) testing for pregnancy in persons; or

(f) the replacement or modification of parts of the anatomy in persons.

trading corporation means a trading corporation within the meaning of paragraph 51(xx) of the Constitution.

United States Pharmacopeia-National Formulary means the English edition of the publication of that name, including any additions or amendments, that was in effect immediately before the commencement of this definition and, if additions or amendments of that publication are made after that commencement, or new editions of that publication are published after that commencement, includes those additions or amendments, or those new editions, from the effective date published by the United States Pharmacopeial Convention or any replacement body.

working day, for a person, means any day except:

(a) Saturday or Sunday; or

(b) a day that is a public holiday in the State or Territory in which the person is located.

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(2) For the purposes of this Act, therapeutic goods are taken to be for use in humans if they are not solely for use in animals.

(2A) The Minister may, by legislative instrument, specify medicines for the purposes of paragraph (a) of the definition of ***restricted medicine*** in subsection (1).

(2B) The Minister may, by legislative instrument, specify classes of medicine for the purposes of paragraph (b) of the definition of ***restricted medicine*** in subsection (1).

(3) The Secretary must, at least once in each year, cause to be published in the *Gazette* or on the Department's website a list of the names of all persons, other than members of the Australian Federal Police, who are, at the time of publication, authorised persons.

(4) The provisions of this Act are in addition to, and not in substitution for, the provisions of any other Act that relate to therapeutic goods.

(5) For the purposes of this Act, the presentation of therapeutic goods is unacceptable if it is capable of being misleading or confusing as to the content or proper use or identification of the goods and, without limiting the previous words in this subsection, the presentation of therapeutic goods is unacceptable:

(a) if it states or suggests that the goods have ingredients, components or characteristics that they do not have; or

(b) if a name applied to the goods is the same as the name applied to other therapeutic goods that are supplied in Australia where those other goods contain additional or different therapeutically active ingredients; or

(c) if the label of the goods does not declare the presence of a therapeutically active ingredient; or

(ca) if the therapeutic goods are medicine included in a class of medicine prescribed by the regulations for the purposes of this paragraph—if the medicine's label does not contain the advisory statements specified under subsection (5A) in relation to the medicine; or

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(d) if a form of presentation of the goods may lead to unsafe use of the goods or suggests a purpose that is not in accordance with conditions applicable to the supply of the goods in Australia; or

(e) in prescribed cases.

(5A) The Minister may, by legislative instrument, specify advisory statements in relation to medicine for the purposes of paragraph (5)(ca).

(5B) For the purposes of subsection (5A), the Minister may specify different advisory statements for different medicines or different classes of medicine.

(6) A reference in this Act to 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 is a reference to such a charge imposed under the *Therapeutic Goods (Charges) Act 1989*.

(7) A reference to an offence against this Act includes a reference to:

(a) an offence against the regulations; and

(b) an offence against 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 against this Act or the regulations; and

(c) an offence against section 136.1, 137.1 or 137.2 of the *Criminal Code* in relation to this Act or the regulations.

(7A) For the purposes of this Act, a corresponding State law ***imposes a duty*** on a Commonwealth officer or Commonwealth authority if:

(a) the corresponding State law confers a function or power on the officer or authority; and

(b) the circumstances in which the function or power is conferred give rise to an obligation on the officer or authority to perform the function or to exercise the power.

(8) To avoid doubt:

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(a) a reference in this Act to therapeutic goods that are registered includes a reference to a medicine that is provisionally registered; and

(b) a reference in this Act to the registration of therapeutic goods includes a reference to the provisional registration of a medicine.

Note: Subsection 29(2) deals with the provisional registration of a medicine.

3AA Homoeopathic preparations and homoeopathic standards

Homoeopathic preparation

(1) For the purposes of this Act, a ***homoeopathic preparation*** is a preparation:

(a) manufactured from a mother substance; and

(b) manufactured in accordance with a manufacturing procedure described in a homoeopathic pharmacopoeia.

Homoeopathic standard

(2) For the purposes of this Act, if:

(a) there are therapeutic goods that are a homoeopathic preparation; and

(b) the goods are the subject of one or more monographs (other than a monograph exempt under subsection (4)) in the homoeopathic pharmacopoeia describing the manufacturing procedure that the preparation was manufactured in accordance with;

then there is a ***homoeopathic standard***, in relation to the goods, that is constituted by the statements (other than statements exempt under subsection (5)) in those monographs, as interpreted in accordance with any interpretation sections of that homoeopathic pharmacopoeia.

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Specifying publications

(3) The Minister may, by legislative instrument, specify either or both of the following for the purposes of the definition of ***homoeopathic pharmacopoeia*** in subsection 3(1):

(a) publications;

(b) parts of publications.

Exempting entire monographs

(4) The Minister may, by legislative instrument, determine that specified monographs in a specified homoeopathic pharmacopoeia are exempt for the purposes of paragraph (2)(b).

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

Exempting parts of monographs

(5) The Minister may, by legislative instrument, determine that specified statements in specified monographs in a specified homoeopathic pharmacopoeia are exempt for the purposes of subsection (2).

3AB Anthroposophic preparations and anthroposophic standards

Anthroposophic preparation

(1) For the purposes of this Act, an ***anthroposophic preparation*** is a preparation:

(a) manufactured from a mother substance; and

(b) manufactured in accordance with a manufacturing procedure described in an anthroposophic pharmacopoeia.

Anthroposophic standard

(2) For the purposes of this Act, if:

(a) there are therapeutic goods that are an anthroposophic preparation; and

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(b) the goods are the subject of one or more monographs (other than a monograph exempt under subsection (4)) in the anthroposophic pharmacopoeia describing the manufacturing procedure that the preparation was manufactured in accordance with;

then there is an ***anthroposophic standard***, in relation to the goods, that is constituted by the statements (other than statements exempt under subsection (5)) in those monographs, as interpreted in accordance with any interpretation sections of that anthroposophic pharmacopoeia.

Specifying publications

(3) The Minister may, by legislative instrument, specify either or both of the following for the purposes of the definition of ***anthroposophic pharmacopoeia*** in subsection 3(1):

(a) publications;

(b) parts of publications.

Exempting entire monographs

(4) The Minister may, by legislative instrument, determine that specified monographs in a specified anthroposophic pharmacopoeia are exempt for the purposes of paragraph (2)(b).

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

Exempting parts of monographs

(5) The Minister may, by legislative instrument, determine that specified statements in specified monographs in a specified anthroposophic pharmacopoeia are exempt for the purposes of subsection (2).

3A Declaration—member of European Community

(1) The Minister may declare, in writing, that a country specified in the declaration is a member of:

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(a) the European Community; or
(b) the European Free Trade Association.

(2) A declaration under subsection (1) must be published in the *Gazette* or on the Department's website.

3B Declaration—country covered by non-EC/EFTA MRA

(1) The Minister may declare, in writing, that a country specified in the declaration is covered by the non-EC/EFTA MRA specified in the declaration.

(2) A declaration under subsection (1) must be published in the *Gazette* or on the Department's website.

3C Exempting monographs in pharmacopoeias

Exempting entire monographs

(1) The Minister may, by legislative instrument, determine that specified monographs in the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopeia-National Formulary are exempt for the purposes of paragraph (b), (c) or (d) of the definition of ***standard*** in subsection 3(1).

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

Exempting parts of monographs

(2) The Minister may, by legislative instrument, determine that specified statements in specified monographs in the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopeia-National Formulary are exempt for the purposes of paragraph (b), (c) or (d) of the definition of ***standard*** in subsection 3(1).

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4 Objects of Act

(1) The objects of this Act are to do the following, so far as the Constitution permits:

(a) provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are:

(i) used in Australia, whether produced in Australia or elsewhere; or

(ii) exported from Australia;

(b) to provide a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and ensure the safe handling, of poisons in Australia.

(1A) The reference in paragraph (1)(a) to the efficacy of therapeutic goods is a reference, if the goods are medical devices, to the performance of the devices as the manufacturer intended.

(2) This Act is therefore not intended to apply to the exclusion of a law of a State, of the Australian Capital Territory or of the Northern Territory to the extent that the law is capable of operating concurrently with this Act.

5 Act to bind Crown

This Act binds the Crown in right of the Commonwealth, of each of the States, of the Australian Capital Territory and of the Northern Territory, but nothing in this Act renders the Crown liable to be prosecuted for an offence or to be subject to civil proceedings for a contravention of a civil penalty provision.

5A Application of the *Criminal Code*—extended geographical jurisdiction

Section 15.2 of the *Criminal Code* (extended geographical jurisdiction—category B) applies to offences against

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subsections 21A(1), (4) and (4A) and sections 22A, 32DO, 41FE, 42E and 42T.

6 Operation of Act

(1) This Act applies to:

(a) things done by corporations; and

(b) things done by natural persons or corporations in so far as those things are done:

(i) in the course of, or in preparation for, trade or commerce between Australia and a place outside Australia, among the States, between a State and a Territory or between 2 Territories; or

(ii) under a law of the Commonwealth relating to the provision of pharmaceutical or repatriation benefits; or

(iii) in relation to the Commonwealth or in relation to an authority of the Commonwealth.

(2) Without limiting the effect of this Act apart from this subsection, this Act also has the effect it would have if the reference in paragraph (1)(a) to things done by corporations were confined to things done by trading corporations for the purposes of their trading activities.

6AAA Commonwealth consent to conferral of functions etc. on its officers and authorities by corresponding State laws

(1) A corresponding State law may confer functions or powers, or impose duties, on:

(a) a Commonwealth officer; or

(b) a Commonwealth authority.

(2) Subsection (1) does not authorise the conferral of a function or power, or the imposition of a duty, by a corresponding State law to the extent to which:

(a) the conferral or imposition, or the authorisation, would contravene any constitutional doctrines restricting the duties

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that may be imposed on Commonwealth officers or Commonwealth authorities; or

(b) the authorisation would otherwise exceed the legislative power of the Commonwealth.

(3) Subsection (1) does not extend to a function, power or duty of a kind specified in regulations made for the purposes of this subsection.

(4) This Act is not intended to exclude or limit the operation of a corresponding State law that confers any functions or powers, or imposes any duties, on a Commonwealth officer or Commonwealth authority to the extent to which that law:

(a) is consistent with subsections (1) to (3); and

(b) is capable of operating concurrently with this Act.

6AAB When duty imposed

Application

(1) This section applies if a corresponding State law purports to impose a duty on a Commonwealth officer or Commonwealth authority.

State legislative power sufficient to support duty

(2) The duty is taken not to be imposed by this Act (or any other law of the Commonwealth) to the extent to which:

(a) imposing the duty is within the legislative powers of the State concerned; and

(b) imposing the duty by the corresponding State law is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority.

Note: If this subsection applies, the duty will be taken to be imposed by force of the corresponding State law (the Commonwealth having consented under section 6AAA to the imposition of the duty by the corresponding State law).

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Commonwealth legislative power sufficient to support duty but State legislative powers are not

(3) If, to ensure the validity of the purported imposition of the duty, it is necessary that the duty be imposed by a law of the Commonwealth (rather than by force of the corresponding State law), the duty is taken to be imposed by this Act to the extent necessary to ensure that validity.

(4) If, because of subsection (3), this Act is taken to impose the duty, it is the intention of the Parliament to rely on all powers available to it under the Constitution to support the imposition of the duty by this Act.

(5) The duty is taken to be imposed by this Act in accordance with subsection (3) only to the extent to which imposing the duty:
  (a) is within the legislative powers of the Commonwealth; and
  (b) is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority.

(6) To avoid doubt, neither this Act (nor any other law of the Commonwealth) imposes a duty on the Commonwealth officer or Commonwealth authority to the extent to which imposing such a duty would:
  (a) contravene any constitutional doctrine restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority; or
  (b) otherwise exceed the legislative power of the Commonwealth.

(7) Subsections (1) to (6) do not limit section 6AAA.

6AAC Imposing duty under State law

(1) This section:
  (a) applies only for the purposes of the application of the provisions of this Act or another law of the Commonwealth

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(with or without modification) as a law of a State by a provision of a corresponding State law; and

(b) does not apply for those purposes if the corresponding State law otherwise provides.

(2) If the corresponding State law purports to impose a duty on a Commonwealth officer or Commonwealth authority to do a particular thing, the duty is taken to be imposed by the corresponding State law to the extent to which imposing the duty:

(a) is within the legislative powers of the State; and

(b) is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority.

(3) To avoid doubt, the corresponding State law does not impose the duty on the Commonwealth officer or Commonwealth authority to the extent to which imposing the duty would:

(a) contravene any constitutional doctrine restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority; or

(b) otherwise exceed the legislative powers of the State.

(4) If imposing on the Commonwealth officer or Commonwealth authority the duty to do that thing would:

(a) contravene any constitutional doctrine restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority; or

(b) otherwise exceed the legislative powers of both the State and the Commonwealth;

the corresponding State law is taken instead to confer on the officer or authority a power to do that thing at the discretion of the officer or authority.

6AAD Conferral of jurisdiction on federal courts

If:

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(a) a provision of a corresponding State law purports to apply a provision of a law of the Commonwealth (the ***applied provision***) as a law of the State; and

(b) the applied provision purports to confer jurisdiction in relation to a matter on a federal court;

the jurisdiction in relation to that matter is taken to be conferred on the court by this section.

6AAE Consequences of State law conferring duty, function or power on Commonwealth officer or Commonwealth authority

(1) If a corresponding State law confers on a Commonwealth officer or Commonwealth authority:

(a) the function of including goods in the Register; or

(b) the power to include goods in the Register;

the officer or authority may include the goods in the Register in accordance with the corresponding State law.

(2) If a corresponding State law authorises or requires a Commonwealth officer or Commonwealth authority to cancel the inclusion of goods in the Register, the officer or authority may cancel the inclusion of the goods in the Register in accordance with the corresponding State law.

(3) The inclusion of goods in the Register under subsection (1) does not subject any person to any liability whatever under this Act, except a liability under Part 6-1.

(4) A Commonwealth officer or Commonwealth authority may make any notations in the Register that the officer or authority considers necessary to identify entries that relate to goods included in the Register under subsection (1).

(5) Goods may be included in the Register under subsection (1) even though the same goods have already been included in the Register under another provision of this Act.

(6) A reference in this section to the inclusion of goods in the Register is a reference to the inclusion of the goods:

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(a) in the part of the Register for goods known as registered goods; or

(aa) in the part of the Register for goods known as provisionally registered goods; or

(b) in the part of the Register for goods known as listed goods; or

(ba) in the part of the Register for biologicals included under Part 3-2A; or

(c) in the part of the Register for medical devices included under Chapter 4.

6B Review of certain decisions under State laws

(1) Application may be made to the Administrative Appeals Tribunal for review of a reviewable State decision.

(2) A decision made by the Secretary in the performance of a function, or the exercise of a power, conferred by a corresponding State law is a reviewable State decision for the purpose of this section if:

(a) the law under which the decision was made provides for review by the Administrative Appeals Tribunal; and

(b) the decision is declared by the regulations to be a reviewable decision for the purposes of this section.

(3) For the purposes of subsection (1), the *Administrative Appeals Tribunal Act 1975* has effect as if a corresponding State law were an enactment.

6C Fees payable to Commonwealth under State laws

(1) This section applies to fees payable to the Commonwealth under a State law in respect of the performance or exercise of functions or powers conferred by that law on the Secretary.

(2) The Secretary may make arrangements with the appropriate authority of a State, of the Australian Capital Territory or of the Northern Territory in relation to the payment to the Commonwealth of fees to which this section applies.

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7 Declaration that goods are/are not therapeutic goods

(1) Where the Secretary is satisfied that particular goods or classes of goods:

(a) are or are not therapeutic goods; or

(b) when used, advertised, or presented for supply in a particular way, are or are not therapeutic goods;

the Secretary may, by order published in the *Gazette* or on the Department's website, declare that the goods, or the goods when used, advertised, or presented for supply in that way, are or are not, for the purposes of this Act, therapeutic goods.

(1A) In deciding whether particular goods or classes of goods:

(a) are therapeutic goods; or

(b) when used, advertised, or presented for supply in a particular way, are therapeutic goods;

the Secretary must disregard paragraphs (e) and (f) of the definition of ***therapeutic goods*** in subsection 3(1).

(2) The Secretary may exercise his or her powers under this section of his or her own motion or following an application made in writing to the Secretary.

(3) A declaration under this section takes effect on the day on which the declaration is published in the *Gazette* or on the Department's website or on such later day as is specified in the order.

(4) If a declaration under this section:

(a) is a declaration that particular goods or classes of goods are not therapeutic goods; and

(b) applies wholly or partly to goods that, apart from this section, would be medical devices;

the goods are not medical devices, or are not medical devices when used, advertised, or presented for supply in the way specified in the declaration.

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7AA Excluded goods

(1) The Minister may, by legislative instrument, determine that specified goods (other than goods declared to be therapeutic goods under an order in force under section 7) are excluded goods for the purposes of this Act.

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

(2) The Minister may, by legislative instrument, determine that specified goods (other than goods declared to be therapeutic goods under an order in force under section 7), when used, advertised, or presented for supply in a way specified in the determination, are excluded goods for the purposes of this Act.

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

(3) Before making a determination under this section, the Minister must have regard to the following matters:

(a) whether it is likely that the specified goods, if not regulated under this Act, might harm the health of members of the public;

(b) whether it is appropriate in all the circumstances to apply the national system of controls relating to the quality, safety, efficacy and performance of therapeutic goods established by this Act to regulate the specified goods;

(c) whether the kinds of risks from the specified goods to which members of the public might be exposed could be more appropriately dealt with under another regulatory scheme.

(4) The Minister may have regard to any other matter he or she considers relevant.

7A Authorised persons

The Secretary may, in writing, authorise any of the following persons to exercise powers under a specified provision of this Act:

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(a) an officer of the Department, of another Department or of an authority of the Commonwealth;

(b) an officer of:

(i) a Department of State of a State; or

(ii) a Department or administrative unit of the Public Service of a Territory; or

(iii) an authority of a State or of a Territory;

being a Department, unit or authority that has functions relating to health matters or law enforcement matters.

7B Kits

(1) If a package contains one or more goods, the package and each of the goods in the package together constitute a kit for the purposes of this Act if:

(a) the package and each of the goods are for use as a unit; and

(b) the package and the goods do not constitute a composite pack or a system or procedure pack; and

(c) at least one of the goods is therapeutic goods; and

(d) each item of the therapeutic goods consists of goods that are:

(i) registered or listed; or

(ii) exempt goods in relation to Part 3-2; or

(iii) included in the Register under Part 3-2A; or

(iv) exempt under subsection 32CA(2) or section 32CB.

(2) A package and therapeutic goods in the package together constitute a composite pack if:

(a) the therapeutic goods are of 2 or more kinds; and

(b) the package does not contain any medical devices or therapeutic devices; and

(c) the therapeutic goods are for administration as a single treatment or as a single course of treatment; and

(d) it is necessary that the therapeutic goods be combined before administration or that they be administered in a particular sequence.

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(3) To avoid doubt, it is declared that a kit constitutes therapeutic goods.

7C Secretary may arrange for use of computer programs to make decisions

(1) The Secretary may arrange for the use, under the Secretary's control, of computer programs for any purposes for which the Secretary may make decisions under this Act or the regulations.

(2) A decision made by the operation of a computer program under such an arrangement is taken to be a decision made by the Secretary.

(3) The Secretary may substitute a decision (the ***substituted decision***) for a decision (the ***initial decision***) made by the operation of a computer program under such an arrangement if the Secretary is satisfied that the initial decision is incorrect.

(4) However, the substituted decision may only be made before the end of the period of 60 days beginning on the day the initial decision is made.

7D Form for product information for medicine

(1) The Secretary may, by writing, approve a form for product information in relation to medicine.

(2) The Secretary may approve different forms for different medicines or different classes of medicine.

8 Power to obtain information with respect to therapeutic goods

(1) The Secretary may, by notice in writing given to a person who has imported into Australia or has supplied in Australia:

(a) therapeutic goods; or

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(b) goods in relation to which the Secretary is considering making a declaration under section 7; or

(c) goods in relation to which the Minister is considering making a determination under section 7AA (excluded goods);

request the person to give to an officer of the Department identified in the notice, within such reasonable period as is specified in the notice, information required by the notice concerning the composition, indications, directions for use or labelling of the goods or concerning advertising material relating to the goods.

(1A) A notice under subsection (1) may require the information to be given:

(a) in writing; or

(b) in accordance with specified software requirements:

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

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

(2) A person must not fail to comply with a notice given to the person under this section.

Penalty: 60 penalty units.

(3) Subsection (2) does not apply if the person has a reasonable excuse.

Note: The defendant bears an evidential burden in relation to the matter in subsection (3). See subsection 13.3(3) of the *Criminal Code*.

(4) An offence under subsection (2) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

9 Arrangements with States etc.

(1) The Minister may make arrangements with the appropriate Minister of a State, of the Australian Capital Territory or of the Northern Territory for the carrying out by that State or Territory, on behalf of the Commonwealth, of:

(a) the evaluation of therapeutic goods for registration; or

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(aa) the evaluation of a biological, other than a Class 1 biological, for inclusion in the Register under Part 3-2A; or

(b) the inspection of manufacturers of therapeutic goods; or

(c) other functions under this Act or the regulations.

(2) An arrangement under this section may provide for the payment to a State or Territory of amounts in respect of the performance of functions under the arrangement.

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Chapter 2—Australian Register of Therapeutic Goods

9A Australian Register of Therapeutic Goods

(1) The Secretary is to cause to be maintained a register, to be known as the Australian Register of Therapeutic Goods, for the purpose of compiling information in relation to, and providing for evaluation of, therapeutic goods for use in humans.

(2) Subject to subsection (3), the Register is to be kept in such form as the Secretary determines.

(3) The Register is to contain these 5 parts:

(a) a part for goods to be known as registered goods; and

(aa) a part for goods to be known as provisionally registered goods; and

(b) a part for goods to be known as listed goods; and

(ba) a part for biologicals included in the Register under Part 3-2A; and

(c) a part for medical devices included in the Register under Chapter 4.

(4) The regulations may prescribe:

(a) the therapeutic goods, or the classes of therapeutic goods, that are required to be included in each part of the Register; and

(b) the ways in which goods that are included in one part of the Register may be transferred, or may be required to be transferred, to another part of the Register; and

(c) the ways in which goods that have been assigned a registration or listing number may be assigned a different registration or listing number; and

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(ca) the ways in which a biological that has been assigned a number under subsection 32DB(2), 32DF(2) or 32DN(5) may be assigned a different number (which may be any combination of numbers and either or both of letters and symbols); and

(d) the ways in which medical devices that have been assigned a device number may be assigned a different device number.

(5) The Minister may, by notice published in the *Gazette* or on the Department's website:

(a) require that specified therapeutic goods be included in the part of the Register for listed goods; and

(b) specify the conditions subject to which such goods may be included in that part of the Register.

(6) If the regulations are amended to require any of those goods to be included in the part of the Register for listed or registered goods, then the notice ceases to have effect in respect of the goods included in the regulations.

9B When registrations or listings of medical devices are taken to be cancelled

(1) The registration or listing of a medical device to which subsection 15A(5) applied is taken to be cancelled:

(a) on the second anniversary of the day on which Chapter 4 commences; or

(b) if the medical device is of a kind included in the Register under Chapter 4 before that second anniversary—when that inclusion takes effect.

(2) The registration or listing of any other medical device is taken to be cancelled at the time shown in the table:

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Time of cancellation of registration or listing		
	Circumstances	**Time**
1	That kind of medical device is included in the Register under Chapter 4 before 4 October 2007 because of an application finally determined before that day	When that kind of medical device is included in the Register under Chapter 4
2	An effective application for a conformity assessment certificate relating to that kind of medical device is made, but not finally determined, before 4 October 2007	The end of 30 days after the application is finally determined or, if the application lapses, the later of the following times (or either of them if they are the same): (a) the time the application lapses; (b) the start of 4 October 2007
3	An effective application to include that kind of medical device in the Register under Chapter 4 is made, but not finally determined, before 4 October 2007, and item 2 does not apply	Whichever one of the following times applies, or the earlier of them: (a) the time that kind of medical device is included in the Register under Chapter 4 (even if that time is before 4 October 2007); (b) the time the application is finally determined, if the application is unsuccessful when it is finally determined; or, if the application lapses, the later of the following times (or either of them if they are the same): (c) the time the application lapses; (d) the start of 4 October 2007
4	None of items 1, 2 and 3 applies	The start of 4 October 2007

Note: 4 October 2007 is the fifth anniversary of the day Chapter 4 commenced.

(2A) For the purposes of subsection (2), an application is ***finally determined*** at the first time both the following conditions are met:

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(a) a decision has been made under Part 4-4 or 4-5 whether or not to grant the conformity assessment certificate or include the kind of medical device in the Register (as appropriate);

(b) there is no longer any possibility of a change in the outcome of the decision in terms of the grant (or not) of the conformity assessment certificate or the inclusion (or not) of the kind of medical device in the Register.

For the purposes of paragraph (b), ignore any possibility of a discretion being exercised, after the period has ended, to extend a period for seeking review by a tribunal or court of the decision or for starting other proceedings (including appeals) arising out of the application, the decision or the review.

Note: In certain circumstances a decision may be taken to have been made under Part 4-4 or Part 4-5. For example, see section 41EH.

(3) This section does not prevent the Secretary from taking action under section 30.

9C Inspection of entries in Register

(1) A person in relation to whom therapeutic goods are entered on the Register may make a written request to the Secretary for a copy of the entry in the Register in relation to the goods.

(2) If the person makes such a request, the Secretary must send to the person a copy of so much (if any) of that entry as is contained in any computer database maintained by the Department for purposes connected with the administration of this Act (other than any part of that entry that was supplied in confidence by another person).

(3) If the person makes such a request, then, instead of providing a copy of an entry to the person, the Secretary may, if the request is for the provision of an electronic copy, provide the information contained in the entry:

(a) on a data processing device; or

(b) by way of electronic transmission.

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9D Variation of entries in Register

(1) The Secretary may:

(a) following a request by a person in relation to whom therapeutic goods are entered on the Register; or

(b) on the Secretary's own initiative;

vary the entry in the Register in relation to the goods if the entry contains information that is incomplete or incorrect.

(1A) If:

(a) a medicine is included in the part of the Register for goods known as provisionally registered goods; and

(b) it appears to the Secretary that the quality, safety or efficacy of the medicine is unacceptable in relation to a class of persons;

the Secretary may, on the Secretary's own initiative, vary the entry in the Register in relation to the medicine:

(c) to reduce the class of persons for whom the medicine is suitable or to change the directions for use; or

(d) to add a warning, or precaution, that does not include any comparison of the medicine with any other medicine by reference to quality, safety or efficacy.

Note: The Secretary may also vary the product information relating to the medicine: see subsection 25AA(4).

(1B) If:

(a) a medicine is included in the part of the Register for goods known as provisionally registered goods; and

(b) the Secretary makes a decision under subsection 29(9) to extend the provisional registration period for the medicine;

the Secretary may, on the Secretary's own initiative, vary the entry in the Register in relation to the medicine to reduce the class of persons for whom the medicine is suitable or to change the directions for use.

Note: The Secretary may also vary the product information relating to the medicine: see subsection 25AA(4).

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(1C) If the Secretary proposes to make a variation under subsection (1A) or (1B), the Secretary must:

(a) give the person in relation to whom the medicine is registered written notice of the proposed variation and of the reasons for the proposed variation; and

(b) give the person a reasonable opportunity to make a submission to the Secretary in relation to the proposed variation; and

(c) if the person makes a submission in accordance with paragraph (b)—take the submission into account before making a decision whether or not to make the variation.

(1D) Subsections (1A) and (1B) apply despite subsection 16(1).

(2) If:

(a) the person in relation to whom therapeutic goods are registered or listed has requested the Secretary to vary information included in the entry in the Register that relates to the goods; and

(b) the only effect of the variation would be:

(i) to reduce the class of persons for whom the goods are suitable; or

(ii) to add a warning, or precaution, that does not include any comparison of the goods with any other therapeutic goods by reference to quality, safety or efficacy;

the Secretary must vary the entry in accordance with the request.

(2A) Subsection (2), to the extent to which it relates to subparagraph (2)(b)(i), applies despite subsection 16(1).

(2C) If:

(a) the person in relation to whom therapeutic goods are registered or listed has requested the Secretary to vary the entry in the Register that relates to the goods; and

(b) the variation is of a kind specified in the regulations; and

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(c) the conditions (if any) specified in the regulations are satisfied;

the Secretary must vary the entry in accordance with the request.

(2D) Subsection (2C), to the extent that it relates to therapeutic goods that are registered, applies despite subsection 16(1).

(3) If:

(a) the person in relation to whom therapeutic goods are registered or listed has requested the Secretary to vary information included in the entry in the Register that relates to the goods; and

(b) subsection (2) does not apply to the request; and

(ba) subsection (2C) does not apply to the request; and

(c) the Secretary is satisfied that the variation requested does not indicate any reduction in the quality, safety or efficacy of the goods for the purposes for which they are to be used;

the Secretary may vary the entry in accordance with the request.

(3AA) If:

(a) the person in relation to whom a biological is included in the Register has requested the Secretary to vary information included in the entry in the Register that relates to the biological; and

(b) the only effect of the variation would be:

(i) to reduce the class of persons for whom the biological is suitable; or

(ii) to add a warning, or precaution, that does not include any comparison of the biological with any other therapeutic goods by reference to quality, safety or efficacy;

the Secretary must vary the entry in accordance with the request.

(3AC) If:

(a) the person in relation to whom a biological is included in the Register has requested the Secretary to vary the entry in the Register that relates to the biological; and

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(b) the variation is of a kind specified in the regulations; and

(c) the conditions (if any) specified in the regulations are satisfied;

the Secretary must vary the entry in accordance with the request.

(3A) If:

(a) the person in relation to whom a biological is included in the Register has requested the Secretary to vary information included in the entry in the Register that relates to the biological; and

(aa) subsection (3AA) does not apply to the request; and

(ab) subsection (3AC) does not apply to the request; and

(b) the Secretary is satisfied that the variation requested does not indicate any reduction in the quality, safety or efficacy of the biological for the purposes for which it is to be used;

the Secretary may vary the entry in accordance with the request.

(3B) If:

(a) a particular biological ceases to be a biological because of a determination under subsection 32A(3); and

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

the Secretary must move the entry relating to the biological from the part of the Register for biologicals to whichever other part of the Register is applicable.

(3C) If:

(a) the person in relation to whom a kind of medical device is included in the Register has requested the Secretary to vary information included in the entry in the Register that relates to the kind of medical device; and

(b) the only effect of the variation would be:

(i) to reduce the class of persons for whom the kind of medical device is suitable; or

(ii) to add a warning, restriction or precaution, that does not include any comparison of the kind of medical device with any other therapeutic goods by reference to quality, safety or performance;

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the Secretary must vary the entry in accordance with the request.

(3CB) If:

(a) the person in relation to whom a kind of medical device is included in the Register has requested the Secretary to vary the entry in the Register that relates to the kind of medical device; and

(b) the variation is of a kind specified in the regulations; and

(c) the conditions (if any) specified in the regulations are satisfied;

the Secretary must vary the entry in accordance with the request.

(3D) If:

(a) the person in relation to whom a kind of medical device is included in the Register has requested the Secretary to vary information included in the entry in the Register that relates to the kind of medical device; and

(b) subsection (3C) does not apply to the request; and

(ba) subsection (3CB) does not apply to the request; and

(c) the Secretary is satisfied that the variation requested does not indicate any reduction in the quality, safety or performance of the kind of medical device for the purposes for which it is to be used;

the Secretary may vary the entry in accordance with the request.

(4) If:

(a) particular therapeutic goods cease to be medical devices because of a declaration under subsection 41BD(3); and

(b) those goods are included in the Register under Chapter 4 as a kind of medical device;

the Secretary must move the entry relating to the goods from the part of the Register for medical devices to whichever other part of the Register is applicable.

Note: Variations to the Register also occur to give effect to limited cancellations of entries of kinds of medical devices from the Register: see subsection 41GO(2).

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Form and manner of requests

(6) The Secretary may, by writing:
  (a) approve a form for particular kinds of requests under this section; and
  (b) approve the manner of making particular kinds of requests under this section.

(7) If:
  (a) the Secretary has approved a form for, and the manner of making, a kind of request under this section; and
  (b) either:
    (i) the kind of request is one under subsection (3) and which, under the regulations, must be decided within 175 or 255 working days; or
    (ii) the kind of request is one prescribed by the regulations for the purposes of this subparagraph;

then a request of that kind is not effective unless:
  (c) the request is in accordance with that form; and
  (d) the request contains the information required by that form; and
  (e) the request is made in that manner; and
  (f) any prescribed application fee has been paid; and
  (g) the request is accompanied by information that is:
    (i) of a kind determined under subsection (8); and
    (ii) in a form approved, in writing, by the Secretary.

(8) The Secretary may, by legislative instrument, determine a kind of information for the purposes of subparagraph (7)(g)(i).

Note: See also subsection 33(3A) of the *Acts Interpretation Act 1901*.

9E Publication of list of goods on Register

The Secretary must, at least once every 12 months, publish a list of the therapeutic goods included in the Register.

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9F Removal of entries from Register

(1) This section applies if:

(a) there is an entry on the Register in relation to goods; and

(b) the Secretary is satisfied that the goods are not therapeutic goods.

(2) The Secretary may, by written notice given to the person in relation to whom the goods are entered on the Register, remove the entry of the goods from the Register.

(3) Before removing the entry, the Secretary must:

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

(b) invite the person to make written submissions to the Secretary in relation to the proposed removal within the period specified in the notice (being not less than 20 working days after the day the notice is given).

(4) The Secretary must not give the person a notice under subsection (2) until the Secretary has had regard to any submissions the person makes under paragraph (3)(b).

(5) A notice under subsection (2) is not a legislative instrument.

(6) If the Secretary removes an entry of goods from the Register under this section, the removal has effect on the day specified in the notice under subsection (2) in relation to the goods, being a day not earlier than 20 working days after the day on which the notice is given to the person.

(7) If the Secretary removes an entry of goods from the Register under this section, the Secretary must, as soon as practicable after the removal, cause to be published in the *Gazette*, or on the Department's website, a notice setting out particulars of the removal.

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9G Criminal offences for false statements in requests for variation of entries in Register

(1) A person commits an offence if:

(a) the person makes a statement; and

(b) the statement is made in or in connection with a request under section 9D for the variation of an entry in the Register in relation to therapeutic goods; and

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

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:

(a) the person makes a statement; and

(b) the statement is made in or in connection with a request under section 9D for the variation of an entry in the Register in relation to therapeutic goods; and

(c) the statement 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 makes a statement; and

(b) the statement is made in or in connection with a request under section 9D for the variation of an entry in the Register in relation to therapeutic goods; and

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(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.

9H Civil penalty for false statements in requests for variation of entries in Register

A person contravenes this section if the person in or in connection with a request under section 9D for the variation of an entry in the Register in relation to therapeutic goods, makes a statement that 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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Chapter 3—Medicines and other therapeutic goods that are not medical devices

Note: This Chapter still applies to medical devices while they are registered or listed goods. Section 9B automatically cancels the registration or listing of those goods over time.

Part 3-1—Standards

10 Determination of standards

(1) The Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order (whether or not those goods are the subject of a monograph in the British Pharmacopoeia, the European Pharmacopoeia, the United States Pharmacopeia-National Formulary, a homoeopathic pharmacopoeia or an anthroposophic pharmacopoeia).

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

(2) Without limiting the generality of subsection (1), an order establishing a standard for therapeutic goods may:

(a) be specified by reference to:

(i) the quality of the goods; or

(ii) the quantity of the goods when contained in specified containers; or

(iii) procedures to be carried out in the manufacture of the goods; or

(iv) a monograph in the British Pharmacopoeia, the European Pharmacopoeia, the United States Pharmacopeia-National Formulary, a homoeopathic pharmacopoeia or an anthroposophic pharmacopoeia; or

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

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(vi) such a monograph as modified in a manner specified in the order establishing the standard; or

(vii) a standard published by Standards Australia; or

(viii) such other matters as the Minister thinks fit; or

(b) require that a matter relating to the standard be determined in accordance with a particular test; or

(c) require that therapeutic goods or a class of therapeutic goods identified in the order be labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the order.

(3) Without limiting the generality of paragraph (2)(c), the Minister may, in an order establishing a standard, direct that there be set out, in a manner specified in the order, on:

(a) therapeutic goods or a class of therapeutic goods identified in the order; or

(b) a container or package containing therapeutic goods or a class of therapeutic goods identified in the order; or

(c) a label of therapeutic goods or a class of therapeutic goods identified in the order;

such particulars as are required by the order.

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

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

(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.

10A Application of standards to medical devices

A standard under section 10 does not apply to a medical device unless Part 3-2 applies to the device.

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Note: Section 15A sets out when Part 3-2 applies to a medical device.

13 Special provisions relating to Ministerial standards and default standards

(1) For the purposes of this Act, if a statement (the ***main statement***) in a monograph in the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopeia-National Formulary refers to a statement in a monograph in another publication, the main statement is taken to include the other statement.

(2) If:

(a) a standard under section 10 (the ***Ministerial standard***) applies to therapeutic goods; and

(b) requirements applicable to the goods are specified in a default standard; and

(c) those requirements are inconsistent with the requirements specified in the Ministerial standard;

the requirements referred to in paragraph (b) are, so far as they are inconsistent, to be disregarded for the purposes of this Act.

(3) If:

(a) a default standard applies to a class of therapeutic goods; and

(b) another default standard applies to only some of the therapeutic goods within that class; and

(c) those standards are inconsistent;

the standard referred to in paragraph (a) does not apply in relation to the goods referred to in paragraph (b).

(4) If:

(a) therapeutic goods consist, or are represented to consist, of a mixture of ingredients or of a combination of component parts; and

(b) a default standard is applicable to one or more of the ingredients or one or more of the component parts; and

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(c) a default standard is applicable to the mixture or combination;

the standard referred to in paragraph (b) does not apply in relation to the goods.

(5) If:

(a) therapeutic goods consist, or are represented to consist, of a mixture of ingredients or of a combination of component parts; and

(b) there is no standard applicable to the mixture or combination but a standard is applicable to one or more of the ingredients or one or more of the component parts;

the Minister may, by order published in the *Gazette* or on the Department's website, determine that the standard does not apply to the goods. The order has effect accordingly.

(6) An order under subsection (5) is not a legislative instrument.

(7) For the purposes of this Act, in working out at a particular time if therapeutic goods conform with a default standard applicable to the goods, if:

(a) after applying subsections (2) to (5), 2 or more default standards are applicable to the goods at that time; and

(b) at that time, the goods conform with at least one of those standards but do not conform with at least one of those standards;

then the default standards that the goods do not conform with are taken not to apply to the goods at that time.

13A Special provisions relating to homoeopathic standards and anthroposophic standards

(1) For the purposes of this Act, if a statement (the ***main statement***) in a monograph in a homoeopathic pharmacopoeia or an anthroposophic pharmacopoeia refers to a statement in a monograph in another publication, the main statement is taken to include the other statement.

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(2) If:

(a) a standard under section 10 (the ***Ministerial standard***) applies to therapeutic goods; and

(b) requirements applicable to the goods are specified in a homoeopathic standard or an anthroposophic standard; and

(c) those requirements are inconsistent with the requirements specified in the Ministerial standard;

the requirements referred to in paragraph (b) are, so far as they are inconsistent, to be disregarded for the purposes of this Act.

14 Criminal offences for importing, supplying or exporting goods that do not comply with standards

Offences relating to importing goods into Australia

(1) A person commits an offence if:

(a) the person imports therapeutic goods into Australia; and

(b) the goods are imported without the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods (other than by reason of a matter relating to labelling or packaging); 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 the goods do not conform with the standard.

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.

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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 therapeutic goods into Australia; and

(b) the goods are imported without the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods (other than by reason of a matter relating to labelling or packaging).

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

(4A) A person commits an offence if:

(a) the person imports therapeutic goods into Australia; and

(b) the goods are imported without the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods (other than by reason of a matter relating to labelling or packaging).

Penalty: 100 penalty units.

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

Exception

(5A) Subsection (1), (4) or (4A) does not apply if:

(a) the therapeutic goods are a biological; and

(b) the person imports the biological after the circumstances prescribed by the regulations for the purposes of this paragraph have occurred.

Note: A defendant bears an evidential burden in relation to the matter in subsection (5A): see subsection 13.3(3) of the *Criminal Code*.

Offences relating to supplying goods for use in Australia

(6) A person commits an offence if:

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(a) the person supplies therapeutic goods for use in Australia; and
(b) the goods are supplied without the consent in writing of the Secretary; and
(c) the goods do not conform with a standard applicable to the goods; 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 the goods do not conform with the standard.

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 (9) instead: see section 53A.

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

(9) A person commits an offence if:
(a) the person supplies therapeutic goods for use in Australia; and
(b) the goods are supplied without the consent in writing of the Secretary; and
(c) the goods do not conform with a standard applicable to the goods.

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

(9AA) A person commits an offence if:
(a) the person supplies therapeutic goods for use in Australia; and

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(b) the goods are supplied without the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods.

Penalty: 100 penalty units.

(9AB) An offence against subsection (9AA) is an offence of strict liability.

Exception

(9A) Subsection (6), (9) or (9AA) does not apply if:

(a) the therapeutic goods are a biological; and

(b) the person supplies the biological after the circumstances prescribed by the regulations for the purposes of this paragraph have occurred.

Note: A defendant bears an evidential burden in relation to the matter in subsection (9A): see subsection 13.3(3) of the *Criminal Code*.

Offences relating to exporting goods from Australia

(10) A person commits an offence if:

(a) the person exports therapeutic goods from Australia; and

(b) the goods are exported without the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods (other than a standard relating to the labelling of the goods for supply in Australia); 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 the goods do not conform with the standard.

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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 (13) instead: see section 53A.

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

(13) A person commits an offence if:

(a) the person exports therapeutic goods from Australia; and

(b) the goods are exported without the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods (other than a standard relating to the labelling of the goods for supply in Australia).

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

(13AA) A person commits an offence if:

(a) the person exports therapeutic goods from Australia; and

(b) the goods are exported without the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods (other than a standard relating to the labelling of the goods for supply in Australia).

Penalty: 100 penalty units.

(13AB) An offence against subsection (13AA) is an offence of strict liability.

Exception

(13A) Subsection (10), (13) or (13AA) does not apply if:

(a) the therapeutic goods are a biological; and

(b) the person exports the biological after the circumstances prescribed by the regulations for the purposes of this paragraph have occurred.

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Note: A defendant bears an evidential burden in relation to the matter in subsection (13A): see subsection 13.3(3) of the *Criminal Code*.

Decisions on whether to give consent

(14) The Secretary must, as soon as practicable after making a decision to give a consent, cause particulars of the decision to be published in the *Gazette* or on the Department's website.

(15) The Secretary must, within 28 days after making a decision to refuse to give a consent, notify the applicant in writing of the decision and of the reasons for the decision.

14A Civil penalties for importing, supplying or exporting goods that do not comply with standards

Civil penalty relating to importing goods into Australia

(1) A person contravenes this subsection if:
  (a) the person imports therapeutic goods into Australia; and
  (b) the person does not have the consent in writing of the Secretary; and
  (c) the goods do not conform with a standard applicable to the goods (other than by reason of a matter relating to labelling or packaging).

Maximum civil penalty:
  (a) for an individual—5,000 penalty units; and
  (b) for a body corporate—50,000 penalty units.

Exception

(1A) Subsection (1) does not apply if:
  (a) the therapeutic goods are a biological; and
  (b) the person imports the biological after the circumstances prescribed by the regulations for the purposes of this paragraph have occurred.

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Civil penalty relating to supplying goods for use in Australia

(2) A person contravenes this subsection if:
(a) the person supplies therapeutic goods for use in Australia; and
(b) the person does not have the consent in writing of the Secretary; and
(c) the goods do not conform with a standard applicable to the goods.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

Exception

(2A) Subsection (2) does not apply if:
(a) the therapeutic goods are a biological; and
(b) the person supplies the biological after the circumstances prescribed by the regulations for the purposes of this paragraph have occurred.

Civil penalty relating to exporting goods from Australia

(3) A person contravenes this subsection if:
(a) the person exports therapeutic goods from Australia; and
(b) the person does not have the consent in writing of the Secretary; and
(c) the goods do not conform with a standard applicable to the goods (other than a standard relating to the labelling of the goods for supply in Australia).

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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Exception

(3A) Subsection (3) does not apply if:

(a) the therapeutic goods are a biological; and

(b) the person exports the biological after the circumstances prescribed by the regulations for the purposes of this paragraph have occurred.

Decisions on whether to give consent

(4) The Secretary must, as soon as practicable after making a decision to give a consent, cause particulars of the decision to be published in the *Gazette* or on the Department's website.

(5) The Secretary must, within 28 days after making a decision to refuse to give a consent, notify the applicant in writing of the decision and of the reasons for the decision.

14B Application of *Customs Act 1901*

Where:

(a) the importation or exportation of goods is an offence under subsection 14(1), (4), (4A), (10), (13) or (13AA) or a contravention of subsection 14A(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 goods 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.

15 Criminal offences relating to breaching a condition of a consent

(1) The consent of the Secretary under section 14 or 14A may be given:

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(a) unconditionally or subject to conditions; or
(b) in respect of particular goods or classes of goods.

(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.

(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.

15AA 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 15.

Maximum civil penalty:
(a) for an individual—3,000 penalty units; and

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(b) for a body corporate—30,000 penalty units.

15AB Conditions relating to exceptional release of biologicals

(1) Regulations made for the purposes of paragraphs 14(9A)(b) and 14A(2A)(b) may also prescribe conditions that apply in relation to the supply of a biological that occurs after the circumstances prescribed for the purposes of those paragraphs have occurred.

(2) The conditions prescribed by those regulations must apply only to the person supplying the biological.

(3) A person commits an offence if:
(a) the person does an act or omits to do an act; and
(b) the act or omission results in the breach of any of the conditions referred to in subsection (1).

Penalty for contravention of this subsection: 60 penalty units.

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Part 3-2—Registration and listing of therapeutic goods

Division 1—Preliminary

15A Application of this Part to medical devices

The general rule

(1) This Part does not apply to a medical device unless this section provides otherwise.

Previously registered or listed devices

(2) If a medical device is registered goods or listed goods before the commencement of this section, this Part continues to apply to the device unless the registration or listing is cancelled.

Note: A registration or listing can be cancelled under section 30, or can be taken to be cancelled under section 9B.

Pending applications

(3) This Part continues to apply to a medical device if:

(a) before the commencement of this section, an application was made under Part 3 for registration or listing of therapeutic goods that include that medical device; and

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

(c) the application has not been, and is not, withdrawn either before or after that commencement.

However, this Part ceases to apply to the device if, having been registered goods or listed goods, the registration or listing is cancelled.

(4) For the purposes of paragraph (3)(b), an application is ***finally determined*** when the application, and any applications for review

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or appeals arising out of it, have been finally determined or otherwise disposed of.

Applications made within 2 years relating to certain medical devices

(5) This Part applies to a medical device if:

(a) regulations made for the purposes of this section specified either:

(i) the medical device classification applying to the kind of medical device that includes that device; or

(ii) medical devices of that kind; and

(b) during the period of 2 years after the commencement of this section, an application was made under Part 3-2 for registration or listing of therapeutic goods that include that medical device.

However, this Part ceases to apply to the device if, having been registered goods or listed goods, the registration or listing is cancelled.

Note: Medical devices that are registered or listed because of this subsection are taken to be cancelled 2 years after Chapter 4 commences, or before then if medical devices of that kind are included in the Register under Chapter 4: see subsection 9B(1).

Medical devices that are exempt goods

(6) This Part applies to a medical device, during the period of 2 years after the commencement of this section, if the device is exempt goods.

Existing approvals under section 19

(7) This Part continues to apply to a medical device if:

(a) an approval or authorisation in force under section 19 applies to the device; and

(b) that approval or authorisation was in force immediately before the commencement of this section.

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New approvals under section 19

(8) This Part applies to a medical device if:
  (a) subsection (7) does not apply to the device; and
  (b) during the period of 2 years after the commencement of this section, an approval is granted or an authorisation is given under section 19 that applies to the device.

However, this subsection does not apply after the end of that period.

15B Application of this Part to a biological

(1) Subject to this section, this Part 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 registered goods or listed goods, this Part 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 Part for the registration or listing 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 Part 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;

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(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.

(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 Part 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 Part continues to apply to a biological during a period described in subsection (2) or (3), then this Part 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.

16 Therapeutic goods and gazetted groups

(1) For the purposes of this Part, therapeutic goods (other than medicine of the kind to which subsection (1A) applies) are to be taken to be separate and distinct from other therapeutic goods if they have:
(a) a different formulation, composition or design specification; or
(b) a different strength or size (disregarding pack size); or
(c) a different dosage form or model; or
(d) a different name; or
(e) different indications; or
(f) different directions for use; or
(g) a different type of container (disregarding container size).

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(1A) Medicines that are listable goods (other than export only medicines) are taken to be separate and distinct from other therapeutic goods if the medicines have:

(a) different active ingredients; or

(b) different quantities of active ingredients; or

(c) a different dosage form; or

(d) such other different characteristics as the regulations prescribe;

from the therapeutic goods.

(2) The Secretary may, by order published in the *Gazette*, determine that a group of therapeutic goods (not being medical devices or therapeutic devices) identified in the order is a gazetted therapeutic goods group because the goods within the group have common characteristics.

(3) The Secretary may, by order published in the *Gazette*, determine that a group of therapeutic goods (being therapeutic devices) identified in the order is a gazetted therapeutic devices group because the goods within the group:

(a) have common characteristics; and

(b) have been produced by the same manufacturer.

(3A) The Secretary may, by order published in the *Gazette*, determine that a group of kits identified in the order is a gazetted kits group.

(4) An order under subsection (2), (3) or (3A) may make provision for or in relation to a matter by applying, adopting or incorporating, with or without modification, a document as in force from time to time, if the document is:

(a) published by the Department (whether in electronic form or otherwise); and

(b) available for sale to the public; and

(c) available for inspection (whether by using a visual display unit or otherwise) by the public at offices of the Department specified by the Secretary.

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18 Exempt goods

(1) The regulations may, subject to such conditions (if any) as are specified in the regulations, exempt:

(a) all therapeutic goods, except those included in a class of goods prescribed for the purposes of this paragraph; or

(b) specified therapeutic goods; or

(c) a specified class of therapeutic goods;

from the operation of this Part (except section 31A and sections 31C to 31F).

(2) An exemption in terms of paragraph (1)(a) has effect only in relation to such classes of persons as are prescribed for the purposes of this subsection.

(3) Where the regulations revoke an exemption, the revocation takes effect on the day, not being earlier than 28 days after the day on which the regulations are made, specified in the regulations.

18A Exemption because of emergency

Minister's power

(1) The Minister may exempt from the operation of Division 2 of this Part:

(a) specified therapeutic goods; or

(b) therapeutic goods in a specified class.

The exemption must be made in writing.

(2) The Minister may exempt goods under subsection (1) only if the Minister is satisfied that, in the national interest:

(a) the exemption should be made so that the goods may be stockpiled as quickly as possible in order to create a preparedness to deal with a potential threat to public health that may be caused by a possible future emergency; or

(b) the exemption should be made so that the goods can be made available urgently in Australia in order to deal with an actual

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threat to public health caused by an emergency that has occurred.

When the exemption has effect

(3) The exemption takes effect:
  (a) on the day on which the exemption is made; or
  (b) on a later day that is specified in the exemption.

(4) The exemption ceases to have effect:
  (a) at the end of the period specified by the Minister in the exemption as the period for which the exemption is to have effect; or
  (b) when the exemption is revoked;

whichever first occurs.

(5) The exemption ceases to have effect in relation to particular therapeutic goods:
  (a) when those goods become registered or listed goods; or
  (b) when the Minister varies the exemption by removing those goods from the exemption;

whichever first occurs.

(6) If the Minister revokes the exemption as mentioned in paragraph (4)(b), or varies the exemption as mentioned in paragraph (5)(b), the revocation or variation takes effect:
  (a) if the Minister states in the revocation or variation that the revocation or variation is necessary to prevent imminent risk of death, serious illness or serious injury—on the day on which the revocation or variation is made; or
  (b) in any other case—on the day specified by the Minister in the revocation or variation.

The day specified under paragraph (b) of this subsection must not be earlier than 28 days after the day on which the revocation or variation is made.

Note: The revocation or variation must be made in writing, see subsection 33(3) of the *Acts Interpretation Act 1901*.

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Conditions for the exemption

(7) The exemption is subject to conditions specified in the exemption about any of the following:

(a) the period for which the exemption is to have effect;

(b) the quantity of goods that are exempt;

(c) the source of those goods;

(d) the persons or class of persons who may import, manufacture, supply or export those goods;

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

(f) the storage and security of those goods;

(g) the keeping and disclosure of, and access to, records about those goods;

(h) the disposal of those goods;

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

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

Whether or not goods are exempt under this section is not affected by whether or not there is a breach of a condition of an exemption under this section in relation to those goods.

Note 1: A person may commit an offence by breaching a condition of an exemption under this section, see subsections 20(2A) and (2C), 22(7AB) and (7AD), and 30H(1) and (3).

Note 2: A person may also contravene a civil penalty provision, see section 22AA.

(8) The Minister may revoke or vary the conditions (including by imposing new conditions) after the exemption is made. The revocation or variation must be made in writing.

(9) A revocation or variation under subsection (8) takes effect:

(a) if the Minister states in the revocation or variation that the revocation or variation is necessary to prevent imminent risk

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of death, serious illness or serious injury—on the day on which the revocation or variation is made; or

(b) in any other case—on the day specified by the Minister in the revocation or variation.

The day specified under paragraph (b) must not be earlier than 28 days after the day on which the revocation or variation is made.

Exemption not a legislative instrument

(9A) An exemption under subsection (1) is not a legislative instrument.

Informing persons of exemption etc.

(9B) If the Minister makes an exemption under subsection (1), the Minister must take reasonable steps to give a copy of the following to each person covered by paragraph (7)(d):

(a) the exemption;

(b) any revocation or variation of the exemption under this section.

Notification

(10) The Secretary must cause a document setting out particulars of:

(a) an exemption covered by paragraph (2)(b); and

(b) a revocation or variation under this section of an exemption covered by paragraph (2)(b);

to be published in the *Gazette* within 5 working days after the day on which the Minister makes the exemption, revocation or variation. However, an exemption, or a revocation or variation, is not invalid merely because of a failure to comply with this subsection.

Tabling

(11) The Minister must cause a document setting out particulars of:

(a) an exemption covered by paragraph (2)(b); and

(b) a revocation or variation under this section of an exemption covered by paragraph (2)(b);

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to be tabled before each House of the Parliament within 5 sitting days of that House after the day on which the Minister makes the exemption, revocation or variation. However, an exemption, or a revocation or variation, is not invalid merely because of a failure to comply with this subsection.

Note: There are other requirements in other parts of this Act about goods exempt under this section:

(a) sections 20, 22 and 22AA (breach of a condition of the exemption);
(b) sections 30F and 30FA (goods not conforming to standards etc.);
(c) section 30G (disposal of unused goods);
(d) section 30H (record keeping);
(e) section 31AA (providing information to the Secretary);
(f) sections 35, 35A, 39 and 41 (manufacturing goods that are exempt under this section);
(g) section 46A (search of premises).

19 Exemptions for certain uses

(1) The Secretary may, by notice in writing, grant an approval to a person for the importation into, or the exportation from, Australia or the supply in Australia of specified therapeutic goods that are not registered goods, listed goods or exempt goods:

(a) for use in the treatment of another person; or
(b) for use solely for experimental purposes in humans;

and such an approval may be given subject to such conditions as are specified in the notice of approval.

(1AA) An approval for use of the kind referred to in paragraph (1)(a) must not be granted to a person unless the person is a health practitioner.

(1A) An approval mentioned in paragraph (1)(a) or (b) is subject to the conditions (if any) specified in the regulations for the purposes of that paragraph. Those conditions (if any) are in addition to any conditions imposed on the approval under subsection (1).

(2) An application for an approval must be made to the Secretary and must:

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(a) in the case of an application for use of the kind referred to in paragraph (1)(a)—be in a form (if any) approved, in writing, by the Secretary and be accompanied by such information relating to the goods the subject of the application as is required by the Secretary; and

(b) in the case of an application for use of the kind referred to in paragraph (1)(b):

(i) be made in writing; and

(ii) be accompanied by such information relating to the goods the subject of the application as is required by the Secretary; and

(iii) be accompanied by the prescribed evaluation fee.

(3) Without limiting the conditions to which an approval under subsection (1) may be made subject, those conditions may include a condition relating to the charges that may be made for the therapeutic goods to which the approval relates.

(4) Where an application for an approval is made, the Secretary must, after having considered the application and, in the case of an application for the use of therapeutic goods for experimental purposes in humans, after having evaluated the information submitted with the application, notify the applicant of the decision on the application within 28 days of making the decision and, in the case of a decision not to grant the approval, of the reasons for the decision.

(4A) The use by a person for experimental purposes in humans of specified therapeutic goods that are the subject of an approval granted to someone else under paragraph (1)(b) 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 the goods for those purposes;

(b) the principles to be followed in the use of the goods for those purposes;

(c) the monitoring of the use, and the results of the use, of the goods for those purposes;

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(d) the circumstances in which the person must cease the use of the goods for those purposes.

(5) The Secretary may, in writing, authorise a specified medical practitioner to supply:

(a) specified therapeutic goods for use in the treatment of humans; or

(b) a specified class of such goods;

to the class or classes of recipients specified in the authority.

(5AA) An application for an authority under subsection (5) must be in a form (if any) approved, in writing, by the Secretary.

(5A) An authority may be given subject to the conditions (if any) specified in the authority.

(5B) The Secretary may impose conditions (or further conditions) on an authority given to a person under subsection (5) by giving to the person written notice of the conditions (or further conditions).

(6) An authority under subsection (5) 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

(aa) to a medical practitioner who has the approval of an ethics committee to supply the specified therapeutic goods or the specified class of such goods; and

(b) in relation to a class or classes of recipients prescribed by the regulations for the purposes of this paragraph.

Paragraph (aa) does not apply in the exceptional circumstances (if any) prescribed by the regulations for the purposes of this subsection.

(7) The regulations may prescribe the circumstances in which therapeutic goods may be supplied under an authority under subsection (5).

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(7A) The Minister may, by legislative instrument, make rules authorising any health practitioner who is included in a specified class of health practitioners to supply:

(a) specified therapeutic goods for use in the treatment of humans; or

(b) a specified class of such goods;

to the class or classes of recipients specified in those rules, so long as:

(c) the goods are supplied in the circumstances specified in those rules; and

(d) the conditions (if any) specified in those rules are satisfied.

(7B) In making rules under subsection (7A), 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.

(7C) If:

(a) a person is authorised, by subsection (7A) rules, to supply therapeutic goods; and

(b) the person supplies those goods 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.

(7D) A notification under subsection (7C) 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.

(7E) 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

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

(7F) A person commits an offence if:

(a) the person is subject to a requirement under subsection (7C); and

(b) the person omits to do an act; and

(c) the omission breaches the requirement.

Penalty: 10 penalty units.

(7G) An offence against subsection (7F) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

(7GA) Subsection (7F) does not apply in relation to a person and a requirement to notify a supply of therapeutic goods 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 (7D).

Note: A defendant bears an evidential burden in relation to the matter in subsection (7GA): see subsection 13.3(3) of the *Criminal Code*.

(7H) In recommending to the Governor-General that regulations should be made for the purposes of paragraph (7D)(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 (7A).

(8) The regulations may prescribe the circumstances in which an approval under paragraph (1)(a) must not be given, including but not limited to, circumstances relating to the following:

(a) therapeutic goods included in a specified class;

(b) therapeutic goods when used in the treatment of a specified class of persons;

(c) therapeutic goods when used for a particular indication.

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(9) In this section, ***medical practitioner*** means a person who is registered, in a State or internal Territory, as a medical practitioner.

19A Exemptions where unavailability etc. of therapeutic goods

(1) The Secretary may, by notice in writing, grant an approval to a person for the importation into Australia, or the supply in Australia, of specified therapeutic goods if the Secretary is satisfied that:

(a) registered goods that could act as a substitute for the goods are unavailable or are in short supply; and

(b) either:

(i) the goods that are the subject of the application are registered or approved for general marketing in at least one foreign country specified by the Secretary in a determination under subsection (3); or

(ii) an application under section 23 has been made for registration of the goods and the application has passed preliminary assessment; and

(c) the goods are of a kind:

(i) included in Schedule 10 of the Therapeutic Goods Regulations; or

(ii) specified by the Secretary in a determination under subsection (4); and

(d) the approval is necessary in the interests of public health.

(1A) The Secretary may, by notice in writing, grant an approval to a person for the importation into Australia, or the supply in Australia, of specified therapeutic goods if the Secretary is satisfied that:

(a) registered goods that could act as a substitute for the goods are unavailable or are in short supply; and

(b) either:

(i) the goods that are the subject of the application are not registered or approved for general marketing in any of the foreign countries specified by the Secretary in a determination under subsection (3); or

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(ii) the goods that are the subject of the application are registered or approved for general marketing in at least one foreign country specified by the Secretary in a determination under subsection (3), but are not readily available for importation into, and supply in, Australia; and

(c) the goods are registered or approved for general marketing in a foreign country; and

(d) the manufacturing and quality control procedures used in the manufacture of the goods are acceptable; and

(e) the goods are of a kind:

(i) included in Schedule 10 of the Therapeutic Goods Regulations; or

(ii) specified by the Secretary in a determination under subsection (4); and

(f) the approval is necessary in the interests of public health.

(2) The Secretary may, by notice in writing, grant an approval to a person for the importation into Australia, or the supply in Australia, of specified therapeutic goods if the Secretary is satisfied that:

(a) registered goods that could act as a substitute for the goods do not exist; and

(b) an application under section 23 has been made for registration of the goods; and

(ba) the application has passed preliminary assessment; and

(c) the goods are of a kind:

(i) included in Schedule 10 of the Therapeutic Goods Regulations; or

(ii) specified by the Secretary in a determination under subsection (4); and

(d) the approval is necessary in the interests of public health.

(3) The Secretary may, for the purposes of subparagraph (1)(b)(i), make written determinations specifying the foreign countries in which registration or approval for general marketing of the goods is a prerequisite for approval by the Secretary under subsection (1).

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(4) The Secretary may make written determinations specifying the kinds of goods that can be the subject of an approval under this section.

(5) Determinations under subsections (3) and (4) are legislative instruments.

(6) The Secretary may grant the approval subject to any conditions that are specified in the notice of approval.

(7) The Secretary may grant the approval for such period as is specified in the notice of approval.

(8) The approval lapses if:
  (a) the period specified in the notice of approval expires; or
  (b) a decision has been made under subsection 25(3) in relation to the goods.

(9) The approval lapses if:
  (a) the Secretary is satisfied that paragraph (1)(a), (b), (c) or (d), paragraph (1A)(a), (b), (c), (d), (e) or (f), or paragraph (2)(a), (b), (ba), (c) or (d), as the case requires, no longer applies in relation to the goods, 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.

(10) 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 goods before the lapsing of the first-mentioned approval. The other approval may be expressed to take effect on the expiry of that period.

(11) An approval under subsection (1), (1A) or (2) is not a legislative instrument.

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19B Criminal offences relating to registration or listing etc. of imported, exported, manufactured and supplied therapeutic goods

Offences relating to importing, exporting, manufacturing or supplying goods for use in humans

(1) A person commits an offence if:

(a) the person:

(i) imports into Australia therapeutic goods for use in humans; or

(ii) exports from Australia therapeutic goods for use in humans; or

(iii) manufactures in Australia therapeutic goods for use in humans; or

(iv) supplies in Australia therapeutic goods for use in humans; and

(b) none of the following subparagraphs applies in relation to the goods:

(i) the goods are registered goods or listed goods in relation to the person;

(ii) the goods are exempt goods;

(iii) the goods are exempt under section 18A;

(iv) the goods are the subject of an approval or authority under section 19;

(v) the goods are the subject of an approval under section 19A; and

(c) 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.

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: A person may commit an offence against subsection 20(2A) or (2C), or may contravene section 22AA (a civil penalty provision), by importing into Australia therapeutic goods that are exempt under section 18A.

Note 3: 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 into Australia therapeutic goods for use in humans; or

(ii) exports from Australia therapeutic goods for use in humans; or

(iii) manufactures in Australia therapeutic goods for use in humans; or

(iv) supplies in Australia therapeutic goods for use in humans; and

(b) none of the following subparagraphs applies in relation to the goods:

(i) the goods are registered goods or listed goods in relation to the person;

(ii) the goods are exempt goods;

(iii) the goods are exempt under section 18A;

(iv) the goods are the subject of an approval or authority under section 19;

(v) the goods are the subject of an approval under section 19A.

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

(4A) A person commits an offence if:

(a) the person:

(i) imports into Australia therapeutic goods for use in humans; or

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(ii) exports from Australia therapeutic goods for use in humans; or

(iii) manufactures in Australia therapeutic goods for use in humans; or

(iv) supplies in Australia therapeutic goods for use in humans; and

(b) none of the following subparagraphs applies in relation to the goods:

(i) the goods are registered goods or listed goods in relation to the person;

(ii) the goods are exempt goods;

(iii) the goods are exempt under section 18A;

(iv) the goods are the subject of an approval or authority under section 19;

(v) the goods are the subject of an approval under section 19A.

Penalty: 100 penalty units.

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

Defence if person was not the sponsor of the goods

(5) It is a defence to a prosecution under subsection (1), (4) or (4A) if the defendant proves that the defendant was not the sponsor of the goods at the time of the importation, exportation, manufacture or supply, as the case may be.

Note: The defendant bears a legal burden in relation to the matter in subsection (5): see section 13.4 of the *Criminal Code*.

Exception

(6) 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 efficacy of the goods; or

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(ii) a matter relating to the labelling or packaging of the goods; or

(iii) the improper use of the goods; or

(b) harm or injury would not, or would not be likely to, directly result from:

(i) the quality, safety or efficacy of the goods; or

(ii) a matter relating to the labelling or packaging of the goods; or

(iii) the improper use of the goods.

Note: A defendant bears an evidential burden in relation to the matters in subsection (6): see subsection 13.3(3) of the *Criminal Code*.

Application of Customs Act 1901

(7) Where:

(a) the importation or exportation of goods is an offence under subsection (1), (4) or (4A); 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 goods 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.

19C Notice required to adduce evidence in support of exception under subsection 19B(6)

(1) If:

(a) a defendant is committed for trial for an offence against subsection 19B(1); or

(b) an offence against subsection 19B(1) is to be heard and determined by a court of summary jurisdiction;

the committing magistrate or the court must:

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(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 19B(6) 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
(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.

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(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*.

19D Civil penalties relating to registration or listing etc. of imported, exported, manufactured and supplied therapeutic goods

Civil penalty relating to importing, exporting, manufacturing or supplying goods for use in humans

(1) A person contravenes this subsection if:
  (a) the person does any of the following:
    (i) imports into Australia therapeutic goods for use in humans;
    (ii) exports from Australia therapeutic goods for use in humans;
    (iii) manufactures in Australia therapeutic goods for use in humans;

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(iv) supplies in Australia therapeutic goods for use in humans; and

(b) none of the following subparagraphs applies in relation to the goods:

(i) the goods are registered goods or listed goods in relation to the person;

(ii) the goods are exempt goods;

(iii) the goods are exempt under section 18A;

(iv) the goods are the subject of an approval or authority under section 19;

(v) the goods are the subject of an approval under section 19A.

Maximum civil penalty:

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

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

Note: A person may commit an offence against subsection 20(2A) or (2C), or may contravene section 22AA (a civil penalty provision), by importing into Australia therapeutic goods that are exempt under section 18A.

Exception if person was not the sponsor of the goods

(2) Subsection (1) does not apply if the person proves that he or she was not the sponsor of the goods at the time of the importation, exportation, manufacture or supply, as the case may be.

Civil penalty relating to the importing of registered or listed goods

(3) A person contravenes this subsection if:

(a) therapeutic goods are registered or listed in relation to the person (other than listed goods that are therapeutic devices); and

(b) the person imports the goods into Australia; and

(c) the registration number or listing number of the goods is not set out on the label of the goods in the prescribed manner before the goods are supplied in Australia.

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Maximum civil penalty:

(a) for an individual—200 penalty units; and

(b) for a body corporate—2,000 penalty units.

Civil penalty relating to the supply of registered or listed goods

(4) A person contravenes this subsection if:

(a) therapeutic goods are registered or listed in relation to the person (other than listed goods that are therapeutic devices); and

(b) the person supplies the goods in Australia; and

(c) the registration number or listing number of the goods is not set out on the label of the goods in the prescribed manner.

Maximum civil penalty:

(a) for an individual—200 penalty units; and

(b) for a body corporate—2,000 penalty units.

Application of Customs Act 1901

(5) Where:

(a) the importation or exportation of goods contravenes subsection (1); 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 goods 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.

20 Criminal offences relating to notifying the Secretary and to importing goods exempt under section 18A

(1B) A person commits an offence if:

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(a) the person is the sponsor of therapeutic goods for use in humans; and

(b) the person:

(i) imports the goods into Australia; or

(ii) exports the goods from Australia; or

(iii) manufactures the goods in Australia; or

(iv) supplies the goods in Australia; and

(c) the person has not, at the time of the importation, export, manufacture or supply, properly notified to the Secretary either or both of the following:

(i) the manufacturer of the goods;

(ii) premises used in the manufacture of the goods.

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

(1BA) A person commits an offence if:

(a) the person is the sponsor of therapeutic goods for use in humans; and

(b) the person:

(i) imports the goods into Australia; or

(ii) exports the goods from Australia; or

(iii) manufactures the goods in Australia; or

(iv) supplies the goods in Australia; and

(c) the person has not, at the time of the importation, export, manufacture or supply, properly notified to the Secretary either or both of the following:

(i) the manufacturer of the goods;

(ii) premises used in the manufacture of the goods.

Penalty: 100 penalty units.

(1BB) An offence against subsection (1BA) is an offence of strict liability.

(1C) For the purposes of paragraphs (1B)(c) and (1BA)(c):

(a) a manufacturer is ***properly notified*** to the Secretary if:

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(i) the manufacturer was nominated, as a manufacturer of the goods, in an application for the registration or listing of the goods; or

(ii) the Secretary was subsequently informed in writing that the manufacturer is a manufacturer of the goods; and

(b) premises are ***properly notified*** to the Secretary if:

(i) the premises were nominated, as premises used in the manufacture of the goods, in an application for the registration or listing of the goods; or

(ii) the Secretary was subsequently informed in writing that the premises are used in the manufacture of the goods.

(2A) A person commits an offence if:

(a) the person imports therapeutic goods into Australia; and

(b) the goods are exempt under section 18A; and

(c) the importation breaches a condition of the exemption.

Penalty: Imprisonment for 4 years or 240 penalty units, or both.

(2B) Strict liability applies to paragraph (2A)(b).

Note: For strict liability, see section 6.1 of the *Criminal Code*.

(2C) A person commits an offence if:

(a) the person imports therapeutic goods into Australia; and

(b) the goods are exempt under section 18A; and

(c) the importation breaches a condition of the exemption.

Penalty: 60 penalty units.

(2D) An offence under subsection (2C) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

20A Civil penalty relating to the importation, exportation, manufacture or supply of sponsored goods without proper notification

(1) A person contravenes this section if:

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(a) the person does any of the following:
  (i) imports therapeutic goods into Australia;
  (ii) exports therapeutic goods from Australia;
  (iii) manufactures therapeutic goods in Australia;
  (iv) supplies therapeutic goods in Australia; and
(b) the person is the sponsor of the goods for use in humans; and
(c) the person has not, at or before the time of the importation, exportation, manufacture or supply, properly notified to the Secretary either or both of the following:
  (i) the manufacturer of the goods;
  (ii) premises used in the manufacture of the goods.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

*Meaning of **properly notified***

(2) For the purposes of paragraph (1)(c):
(a) a manufacturer is ***properly notified*** to the Secretary if:
  (i) the manufacturer was nominated, as a manufacturer of the goods, in an application for the registration or listing of the goods; or
  (ii) the Secretary was subsequently informed in writing that the manufacturer is a manufacturer of the goods; and
(b) premises are ***properly notified*** to the Secretary if:
  (i) the premises were nominated, as premises used in the manufacture of the goods, in an application for the registration or listing of the goods; or
  (ii) the Secretary was subsequently informed in writing that the premises are used in the manufacture of the goods.

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21 Offence relating to wholesale supply

A person must not supply in Australia therapeutic goods for use in humans (other than listable devices), being goods of which the person is not a sponsor, to another person who is not the ultimate consumer of the goods unless:

(a) the goods are registered goods or listed goods; or
(b) the goods are exempt goods; or
(ba) the goods are exempt under section 18A; or
(c) the goods are the subject of an approval or authority under section 19; or
(d) the goods are the subject of an approval under section 19A.

Penalty: 120 penalty units.

21A General criminal offences relating to this Part

Offences for making a false or misleading statement

(1) A person commits an offence if:
(a) the person makes a statement; and
(b) the statement is made in or in connection with a certification of any matter under subsection 26A(2) or 26AB(2); and
(c) the statement is false or misleading in a material particular; and
(d) either:
(i) the use of the medicine has resulted in, will result in, or is likely to result in, harm or injury to any person; or
(ii) the use of the medicine, if the medicine 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.

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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; and

(b) the statement is made in or in connection with a certification of any matter under subsection 26A(2) or 26AB(2); and

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

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

(4A) A person commits an offence if:

(a) the person makes a statement; and

(b) the statement is made in or in connection with a certification of any matter under subsection 26A(2) or 26AB(2); and

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

Penalty: 100 penalty units.

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

Offences relating to breaching a condition of registration or listing of therapeutic goods

(5) A person commits an offence if:

(a) therapeutic goods are registered or listed 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 registration or listing of the goods; 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 (8) 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.

(8) A person commits an offence if:

(a) therapeutic goods are registered or listed 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 registration or listing of the goods.

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

(8A) A person commits an offence if:

(a) therapeutic goods are registered or listed 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 registration or listing of the goods.

Penalty: 100 penalty units.

(8B) An offence against subsection (8A) is an offence of strict liability.

Offences relating to the supply of therapeutic goods in breach of authority etc.

(9) A person commits an offence if:

(a) the Secretary has authorised, under subsection 19(5), the person to supply therapeutic goods; and

(b) the person supplies those goods; and

(c) any of the following applies:

(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 19(7); 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:

(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 19(7).

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

(9A) A person commits an offence if:

(a) the Secretary has authorised, under subsection 19(5), the person to supply therapeutic goods; and

(b) the person supplies those goods; and

(c) any of the following applies:

(i) the supply is not in accordance with the authority;

(ii) the supply is not in accordance with the conditions to which the authority is subject;

(iii) the supply is not in accordance with regulations made for the purpose of subsection 19(7).

Penalty: 500 penalty units.

(10) A person commits an offence if:

(a) the Secretary has authorised, under subsection 19(5), the person to supply therapeutic goods; and

(b) the person supplies those goods; and

(c) any of the following applies:

(i) the supply is not in accordance with the authority;

(ii) the supply is not in accordance with the conditions to which the authority is subject;

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(iii) the supply is not in accordance with regulations made for the purpose of subsection 19(7).

Penalty: 100 penalty units.

(11) An offence against subsection (10) is an offence of strict liability.

(11A) 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 19(7A) rules; and

(c) the person supplies:

(i) therapeutic goods specified in those rules; or

(ii) therapeutic goods included in a class of therapeutic goods 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; and

(e) 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

(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.

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(11C) 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 19(7A) rules; and

(c) the person supplies:

(i) therapeutic goods specified in those rules; or

(ii) therapeutic goods included in a class of therapeutic goods 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.

(11D) 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 19(7A) rules; and

(c) the person supplies:

(i) therapeutic goods specified in those rules; or

(ii) therapeutic goods included in a class of therapeutic goods 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.

(11E) An offence against subsection (11D) is an offence of strict liability.

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Offences relating to using therapeutic goods without approval etc.

(12) A person commits an offence if:
- (a) the person uses therapeutic goods; and
- (b) the goods are used:
  - (i) in the treatment of another person; or
  - (ii) solely for experimental purposes in humans; and
- (c) the goods are not:
  - (i) exempt goods; or
  - (ii) listed goods; or
  - (iii) registered goods; or
  - (iv) goods exempt under section 18A; or
  - (v) goods that are the subject of an approval under section 19A; and
- (d) the goods are not used in accordance with:
  - (i) an approval or authority under section 19; or
  - (ii) a condition applicable under regulations made for the purposes of subsection 19(4A); and
- (e) either:
  - (i) if the person used the goods in the treatment of another person—the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to that person; or
  - (ii) if the person used the goods solely for experimental purposes in humans—the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any of those persons.

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

(12A) A person commits an offence if:
- (a) the person uses therapeutic goods; and
- (b) the goods are used:
  - (i) in the treatment of another person; or
  - (ii) solely for experimental purposes in humans; and
- (c) the goods are not:

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(i) exempt goods; or
(ii) listed goods; or
(iii) registered goods; or
(iv) goods exempt under section 18A; or
(v) goods that are the subject of an approval under section 19A; and

(d) the goods are not used in accordance with:
(i) an approval or authority under section 19; or
(ii) a condition applicable under regulations made for the purposes of subsection 19(4A).

Penalty: 500 penalty units.

(13) A person commits an offence if:
(a) the person uses therapeutic goods; and
(b) the goods are used:
(i) in the treatment of another person; or
(ii) solely for experimental purposes in humans; and
(c) the goods are not:
(i) exempt goods; or
(ii) listed goods; or
(iii) registered goods; or
(iv) goods exempt under section 18A; or
(v) goods that are the subject of an approval under section 19A; and
(d) the goods are not used in accordance with:
(i) an approval or authority under section 19; or
(ii) a condition applicable under regulations made for the purposes of subsection 19(4A).

Penalty: 100 penalty units.

(14) An offence against subsection (13) is an offence of strict liability.

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21B General civil penalties relating to this Part

Civil penalty for making a false or misleading statement

(1) A person contravenes this subsection if the person, in or in connection with a certification of any matter under subsection 26A(2) or 26AB(2), makes a statement that 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.

Civil penalty relating to breaching a condition of registration or listing of therapeutic goods

(2) A person contravenes this subsection if:

(a) therapeutic goods are registered or listed in relation to the person; and

(b) the person does an act or omits to do an act that breaches a condition of the registration or listing of the goods.

Maximum civil penalty:

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

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

Civil penalty for falsely representing therapeutic goods

(3) A person contravenes this subsection if:

(a) the person represents therapeutic goods that are not included in the Register as being so included; or

(b) the person represents therapeutic goods that are not exempt goods as being exempt goods; or

(c) the person represents therapeutic goods that are not goods exempt under section 18A as being goods exempt under that section; or

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(d) the person represents therapeutic goods that are included in one part of the Register as being included in another part of the Register; or

(e) the person represents therapeutic goods that are not the subject of an approval or authority under section 19 as being the subject of such an approval or authority; or

(f) the person represents therapeutic goods that are not the subject of an approval under section 19A as being the subject of such an approval.

Maximum civil penalty:

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

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

Civil penalty for advertising therapeutic goods for an indication

(4) A person contravenes this subsection if:

(a) the person, by any means, advertises therapeutic goods for an indication; and

(b) the therapeutic goods are included in the Register; and

(c) the indication is not an indication 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.

22 General offences relating to this Part

(1) A person must not set out or cause to be set out, on a container or package that contains therapeutic goods or on a label of goods of that kind, a number that purports to be the registration number or listing number of the goods in relation to a particular person if the number is not that number.

Penalty: 60 penalty units.

(2) A person commits an offence if:

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(a) the person, by any means, advertises therapeutic goods for an indication; and
(b) the therapeutic goods are included in the Register; and
(c) the indication is not an indication accepted in relation to that inclusion; and
(d) either:
(i) the use of the goods for the advertised indication 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 for the advertised indication, 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.

(3) A person commits an offence if:
(a) the person, by any means, advertises therapeutic goods for an indication; and
(b) the therapeutic goods are included in the Register; and
(c) the indication is not an indication accepted in relation to that inclusion.

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

(5) A person commits an offence if:
(a) the person, by any means, advertises therapeutic goods for an indication; and
(b) the therapeutic goods are included in the Register; and
(c) the indication is not an indication accepted in relation to that inclusion.

Penalty: 100 penalty units.

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

(6) A person commits an offence if:

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(a) the person claims, by any means, that the person or another person can arrange the supply of therapeutic goods; and

(b) none of the following subparagraphs applies in relation to the goods:

(i) the goods are registered goods or listed goods;

(ii) the goods are exempt goods;

(iii) the goods are exempt under section 18A;

(iv) the goods are the subject of an approval or authority under section 19 that covers the supply of the goods by the person or other person;

(v) the goods are the subject of an approval under section 19A that covers the supply of the goods by the person or other person.

Penalty: 60 penalty units.

(7) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission results in the breach of:

(i) a condition of an exemption applicable under regulations made for the purposes of subsection 18(1); or

(ii) a condition of an approval under section 19; or

(iii) a condition applicable under regulations made for the purposes of subsection 19(4A); or

(iv) a condition of an approval under section 19A.

(7AA) An offence against subsection (7) is punishable on conviction by a fine of not more than 60 penalty units.

(7AB) A person commits an offence if:

(a) the person does an act or omits to do an act in relation to therapeutic goods; and

(b) the goods are exempt under section 18A; and

(c) the act or omission results in the breach of a condition of the exemption; and

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(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 1: A person may commit an offence against subsection 20(2A) or (2C), or contravene section 22AA (a civil penalty provision), by breaching a condition of an exemption of therapeutic goods under section 18A that relates to the importation of the goods.

Note 2: A person may commit an offence against subsection 30H(1) or (3) by breaching a condition of an exemption of therapeutic goods under section 18A that relates to records about the goods.

Note 3: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

(7AC) Strict liability applies to paragraph (7AB)(b).

Note: For strict liability, see section 6.1 of the *Criminal Code*.

(7AD) A person commits an offence if:

(a) the person does an act or omits to do an act in relation to therapeutic goods; and
(b) the goods are exempt under section 18A; 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.

(7AE) Strict liability applies to paragraph (7AD)(b).

Note: For strict liability, see section 6.1 of the *Criminal Code*.

22AA 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 therapeutic goods; and
(b) the goods are exempt under section 18A; and
(c) the act or omission breaches a condition of the exemption.

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.

22A Criminal offences for false statements in applications for registration

(1) A person commits an offence if:
(a) the person makes a statement; and
(b) the statement is made in or in connection with an application for registration of therapeutic goods; and
(c) the statement is false or misleading in a material particular; 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.

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; and
(b) the statement is made in or in connection with an application for registration of therapeutic goods; and
(c) the statement 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 makes a statement; and

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(b) the statement is made in or in connection with an application for registration of therapeutic goods; 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.

22B Civil penalty for false statements in applications for registration

A person contravenes this section if the person in or in connection with an application for registration of therapeutic goods, makes a statement that 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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Division 1A—Provisional determinations for medicine

22C Applications for provisional determination

(1) A person may make an application to the Secretary for a provisional determination relating to a medicine of a kind prescribed by the regulations for the purposes of this subsection.

Note: If the Secretary makes the determination, the person applies under section 23 for registration of the medicine and that application passes preliminary assessment, then a different kind of evaluation of the medicine will occur under section 25.

(2) An application under subsection (1) must:
(a) be made in accordance with a form approved, in writing, by the Secretary; and
(b) be accompanied by the prescribed application fee; and
(c) contain the information that the form requires, and any further information, statement or document the Secretary requires, whether in the form or otherwise; and
(d) satisfy any other requirement prescribed by the regulations for the purposes of this paragraph.

(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.

22D Provisional determinations

(1) If a person makes an application, in accordance with subsection 22C(2), for a provisional determination relating to a medicine, the Secretary must decide to make, or to refuse to make, the determination.

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Criteria

(2) The Secretary may make the determination if the Secretary is satisfied that the criteria prescribed by the regulations for the purposes of this subsection are met in relation to the medicine.

Content of determination

(3) The determination must specify:
  (a) the person to whom the determination relates; and
  (b) the medicine to which the determination relates; and
  (c) the indication of the medicine to which the determination relates; and
  (d) each active ingredient of the medicine to which the determination relates.

The determination may specify any other matters that the Secretary considers appropriate.

Notice of decision

(4) As soon as practicable after making the decision, the Secretary must:
  (a) give the person written notice of the decision; and
  (b) if the Secretary refuses to make the determination—set out the reasons for the refusal in the notice.

22E Period during which provisional determination is in force

(1) A provisional determination under section 22D relating to a medicine:
  (a) comes into force on the day on which the Secretary gives the person notice under subsection 22D(4); and
  (b) subject to this section and section 22F, remains in force for the initial period.

Note: For revocation of the determination, see section 22F.

(2) The ***initial period*** is 6 months or another period prescribed by the regulations for the purposes of this subsection.

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Extensions

(3) The person may make an application to the Secretary to extend the initial period.

(4) The application must:
  (a) be in a form approved, in writing, by the Secretary; and
  (b) be made at least 28 days before the determination would otherwise cease to be in force; and
  (c) be accompanied by the prescribed application fee.

(5) On receiving the application, the Secretary must decide to extend, or to refuse to extend, the initial period.

(6) The Secretary may extend the initial period by 6 months, or another period prescribed by the regulations for the purposes of this subsection, if the Secretary:
  (a) is still satisfied that the criteria prescribed by the regulations for the purposes of subsection 22D(2) are met in relation to the medicine; and
  (b) is satisfied that, if the Secretary were to make the extension, the person would make an application under section 23 for provisional registration of the medicine before the end of the extended period.

(7) As soon as practicable after making the decision, the Secretary must:
  (a) give the person written notice of the decision; and
  (b) if the Secretary refuses to extend the initial period—set out the reasons for the refusal in the notice.

(8) Only one extension may be given.

Effect of application under section 23

(9) If the person to whom the provisional determination relates makes an application under section 23 for provisional registration of the medicine before the end of the initial period (or that period as extended), the determination remains in force until:

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(a) the person withdraws the application; or
(b) the application lapses in accordance with subsection 24(2); or
(c) the person gives the Secretary written notice under subsection 24E(2) that the person wishes to treat the application as having been refused; or
(d) the application is finally determined.

(10) For the purposes of paragraph (9)(d), 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.

22F Revocation of provisional determination

Revocation on Secretary's own initiative

(1) The Secretary may revoke a provisional determination under section 22D relating to a person and a medicine if the Secretary is satisfied that the criteria prescribed by the regulations for the purposes of subsection 22D(2) are no longer met in relation to the medicine.

Revocation on request

(2) The Secretary must revoke a provisional determination under section 22D relating to a person and a medicine if the person requests the Secretary, in writing, to do so.

Notice of revocation

(3) As soon as practicable after making a revocation under this section, the Secretary must:
(a) give the person written notice of the revocation; and
(b) for a revocation under subsection (1)—set out the reasons for the revocation in the notice.

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Day revocation takes effect

(4) A revocation under this section takes effect on the day on which the Secretary gives the person notice of the revocation.

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Division 2—Registration and listing

23 Applications generally

A person may make an application to the Secretary for registration or listing of therapeutic goods.

23AA Applications for provisional registration of medicine

If:

(a) a person makes an application under section 23 for the registration of a medicine; and

(b) a provisional determination under section 22D relating to the person, the medicine and the indication to which the application relates is in force when the application is made;

then, for the purposes of this Act, the application is taken to be an application for provisional registration of the medicine.

23A Classes of therapeutic goods

The Secretary may, by notifiable instrument, specify different classes of therapeutic goods for the purposes of section 23B.

23B Requirements relating to applications for registration of therapeutic goods and listing of medicines under section 26AE

(1) If an application is made under section 23 for:

(a) registration of therapeutic goods (including an application for provisional registration of a medicine); or

(b) the listing of a medicine under section 26AE;

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:

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(a) the application must be made:
  (i) in accordance with the form approved, in writing, by the Secretary for that class of therapeutic goods; or
  (ii) in such other manner as is approved, in writing, by the Secretary for that class of therapeutic goods;
(b) the prescribed application fee for that class of therapeutic goods 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 (9) for that class of therapeutic goods; and
  (ii) in a form determined under subsection (10) for that class of therapeutic goods;
(e) if the application is for the registration of restricted medicine—the application must be accompanied by product information, in relation to the medicine, that is in the form approved under section 7D in relation to the medicine;
(f) if the Secretary so requires—the applicant must:
  (i) deliver to the Department a reasonable number of samples of the goods; and
  (ii) do so in a manner approved, in writing, by the Secretary.

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 passed preliminary assessment, the Secretary must give a written notice to the applicant stating that the application has passed preliminary assessment.

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(5) Subsection (4) does not apply if the period within which the Secretary must, under section 25, evaluate the goods to which the application relates is prescribed by reference to the prescribed period within which the Secretary is required to consider an application under subsection 9D(3) to vary an entry in the Register.

(6) If the application has not passed preliminary assessment, the Secretary must, by written notice given to the applicant, refuse the application.

Approval of forms etc.

(7) For the purposes of paragraph (2)(a), the Secretary may approve different forms and different manners for making applications for different classes of therapeutic goods that are specified under section 23A.

(8) 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.

Determination of kinds and forms of information

(9) The Secretary may, by legislative instrument, determine a kind of information for the purposes of the application of subparagraph (2)(d)(i) to a class of therapeutic goods that is specified under section 23A.

(10) The Secretary may, by legislative instrument, determine a form of information for the purposes of the application of subparagraph (2)(d)(ii) to a class of therapeutic goods that is specified under section 23A.

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23C Requirements relating to applications for listing of therapeutic goods under section 26 or 26A

(1) This section applies if an application is made under section 23 for listing of therapeutic goods under section 26 or 26A.

(2) The application complies with this section if:

(a) the application is 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 for the purposes of this paragraph; and

(b) the application is delivered to an office of the Department specified by the Secretary; and

(c) the prescribed application fee has been paid; and

(d) the applicant has delivered to the office to which the application was made such information, in a form approved, in writing, by the Secretary, as will allow the determination of the application; and

(e) if the Secretary so requires—the applicant has delivered to the office to which the application was made a reasonable number of samples of the goods.

Note: To be listed, an application must comply with this section: see sections 26, 26AA, 26A and 26AB.

(3) The Secretary may, by legislative instrument, determine forms of information for the purposes of the application of paragraph (2)(d).

(4) 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.

24 Applications for registration

(1) This section applies if:

(a) an application is made for the registration of therapeutic goods under section 23; and

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(b) the goods are goods that are required to be registered; and
(c) the application has passed preliminary assessment.

(1A) A fee specified in, or determined in accordance with, the regulations is payable by the applicant in respect of the evaluation of the goods for registration, and the Secretary must notify each such applicant of the amount of the evaluation fee.

(2) An application for registration of therapeutic goods lapses if:
(a) any part of the evaluation fee payable in respect of those goods remains unpaid at the end of the period of 2 months after the day on which the amount became due and payable; or
(b) the application contains information that is inaccurate or misleading in a material particular; or
(c) 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 31, is inaccurate or misleading in a material particular; or
(d) the applicant fails to comply with a requirement under section 31 to give information consisting of individual patient data in relation to the goods.

(3) In this section, ***individual patient data***, in relation to therapeutic goods, means information, derived from clinical trials, relating to individuals before, during and after the administration of the goods to those individuals, including, but not limited to, demographic, biochemical and haematological information.

24A When evaluation fee due for payment

Subject to section 24B, an evaluation fee under section 24 payable by an applicant is due and payable on the day on which the applicant is notified of the amount of the evaluation fee.

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24B Payment of evaluation fee by instalments

(1) The regulations may provide for the payment of an evaluation fee under section 24 to be made by such instalments and at such times as are ascertained in accordance with the regulations, and the evaluation 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 evaluation fee under section 24 by instalments if any part of an instalment of:

(a) that or any other evaluation fee under section 24 payable by the person; or

(b) any assessment fee under section 41LA 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).

24C Recovery of evaluation fee

An evaluation fee under section 24 may be recovered by the Commonwealth as a debt due to the Commonwealth.

24D Refund of evaluation fee where evaluation not completed within prescribed period

(1) This section applies to an application under section 23 in relation to therapeutic goods for the evaluation of which a period is prescribed under paragraph 63(2)(da).

(2) If:

(a) the applicant has paid the whole of the evaluation fee; and

(b) the evaluation is completed, but not within the period referred to in subsection (1);

then 25% of the evaluation fee must be refunded to the applicant.

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(3) For the purposes of subsection (2), the evaluation is taken to be completed when the applicant is notified of the Secretary's decision under subsection 25(3) in relation to the goods.

24E Deemed refusal of application

(1) This section applies in the case of an application under section 23 in relation to therapeutic goods for the evaluation of which a period is prescribed under paragraph 63(2)(da).

(2) If, at the end of the period referred to in subsection (1), the evaluation has not been completed, the applicant may give the Secretary written notice that the applicant wishes to treat the application as having been refused.

(3) A notice under subsection (2) may be given at any time before the evaluation is completed.

(4) Where a notice has been given, this Act (except for subsection 60(5)) has effect as if:
  (a) the Secretary had decided not to register the goods the subject of the application; and
  (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 under subsection (2).

25 Evaluation of therapeutic goods

(1) If:
  (a) an application is made for the registration of therapeutic goods in relation to a person under section 23; and
  (b) the application has passed preliminary assessment;

the Secretary must evaluate the goods for registration having regard to:
  (c) unless the application is one referred to in paragraph (d)—whether the quality, safety and efficacy of the goods for the

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purposes for which they are to be used have been satisfactorily established; and

(d) for an application for provisional registration of a medicine:

(i) whether, based on preliminary clinical data, the safety and efficacy of the medicine for the purposes for which it is to be used have been satisfactorily established; and

(ii) whether the quality of the medicine for the purposes for which it is to be used has been satisfactorily established; and

(iii) whether, if the Secretary were to register the medicine, the Secretary is satisfied with the applicant's plan to submit comprehensive clinical data on the safety and efficacy of the medicine before the end of the 6 years that would start on the day that registration would commence; and

(da) if:

(i) the applicant is applying for the registration of restricted medicine; or

(ii) the applicant is applying for the registration of medicine (other than restricted medicine) and the applicant has been given a notice in writing by the Secretary requiring the applicant to give to the Secretary product information, in relation to the medicine, that is in the form approved under section 7D in relation to the medicine;

the product information given by the applicant in relation to the medicine; and

(e) whether the presentation of the goods is acceptable; and

(f) whether the goods conform to any standard applicable to the goods; and

(fa) whether:

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

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

are complied with in relation to the goods; and

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(g) if a step in the manufacture of the goods has been carried out outside Australia—whether the manufacturing and quality control procedures used in the manufacture of the goods are acceptable; and

(h) if the goods have been manufactured in Australia—whether the goods have been manufactured in accordance with Part 3-3; and

(j) whether the goods contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; and

(ja) whether all of the manufacturers of the goods are nominated as manufacturers of the goods in the application; and

(k) such other matters (if any) as the Secretary considers relevant.

Note: The Secretary must not use protected information when evaluating therapeutic goods for registration: see section 25A.

(2) In making a decision for the purposes of paragraph (1)(g), the matters that may be taken into account include:

(a) whether the applicant has provided:

(i) if the goods are not therapeutic devices and a step in the manufacture of the goods has been carried out in a country that is a member of the European Community or a member of EFTA—an EC/EFTA attestation of conformity in relation to the goods; or

(ia) if the goods are not therapeutic devices and a step in the manufacture of the goods has been carried out in a country declared by the Minister under section 3B to be covered by a non-EC/EFTA MRA—a non-EC/EFTA attestation of conformity, for the non-EC/EFTA MRA, in relation to the goods; or

(ii) in any other case—an acceptable form of evidence from a relevant overseas authority establishing that the manufacture of the goods is of an acceptable standard; and

(b) whether the applicant has agreed to provide, where the Secretary considers inspection of the manufacturing

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procedures used in the manufacture of the goods to be necessary:

(i) funds for the carrying out of that inspection by the Department; and

(ii) evidence that the manufacturer has agreed to such an inspection.

(2A) An evaluation under this section of goods in relation to which a period has been prescribed under paragraph 63(2)(da) must be completed within that period.

(2B) If therapeutic goods are exempt from the operation of Part 3-3 or a person is exempt from the operation of that Part in relation to the manufacture of the goods, subsection (1) has effect, in relation to the goods, as if paragraph (h) were omitted.

(2C) If a person is exempt from the operation of Part 3-3 in relation to a step in the manufacture of therapeutic goods, subsection (1) has effect, in relation to the goods, as if the reference in paragraph (h) to Part 3-3 were a reference to that Part to the extent that it applies to that person in relation to the manufacture of the goods.

(2D) If:

(a) therapeutic goods were made outside Australia; and

(b) had the goods been made in Australia, they would have been exempt from the operation of Part 3-3;

subsection (1) has effect, in relation to the goods, as if paragraph (g) were omitted.

(2E) A decision for the purposes of paragraph (1)(g) may also take into account any information provided to the Secretary by a health authority of a Convention country and relating to:

(a) the general standards of manufacturing practice of a particular manufacturer; or

(b) the specific standards of manufacture or control adopted by a particular manufacturer in relation to particular goods.

(2F) For the purposes of subsection (2E), a Convention country is a country that is a party to the Mutual Recognition Convention.

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(2G) Information referred to in subsection (2E) and provided in accordance with the Mutual Recognition Convention is to be treated as equivalent to information obtained as a result of an inspection under Part 3-3 of this Act.

(3) After an evaluation under this section of goods has been completed, the Secretary must decide:

(a) to register the goods; or

(b) not to register the goods.

Note: See also sections 25AA (approved product information for medicine), 25AB (registration of therapeutic goods) and 25AC (notice of decision not to register therapeutic goods).

25AAA Therapeutic goods (priority applicant) determinations

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

(2) A ***therapeutic goods (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 23 application that may be made by the person for the registration of therapeutic goods specified in the determination.

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

(a) applications for therapeutic goods (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).

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

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

(6) A period prescribed under paragraph 63(2)(da) for the evaluation of therapeutic goods covered by a section 23 application for which the applicant is a priority applicant may be shorter than the period prescribed under that paragraph for the evaluation of therapeutic goods covered by a section 23 application for which the applicant is not a priority applicant.

(7) The regulations may provide that, if:
   (a) a person is a priority applicant in relation to a section 23 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 therapeutic goods (priority applicant) determination is in force under the regulations, the determination may be published on the Department's website.

(10) A therapeutic goods (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 therapeutic goods (priority applicant) determination.

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

25AA Approved product information for medicine

(1) The Secretary must approve product information in relation to therapeutic goods if:

(a) the Secretary decides, under subsection 25(3), to register the goods; and

(b) the goods are:

(i) restricted medicine; or

(ii) medicine in respect of which the applicant has been given a notice of the kind referred to in subparagraph 25(1)(da)(ii).

Note: Subsection (4) deals with variation of the product information.

(1A) However, the Secretary must not approve product information in relation to therapeutic goods under subsection (1) unless the Secretary is satisfied that the product information reflects the basis on which the Secretary decided under subsection 25(3) to register the goods.

(1B) If:

(a) there is medicine included in the Register in relation to a person and there is no product information approved under this section in relation to the medicine; and

(b) the medicine becomes restricted medicine;

the Secretary may, by written notice given to the person, require the person to:

(c) give the Secretary product information, in relation to the medicine, that is in the form approved under section 7D in relation to the medicine; and

(d) give the Secretary that product information within the period specified in the notice (which must be at least 30 days after the notice is given).

(1C) If the person complies with subsection (1B), the Secretary must approve product information in relation to the medicine that

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reflects the basis on which the medicine is registered at the time of the approval. The Secretary must, by written notice given to the person, set out the product information so approved.

Note: Subsection (4) deals with variation of the product information.

Transitional

(2) If:

(a) at the start of the day the first instrument made under subsection 3(2A) or (2B) takes effect, there is medicine included in the Register in relation to a person; and

(b) before that day, the Secretary, in a notice given under subsection 25(4) (as in force on that day) to the person in relation to the registration of the medicine, specified the product information that was approved by the Secretary in relation to the medicine;

then that product information (including as varied before that day) is, on and after that day, the product information that is approved under this section in relation to the medicine.

Note: Subsection (4) deals with variation of the product information.

(3) If:

(a) before the day the first instrument made under subsection 3(2A) or (2B) takes effect, a person made an application to include medicine in the Register; and

(b) before that day and in relation to that application, the Secretary, in a notice given under subsection 25(4) (as in force on that day) to the person, specified the product information that was approved by the Secretary in relation to the medicine; and

(c) on or after that day and in relation to that application, the Secretary includes the medicine in the Register in relation to the person;

then that product information (including as varied before that inclusion) is, on and after the day the registration of the medicine commences, the product information that is approved under this section in relation to the medicine.

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Note: Subsection (4) deals with variation of the product information.

Variations

(4) If:

(a) there is medicine included in the Register in relation to a person and there is product information approved under this section in relation to the medicine; and

(b) either:

(i) under section 9D, the Secretary varies the entry in the Register in relation to the medicine; or

(ii) there is a change in the conditions to which the inclusion of the medicine is subject; and

(c) as a result of that variation or change, the Secretary is satisfied that a variation to that product information is required;

the Secretary may, by notice in writing given to the person, make any variations that the Secretary considers appropriate to the product information that is approved in relation to the medicine.

(4A) Without limiting subsection (4), a variation to the product information is not appropriate unless:

(a) if subparagraph (4)(b)(i) applies—the product information, as varied, reflects the basis on which the Secretary decided under section 9D to vary the entry in the Register in relation to the medicine; or

(b) if subparagraph (4)(b)(ii) applies—the product information, as varied, reflects the basis on which the Secretary decided under section 28 to change the conditions to which the inclusion of the medicine is subject.

(5) To avoid doubt, if product information that is approved in relation to medicine is varied under this section, that product information, as varied, becomes the product information that is approved under this section in relation to the medicine.

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25AB Registration of therapeutic goods etc.

Therapeutic devices

(1) If:

(a) an application is made under section 23 for the registration of therapeutic goods in relation to a person; and

(aa) the application has passed preliminary assessment; and

(b) the Secretary decides under subsection 25(3) to register the goods; and

(c) the goods are therapeutic devices;

the Secretary must:

(d) notify the applicant in writing of the decision within 28 days of making the decision; and

(e) include the goods in the Register; and

(f) give the applicant a certificate of registration.

Therapeutic goods that are not therapeutic devices

(2) If:

(a) an application is made under section 23 for the registration of therapeutic goods in relation to a person; and

(aa) the application has passed preliminary assessment; and

(b) the Secretary decides under subsection 25(3) to register the goods; and

(c) the goods are not therapeutic devices;

the Secretary must, in accordance with subsection (3), notify the applicant in writing of the decision within 28 days of making the decision.

(3) The notice must:

(a) set out the decision under subsection 25(3) to register the goods; and

(b) if the goods are restricted medicine or medicine in respect of which the applicant has been given a notice of the kind referred to in subparagraph 25(1)(da)(ii)—set out the product

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information approved under subsection 25AA(1) for the medicine; and

(c) inform the applicant that the goods will not be included in the Register unless and until the applicant gives the Secretary:

(i) the certificate required under subsection 26B(1); or

(ii) a notice (in accordance with a form approved, in writing, by the Secretary) that a certificate under that subsection is not required in relation to the application.

(4) If the applicant gives the Secretary the certificate referred to in subparagraph (3)(c)(i) or the notice referred to in subparagraph (3)(c)(ii), the Secretary must:

(a) include the goods in the Register; and

(b) give the applicant a certificate of registration.

(5) To avoid doubt, if the applicant gives the Secretary the certificate referred to in subparagraph (3)(c)(i) or the notice referred to in subparagraph (3)(c)(ii), the Secretary must include the goods in the Register under paragraph (4)(a) without inquiring into the correctness of the certificate or the notice.

Date registration commences

(6) The registration of therapeutic goods commences on the day specified in the certificate of registration.

25AC Notice of decision not to register therapeutic goods

If:

(a) an application is made under section 23 for the registration of therapeutic goods in relation to a person; and

(aa) the application has passed preliminary assessment; and

(b) the Secretary decides under subsection 25(3) not to register the goods;

the Secretary must notify the applicant in writing of the decision, and the reasons for the decision, within 28 days of making the decision.

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25A When the Secretary must not use protected information

(1) When evaluating therapeutic goods for registration, the Secretary must not use information about other therapeutic goods that is protected information.

(2) Information is ***protected information*** if:

(a) the information was given to the Secretary in relation to an application to register therapeutic goods (the ***new goods***):

(i) not being therapeutic devices; and

(ii) consisting of, or containing, an active component; and

(b) the information is about the active component and is not available to the public; and

(c) when the application to register the new goods was lodged:

(i) no other therapeutic goods consisting of, or containing, that active component were included in the Register; and

(ii) no such therapeutic goods had been included in the Register at any time before then; and

(d) the new goods became registered on or after the commencement of this subsection; and

(e) 5 years have not passed since the day the new goods became registered; and

(f) the person in relation to whom the new goods are registered has not given the Secretary permission in writing for the Secretary to use the information.

(3) For the purposes of subsection (2), an ***active component***, in relation to therapeutic goods, is a substance that is, or one of the substances that together are, primarily responsible for the biological or other effect identifying the goods as therapeutic goods.

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25B Registration of therapeutic device to which EC/EFTA attestation of conformity applies

(1) If:

(a) an application is made under section 23 for the registration of a therapeutic device in relation to a person; and

(aa) the application has passed preliminary assessment; and

(b) the applicant gives to the Secretary an EC/EFTA attestation of conformity as to the matters that would require evaluation under subsection 25(1) if that subsection applied in relation to the device;

the Secretary must register the device unless the Secretary considers that the device may compromise the health or safety of users.

(2) The Secretary must notify the applicant in writing of his or her decision on the application within 28 days of the making of the decision. If the Secretary decides not to register the device, the notice must contain the reasons for that decision.

(3) If the Secretary decides to register the device, the Secretary must:

(a) include the device in the Register; and

(b) give to the applicant a certificate of registration.

(4) The registration of the device commences on the day specified for the purpose in the certificate of registration.

26 Listing of therapeutic goods

(1) Where:

(a) an application is made for the listing of therapeutic goods in relation to a person under section 23; and

(aaa) the application complies with section 23C; and

(aa) if goods are not therapeutic devices—the application is accompanied by either:

(i) the certificate required under subsection 26B(1); or

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(ii) a notice (in accordance with a form approved, in writing, by the Secretary) that a certificate under that subsection is not required in relation to the application; and

(b) the person has complied with any requirements made by the Secretary under section 31 in relation to the goods; and

(ba) the goods are not goods which may be listed under section 26A or 26AE;

then, subject to this section and section 26AA, the Secretary is not to refuse to list the goods in relation to the person except where the Secretary is satisfied that:

(c) the goods are not eligible for listing; or

(d) the goods are not safe for the purposes for which they are to be used; or

(e) the presentation of the goods is unacceptable; or

(f) the goods do not conform to a standard applicable to the goods; or

(fa) either of the following has not been complied with in relation to the goods:

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

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

(g) if a step in the manufacture of the goods (not being therapeutic devices other than devices prescribed for the purposes of this paragraph) has been carried out outside Australia—the manufacturing and quality control procedures used in the manufacture of the goods are not acceptable; or

(h) if the goods have been manufactured in Australia—the goods have been manufactured contrary to Part 3-3; or

(j) if the goods have been manufactured in Australia, or imported into Australia, solely for export—a relevant authority of the country to which the goods are to be exported has not confirmed its willingness to accept the goods and:

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(i) the goods have been refused registration or listing for supply in Australia; or

(ii) the Secretary requires such a confirmation for a reason other than because the goods have been refused registration or listing; or

(k) the goods do not comply with prescribed quality or safety criteria; or

(m) the goods contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; or

(n) one or more of the manufacturers of the goods are not nominated as manufacturers of the goods in the application.

(1AA) If:

(a) a medicine (the ***original medicine***) is included in the Register in relation to a person; and

(b) the person makes an application under section 23 for the listing of a medicine (the ***new medicine***) under this section; and

(ba) the application complies with section 23C; and

(c) the Secretary is satisfied that paragraphs (1)(a) to (ba) are satisfied in relation to the application; and

(d) the Secretary is satisfied that the new medicine has the same characteristics as the original medicine apart from the characteristics specified in an instrument under subsection (1AB);

the Secretary may list the new medicine in relation to the person.

(1AB) The Minister may, by legislative instrument, specify characteristics for the purposes of paragraph (1AA)(d).

(1A) To avoid doubt, if:

(a) an application is made for the listing of therapeutic goods in relation to a person under section 23; and

(aa) the application complies with section 23C; and

(b) the application is accompanied by either:

(i) the certificate required under subsection 26B(1); or

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(ii) a notice that a certificate under that subsection is not required in relation to the application; and

(c) the other requirements in subsection (1) are met;

the Secretary must list the goods under subsection (1) without inquiring into the correctness of the certificate or the notice.

(2) In making a decision for the purposes of paragraph (1)(g), the matters that may be taken into account include:

(a) whether the applicant has provided:

(i) if the goods are not therapeutic devices and a step in the manufacture of the goods has been carried out in a country that is a member of the European Community or a member of EFTA—an EC/EFTA attestation of conformity in relation to the goods; or

(ia) if the goods are not therapeutic devices and a step in the manufacture of the goods has been carried out in a country declared by the Minister under section 3B to be covered by a non-EC/EFTA MRA—a non-EC/EFTA attestation of conformity, for the non-EC/EFTA MRA, in relation to the goods; or

(ii) in any other case—an acceptable form of evidence from a relevant overseas authority establishing that the manufacture of the goods is of an acceptable standard; and

(b) whether the applicant has agreed to provide, where the Secretary considers inspection of the manufacturing procedures used in the manufacture of the goods to be necessary:

(i) funds for the carrying out of that inspection by the Department; and

(ii) evidence that the manufacturer has agreed to such an inspection.

(2A) If therapeutic goods are exempt from the operation of Part 3-3 or a person is exempt from the operation of that Part in relation to the manufacture of the goods, subsection (1) has effect, in relation to the goods, as if paragraph (h) were omitted.

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(2B) If a person is exempt from the operation of Part 3-3 in relation to a step in the manufacture of therapeutic goods, subsection (1) has effect, in relation to the goods, as if the reference in paragraph (h) to Part 3-3 were a reference to that Part to the extent that it applies to that person in relation to the manufacture of the goods.

(2C) If:

(a) therapeutic goods were made outside Australia; and

(b) had the goods been made in Australia, they would have been exempt from the operation of Part 3-3;

subsection (1) has effect, in relation to the goods, as if paragraph (g) were omitted.

(2D) A decision for the purposes of paragraph (1)(g) may also take into account any information provided to the Secretary by a health authority of a Convention country and relating to:

(a) the general standards of manufacturing practice of a particular manufacturer; or

(b) the specific standards of manufacture or control adopted by a particular manufacturer in relation to particular goods.

(2E) For the purposes of subsection (2D), a Convention country is a country that is a party to the Mutual Recognition Convention.

(2F) Information referred to in subsection (2D) and provided in accordance with the Mutual Recognition Convention is to be treated as equivalent to information obtained as a result of an inspection under Part 3-3 of this Act.

(3) Where an application is made, the Secretary must notify the applicant in writing of his or her decision on the application within 28 days of the making of the decision and, in the case of a decision not to list the goods, of the reasons for the decision.

(4) As soon as practicable after an applicant has been informed that therapeutic goods in respect of which an application was made are acceptable for listing, the Secretary must give to the applicant a certificate of listing of the goods, and the listing of the goods commences on the day specified for the purpose in the certificate.

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26AA Listing of therapeutic device to which EC/EFTA attestation of conformity applies

(1) If:

(a) an application is made under section 23 for the listing of a therapeutic device in relation to a person; and

(aa) the application complies with section 23C; and

(b) the applicant gives to the Secretary an EC/EFTA attestation of conformity as to the matters specified in paragraphs 26(1)(c) to (m) in relation to the device;

the Secretary must list the device in relation to the person unless the Secretary considers that the device may compromise the health or safety of users.

(2) The Secretary must notify the applicant in writing of his or her decision within 28 days of the making of the decision. If the Secretary decides not to list the device, the notice must contain the reasons for that decision.

(3) If the Secretary decides to list the device, the Secretary must:

(a) include the device in the Register; and

(b) give to the applicant a certificate of listing.

(4) The listing of the device commences on the day specified for the purpose in the certificate of listing.

26A Listing of certain medicines

(1) If:

(a) an application is made for the listing of medicine in relation to a person under section 23; and

(aa) the application complies with section 23C; and

(b) the application is accompanied by either:

(i) the certificate required under subsection 26B(1); or

(ii) a notice (in accordance with a form approved, in writing, by the Secretary) that a certificate under that

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subsection is not required in relation to the application; and

(c) the requirements of subsection (2) and (where applicable) subsections (2A), (3) and (4A) have been complied with; and

(d) the medicine is not export only medicine; and

(e) the medicine is not one that has previously had its registration or listing cancelled;

the Secretary must list the medicine in relation to the person.

(1A) To avoid doubt, if:

(a) an application is made for the listing of a medicine in relation to a person in accordance with section 23; and

(aa) the application complies with section 23C; and

(b) the application is accompanied by either:

(i) the certificate required under subsection 26B(1); or

(ii) a notice that a certificate under that subsection is not required in relation to the application; and

(c) the other requirements in subsection (1) are met;

the Secretary must list the medicine under subsection (1) without inquiring into the correctness of the certificate or the notice.

(2) The applicant must certify that:

(a) the medicine is eligible for listing; and

(b) the medicine is safe for the purposes for which it is to be used; and

(c) the presentation of the medicine is not unacceptable; and

(ca) the medicine does not contain an ingredient that is not specified in a determination under paragraph 26BB(1)(a); and

(cb) if a determination under paragraph 26BB(1)(b) specifies requirements in relation to ingredients being contained in the medicine—none of the requirements have been contravened; and

(d) the medicine conforms to every standard (if any) applicable to the medicine; and

(da) both of the following are complied with in relation to the medicine:

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(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 under the regulations; and

(e) if the medicine has been manufactured in Australia—each step in the manufacture of the medicine has been carried out by a person who is the holder of a licence to carry out that step; and

(f) the medicine complies with all prescribed quality or safety criteria that are applicable to the medicine; and

(fa) the medicine's specifications comply with any requirements that are prescribed by the regulations for the purposes of this paragraph and that are applicable to the medicine; and

(fb) the medicine's label:

(i) complies with any requirements that are prescribed by the regulations for the purposes of this subparagraph and that are applicable to the medicine; and

(ii) does not make a claim that is inconsistent with any claim made by the applicant in relation to the medicine in, or in connection with, the application; and

(fba) if the medicine's label contains one or more indications—each indication:

(i) is covered by a determination under paragraph 26BF(1)(a); and

(ii) is proposed to be accepted in relation to the inclusion of the medicine in the Register; and

(fc) the applicant holds information or evidence showing the medicine's specifications will be maintained under the conditions set out on the medicine's label until the medicine's expiry date; and

(fd) each indication proposed to be accepted in relation to the inclusion of the medicine in the Register is covered by a determination under paragraph 26BF(1)(a); and

(fe) if a determination under paragraph 26BF(1)(b) specifies requirements in relation to an indication proposed to be accepted in relation to the inclusion of the medicine in the

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Register—none of the requirements have been contravened; and

(g) the medicine does not contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; and

(h) all the manufacturers of the medicine are nominated as manufacturers in the application; and

(i) the applicant has, with manufacturers of the medicine who are manufacturers of the prescribed kind, written agreements containing such matters as are prescribed; and

(j) both:

(i) the applicant holds information or evidence to support any claim (other than a claim that is an indication) proposed to be accepted in relation to the inclusion of the medicine in the Register; and

(ii) the information or evidence complies with any requirements specified in a determination under subsection (2B); and

(ja) both:

(i) the applicant holds information or evidence to support each indication proposed to be accepted in relation to the inclusion of the medicine in the Register; and

(ii) the information or evidence complies with any requirements specified in a determination under subsection (2B); and

(k) the information included in or with the application is correct.

(2A) The applicant must also certify any other matters prescribed by the regulations for the purposes of this subsection.

(2B) The Minister may, by legislative instrument, specify requirements for the purposes of subparagraph (2)(j)(ii) or (2)(ja)(ii).

(3) Subject to subsection (7), if a step in the manufacture of the medicine has been carried out outside Australia, the Secretary must have certified, prior to the application being made, that the manufacturing and quality control procedures used in each such step are acceptable.

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(4) In deciding whether so to certify for the purposes of subsection (3), the matters that may be taken into account include:

(a) whether the applicant has provided:

(i) if a step in the manufacture of the medicine has been carried out in a country that is a member of the European Community or a member of EFTA—an EC/EFTA attestation of conformity in relation to the medicine; or

(ia) if a step in the manufacture of the medicine has been carried out in a country declared by the Minister under section 3B to be covered by a non-EC/EFTA MRA—a non-EC/EFTA attestation of conformity, for the non-EC/EFTA MRA, in relation to the medicine; or

(ii) in any other case—an acceptable form of evidence from a relevant overseas authority establishing that the manufacture of the medicine is of an acceptable standard; and

(b) whether the applicant has agreed to provide, if the Secretary considers inspection of the manufacturing procedures used in the manufacture of the medicine to be necessary:

(i) funds for the carrying out of that inspection by the Department; and

(ii) evidence that the manufacturer has agreed to such an inspection; and

(c) whether the applicant has complied with any requirements made by the Secretary under section 31 in relation to the manufacture or preparation of the medicine.

(4A) If the medicine includes any ingredient of animal origin, the Secretary must have certified, prior to the application being made, that he or she is satisfied of the safety of the ingredient.

(5) If a medicine is exempt from the operation of Part 3-3 or a person is exempt from the operation of that Part in relation to the manufacture of the medicine, subsection (2) has effect, in relation to the medicine, as if paragraph (2)(e) were omitted.

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(6) If a person (the ***manufacturer***) is exempt from the operation of Part 3-3 in relation to a step in the manufacture of a medicine, subsection (2) has effect, in relation to the medicine, as if the reference in paragraph (2)(e) to a person who is the holder of a licence were a reference to the manufacturer to the extent that Part 3-3 applies to the manufacturer in relation to the manufacture of the medicine.

(7) If:

(a) a medicine was made outside Australia; and

(b) had the medicine been made in Australia, it would have been exempt from the operation of Part 3-3;

subsection (3) does not apply in relation to the medicine.

(9) As soon as practicable after a medicine has been listed under this section, the Secretary must give to the applicant a certificate of listing of the medicine. The listing of the medicine commences on the day specified for the purpose in the certificate.

26AB Application for listing of certain medicines following efficacy evaluation

(1) If:

(a) an application is made under section 23 for the listing of medicine in relation to a person; and

(b) the application passes preliminary assessment; and

(c) the requirements of subsections (2), (3), (4) and (6) have been complied with; and

(d) the medicine is not a medicine which may be listed under section 26A; and

(e) the medicine is not export only medicine; and

(f) the medicine is not one that has previously had its registration or listing cancelled;

the Secretary must evaluate the medicine for listing under section 26AE.

(2) The applicant must certify that:

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(a) the medicine is eligible for listing; and
(b) the medicine is safe for the purposes for which it is to be used; and
(c) the presentation of the medicine is not unacceptable; and
(d) the medicine does not contain an ingredient that is not specified in a determination under paragraph 26BB(1)(a); and
(e) if a determination under paragraph 26BB(1)(b) specifies requirements in relation to ingredients being contained in the medicine—none of the requirements have been contravened; and
(f) the medicine conforms to every standard (if any) applicable to the medicine; and
(g) both of the following are complied with in relation to the medicine:
  (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 under the regulations; and
(h) if the medicine has been manufactured in Australia—each step in the manufacture of the medicine has been carried out by a person who is the holder of a licence to carry out that step; and
(i) the medicine complies with all prescribed quality or safety criteria that are applicable to the medicine; and
(j) the medicine's specifications comply with any requirements that are prescribed by the regulations for the purposes of this paragraph and that are applicable to the medicine; and
(k) the medicine's label:
  (i) complies with any requirements that are prescribed by the regulations for the purposes of this subparagraph and that are applicable to the medicine; and
  (ii) does not make a claim that is inconsistent with any claim made by the applicant in relation to the medicine in, or in connection with, the application; and
(l) the applicant holds information or evidence showing the medicine's specifications will be maintained under the

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conditions set out on the medicine's label until the medicine's expiry date; and

(m) the applicant has available sufficient information to substantiate each claim and each indication proposed to be accepted in relation to the inclusion of the medicine in the Register; and

(n) the medicine does not contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; and

(o) all the manufacturers of the medicine are nominated as manufacturers in the application; and

(p) the applicant has, with manufacturers of the medicine who are manufacturers of the prescribed kind, written agreements containing such matters as are prescribed; and

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

(3) The applicant must also certify any other matters prescribed by the regulations for the purposes of this subsection.

(4) Subject to subsection (9), if a step in the manufacture of the medicine has been carried out outside Australia, the Secretary must have certified, prior to the application being made, that the manufacturing and quality control procedures used in each such step are acceptable.

(5) In deciding whether to certify for the purposes of subsection (4), the matters that may be taken into account include:

(a) whether the applicant has provided:

(i) if a step in the manufacture of the medicine has been carried out in a country that is a member of the European Community or a member of EFTA—an EC/EFTA attestation of conformity in relation to the medicine; or

(ii) if a step in the manufacture of the medicine has been carried out in a country declared by the Minister under section 3B to be covered by a non-EC/EFTA MRA—a non-EC/EFTA attestation of conformity, for the non-EC/EFTA MRA, in relation to the medicine; or

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(iii) in any other case—an acceptable form of evidence from a relevant overseas authority establishing that the manufacture of the medicine is of an acceptable standard; and

(b) whether the applicant has agreed to provide, if the Secretary considers inspection of the manufacturing procedures used in the manufacture of the medicine to be necessary:

(i) funds for the carrying out of that inspection by the Department; and

(ii) evidence that the manufacturer has agreed to such an inspection; and

(c) whether the applicant has complied with any requirements made by the Secretary under section 31 in relation to the manufacture or preparation of the medicine.

(6) If the medicine includes any ingredient of animal origin, the Secretary must have certified, prior to the application being made, that he or she is satisfied of the safety of the ingredient.

(7) If a medicine is exempt from the operation of Part 3-3 or a person is exempt from the operation of that Part in relation to the manufacture of the medicine, subsection (2) has effect, in relation to the medicine, as if paragraph (2)(h) were omitted.

(8) If a person (the ***manufacturer***) is exempt from the operation of Part 3-3 in relation to a step in the manufacture of a medicine, subsection (2) has effect, in relation to the medicine, as if the reference in paragraph (2)(h) to a person who is the holder of a licence were a reference to the manufacturer to the extent that Part 3-3 applies to the manufacturer in relation to the manufacture of the medicine.

(9) If:

(a) a medicine was made outside Australia; and

(b) had the medicine been made in Australia, it would have been exempt from the operation of Part 3-3;

subsection (4) does not apply in relation to the medicine.

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26AC Evaluation fees for listing of medicine under section 26AE

(1) This section applies if:

(a) an application is made under section 23 in relation to a medicine for listing under section 26AE; and

(b) the application has passed preliminary assessment.

(2) A fee (the ***evaluation fee***) specified in or determined in accordance with the regulations is payable by the applicant in respect of the evaluation of a medicine for listing under section 26AE.

(3) The Secretary must notify each applicant of the amount of the evaluation fee.

(4) The evaluation fee payable by an applicant:

(a) is due and payable on the day on which the applicant is notified of the amount of the evaluation fee; and

(b) may be recovered by the Commonwealth as a debt due to the Commonwealth.

(5) If:

(a) an application is made under section 23 in relation to a medicine for listing under section 26AE; and

(b) the applicant has paid the whole of the evaluation fee; and

(c) regulations made for the purposes of paragraph 63(2)(daaaa) prescribe a period within which evaluations under section 26AE in relation to the medicine must be completed; and

(d) the evaluation is completed, but not within that period;

then 25% of the evaluation fee must be refunded to the applicant.

(6) For the purposes of paragraph (5)(d), the evaluation is taken to be completed when the applicant is notified of the Secretary's decision under subsection 26AE(3) in relation to the medicine.

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26AD Lapsing and deemed refusal of applications for listing of medicine under section 26AE

Lapsing of applications

(1) An application for the listing of a medicine under section 26AE lapses if:

(a) any part of the evaluation fee referred to in section 26AC remains unpaid at the end of 28 days after the day on which the amount became due and payable; or

(b) the application contains information that is inaccurate or misleading in a material particular; or

(c) information given to the Secretary by, or on behalf of, the applicant in connection with the application is inaccurate or misleading in a material particular.

Deemed refusal of applications

(2) If:

(a) regulations made for the purposes of paragraph 63(2)(daaaa) prescribe a period within which evaluations under section 26AE in relation to the medicine must be completed; and

(b) at the end of that period, the evaluation has not been completed;

the applicant may give the Secretary written notice that the applicant wishes to treat the application as having been refused.

(3) A notice under subsection (2) may be given at any time before the evaluation is completed.

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

(a) the Secretary had decided not to list the medicine which is the subject of the application; 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 under subsection (2).

26AE Evaluation and listing of certain medicines

Evaluation

(1) If:

(a) an application is made under section 23 for the listing of a medicine in relation to a person under this section; and

(b) the application has passed preliminary assessment;

the Secretary must evaluate the medicine having regard to:

(c) whether the efficacy of the medicine for the purposes for which it is to be used has been satisfactorily established; and

(d) such other matters (if any) as the Secretary considers relevant.

(2) If a period in relation to which an evaluation under this section must be completed has been prescribed under paragraph 63(2)(daaaa), the evaluation must be completed within that period.

Secretary must decide whether to list medicine

(3) After an evaluation under this section of goods has been completed, the Secretary must decide:

(a) to list the medicine; or

(b) not to list the medicine.

Decision to list

(4) If the Secretary decides under subsection (3) to list the medicine, the Secretary must, in accordance with subsection (5), notify the applicant in writing of the decision within 28 days of making the decision.

(5) The notice must:

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(a) set out the decision under subsection (3) to list the medicine in relation to the person; and

(b) inform the applicant that the medicine will not be included in the Register unless and until the applicant gives the Secretary:

(i) the certificate required under subsection 26B(1); or

(ii) a notice (in accordance with a form approved, in writing, by the Secretary) that a certificate under that subsection is not required in relation to the application.

(6) If the applicant gives the Secretary the certificate referred to in subparagraph (5)(b)(i) or the notice referred to in subparagraph (5)(b)(ii), the Secretary must:

(a) include the medicine in the Register; and

(b) give the applicant a certificate of listing.

(7) To avoid doubt, if the applicant gives the Secretary the certificate referred to in subparagraph (5)(b)(i) or the notice referred to in subparagraph (5)(b)(ii), the Secretary must include the medicine in the Register under paragraph (3)(a) without inquiring into the correctness of the certificate or the notice.

Date listing commences

(8) The listing of the medicine commences on the day specified for the purpose in the certificate.

Refusal to list medicine

(9) If:

(a) an application is made for the listing of medicine in relation to a person; and

(b) the Secretary decides under subsection (3) not to list the medicine;

the Secretary must notify the applicant in writing of the decision, and the reasons for the decision, within 28 days of making the decision.

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26B Certificates required in relation to patents

(1A) A certificate is required under subsection (1) in relation to an application for registration or listing of therapeutic goods only if:

(a) the applicant is required to submit evidence or information to establish the safety or efficacy of the goods as part of the process of applying for registration or listing; and

(b) in order to satisfy that requirement, the applicant relies (in whole or in part) on evidence or information that another person submitted to the Secretary:

(i) to establish the safety or efficacy of other therapeutic goods that have already been registered or listed; and

(ii) as part of the process of applying for the registration or listing of those other goods.

(1) The certificate required under this subsection is either:

(a) a certificate to the effect that the applicant, acting in good faith, believes on reasonable grounds that it is not marketing, and does not propose to market, the therapeutic goods in a manner, or in circumstances, that would infringe a valid claim of a patent that has been granted in relation to the therapeutic goods; or

(b) a certificate to the effect that:

(i) a patent has been granted in relation to the therapeutic goods; and

(ii) the applicant proposes to market the therapeutic goods before the end of the term of the patent; and

(iii) the applicant has given the patentee notice of the application for registration or listing of the therapeutic goods under section 23.

The certificate must be signed by, or on behalf of, the applicant and must be in a form approved by the Secretary.

(2) A person commits an offence if:

(a) the person gives a certificate required under subsection (1); and

(b) the certificate is false or misleading in a material particular.

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Penalty: 1,000 penalty units.

(3) For the purposes of this section, a patent is taken to have been granted in relation to therapeutic goods if marketing the goods without the authority of the patentee would constitute an infringement of the patent.

(4) In this section:

patent has the same meaning as in the *Patents Act 1990*.

26BA Approved form for notices

An approval of a form for a notice for the purposes of subsection 25AB(3), 26(1), 26A(1) or 26AE(5) may require or permit the notice 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.

26BB Permissible ingredients

(1) The Minister may, by legislative instrument, make a determination specifying either or both of the following:

(a) ingredients;

(b) for some or all of those ingredients—requirements in relation to those ingredients being contained in medicine.

Note: A person seeking the listing of a medicine under section 26A or 26AB must certify that:

(a) the medicine does not contain an ingredient that is not specified in the determination; and

(b) none of the requirements specified in the determination in relation to ingredients being contained in the medicine have been contravened.

Requirements

(2) The requirements referred to in paragraph (1)(b) may relate to particular ingredients not being contained in particular medicine.

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(2A) The requirements referred to in paragraph (1)(b) may relate to a particular ingredient being contained in particular medicine only in the circumstances specified in the determination in relation to the ingredient.

(3) The requirements referred to in paragraph (1)(b) may relate to permitted concentrations or permitted total amounts of ingredients.

(4) Subsections (2), (2A) and (3) do not limit paragraph (1)(b).

(5) A determination under paragraph (1)(b) may make different provision for different classes of medicine.

Limitations on determination under subsection (1)

(6) The Minister may, by legislative instrument, make a determination specifying either or both of the following:
  (a) ingredients that must not be specified under paragraph (1)(a);
  (b) requirements that must not be specified under paragraph (1)(b) in relation to ingredients being contained in medicine.

(7) A determination under paragraph (6)(b) may make different provision for different classes of medicine.

Incorporation of instruments

(8) Despite subsection 14(2) of the *Legislation Act 2003*, a determination under 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.

26BC Variation of determination under section 26BB—Minister's initiative

The Minister may, on his or her own initiative and by legislative instrument, vary a determination under section 26BB.

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26BE Variation of section 26BB determination—application by person

Making an application for recommendation

(1) A person may apply to the Secretary for a recommendation that the Minister vary a section 26BB determination.

(2) An application under subsection (1) must:
  (a) be made in accordance with a form approved, in writing, by the Secretary; and
  (b) set out the recommendation sought; and
  (c) be delivered to an office of the Department specified in the form; and
  (d) be accompanied by the prescribed application fee (if any).

Further information about application for recommendation

(2A) The Secretary may, by written notice given to a person who has made an application under subsection (1), require the person to:
  (a) give the Secretary such further information in connection with the application as is specified in the notice; and
  (b) do so within such reasonable period as is specified in the notice.

Lapsing of application for recommendation

(2B) An application made under subsection (1) lapses if:
  (a) the application contains information that is inaccurate or misleading in a material particular; or
  (b) information given to the Secretary by, or on behalf of, the applicant in connection with the application is inaccurate or misleading in a material particular.

Decision by Secretary whether to make recommendation

(3) If:
  (a) an application is made under subsection (1); and

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(b) any applicable prescribed evaluation fee has been paid; and
(c) if further information is required to be given under subsection (2A) within a specified period—the information is given within that period;

the Secretary must carry out an evaluation of whether to make the recommendation.

(4) After carrying out the evaluation, the Secretary must:
(a) make the recommendation; or
(b) refuse to make the recommendation.

(5) In deciding whether to make the recommendation, the Secretary must have regard to:
(a) the quality and safety of the ingredients concerned; and
(b) such other matters (if any) as the Secretary considers relevant.

(5A) If the Secretary refuses to make the recommendation, the Secretary must:
(a) notify the applicant in writing of his or her decision; and
(b) state in the notice the reasons for the decision.

Partial refund of application fee in certain circumstances

(5B) If:
(a) an application fee is prescribed for the purposes of paragraph (2)(d); and
(b) regulations made for the purposes of paragraph 63(2)(daaa) prescribe a period within which recommendations under this section must be made; and
(c) the Secretary makes a recommendation in relation to an application under subsection (1), but not within that period;

then 25% of the application fee must be refunded to the applicant.

Deemed refusal of applications in certain circumstances

(5C) If:

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(a) regulations made for the purposes of paragraph 63(2)(daaa) prescribe a period within which recommendations under this section must be made; and

(b) at the end of that period, the Secretary has not made a recommendation in relation to an application under subsection (1);

the applicant may give the Secretary written notice that the applicant wishes to treat the application as having been refused.

(5D) A notice under subsection (5C) may be given at any time before the recommendation in relation to the application is made.

(5E) If a notice has been given under subsection (5C), this Act (except subsection 60(5)) has effect as if:

(a) the Secretary had decided not to make a recommendation under this section; and

(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 under subsection (5C).

Minister may vary determination

(6) If the Secretary makes a recommendation under paragraph (4)(a), the Minister must:

(a) by legislative instrument, vary the section 26BB determination; or

(b) refuse to vary the section 26BB determination.

(7) In making a decision under subsection (6), the Minister must have regard to:

(a) the recommendation made under paragraph (4)(a); and

(b) such other matters (if any) as the Minister considers relevant.

Applications or information may be given electronically

(9) An approval of a form mentioned in paragraph (2)(a), or a notice mentioned in subsection (2A), may require or permit an application

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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.

26BF Permissible indications

(1) The Minister may, by legislative instrument, make a determination in relation to either or both of the following:

(a) indications;

(b) requirements in relation to indications.

Note: See paragraphs 26A(2)(fba), (fd) and (fe) (which deal with matters that a person seeking the listing of a medicine under section 26A must certify).

(2) In deciding whether to make a determination under subsection (1) in relation to a particular indication, the Minister may have regard to whether the indication is a therapeutic use that relates to one or more of the following:

(a) maintaining health;

(b) enhancing health;

(c) preventing a dietary deficiency;

(d) a disease, ailment, defect or injury, other than a serious form of the disease, ailment, defect or injury.

(3) Subsection (2) does not limit the matters to which the Minister may have regard in deciding whether to make a determination under subsection (1) in relation to a particular indication.

(4) Without limiting paragraph (1)(b), the requirements may relate to:

(a) the use of particular indications in specified circumstances; or

(b) the use of particular indications if certain specified conditions are met.

(5) A determination under paragraph (1)(b) may make different provision for different classes of medicines.

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26BG Limitations on determination under section 26BF

(1) The Minister may, by legislative instrument, make a determination specifying indications that must not be covered by a determination under paragraph 26BF(1)(a).

(2) The determination may specify an indication either generally or in relation to specified circumstances.

(3) The Minister may, by legislative instrument, vary or revoke a determination under subsection (1).

26BH Variation of determination under section 26BF—Minister's initiative

The Minister may, on his or her own initiative and by legislative instrument, vary a determination under section 26BF.

26BJ Variation of determination under section 26BF—application by person

Application for recommendation to vary section 26BF determination

(1) A person may apply to the Secretary for a recommendation that the Minister vary a determination under section 26BF.

(2) An application under subsection (1) must:
  (a) be made in accordance with a form approved, in writing, by the Secretary; and
  (b) set out the recommendation sought; and
  (c) be delivered to an office of the Department specified in the form; and
  (d) be accompanied by the prescribed application fee (if any).

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Limits on kinds of applications that can be made

(3) A person cannot make an application under subsection (1) for a recommendation the effect of which would be for the determination to cover any of the following:
  (a) an indication specified in a determination under section 26BG;
  (b) an indication that is or contains a restricted representation (within the meaning of Part 5-1);
  (c) unless subsection (4) applies—an indication that is or contains a prohibited representation (within the meaning of Part 5-1);
  (d) unless subsection (5) applies—an indication that refers to preventing, curing or alleviating a disease, ailment, defect or injury.

(4) For the purposes of paragraph (3)(c), this subsection applies if:
  (a) the indication is a therapeutic use that relates to sun protection; and
  (b) the prohibited representation relates to the prevention of skin cancer; and
  (c) the use of the prohibited representation is permitted under section 42DK.

(5) For the purposes of paragraph (3)(d), this subsection applies if the indication refers to:
  (a) the prevention of a dietary deficiency; or
  (b) the prevention of skin cancer or sun damage.

Further information about application for recommendation

(6) The Secretary may, by written notice given to a person who has made an application under subsection (1), require the person to:
  (a) give the Secretary such further information in connection with the application as is specified in the notice; and
  (b) do so within such reasonable time as is specified in the notice.

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Lapsing of application for recommendation

(7) An application made under subsection (1) lapses if:
  (a) the application contains information that is inaccurate or misleading in a material particular; or
  (b) information given to the Secretary by, or on behalf of, the applicant in connection with the application is inaccurate or misleading in a material particular.

Decision on application for recommendation

(8) If:
  (a) an application is made under subsection (1); and
  (b) any applicable prescribed application fee has been paid; and
  (c) if further information is required to be given under subsection (6) within a specified time—the information is given within that time;

the Secretary must decide whether to make the recommendation or refuse to make the recommendation.

(9) In deciding whether to make the recommendation, the Secretary may have regard to whether the indication to which the application relates is a therapeutic use that relates to one or more of the following:
  (a) maintaining health;
  (b) enhancing health;
  (c) preventing a dietary deficiency;
  (d) a disease, ailment, defect or injury, other than a serious form of the disease, ailment, defect or injury;
  (e) sun protection.

(10) If the Secretary refuses to make the recommendation, the Secretary must:
  (a) notify the applicant in writing of his or her decision; and
  (b) state in the notice the reasons for the decision.

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Minister may vary section 26BF determination

(11) If the Secretary makes a recommendation under subsection (8), the Minister must:
  (a) by legislative instrument, vary the determination under subsection 26BF(1); or
  (b) refuse to vary the determination.

(12) In deciding whether to vary a determination under subsection 26BF(1) to include an indication not already covered by the determination, the Minister may have regard to:
  (a) the recommendation made under subsection (8) of this section; and
  (b) whether the indication is a therapeutic use that relates to one or more of the matters in paragraphs (9)(a) to (e) of this section.

(13) Subsection (12) does not limit the matters to which the Minister may have regard in deciding whether to vary the determination.

Applications or information may be given electronically

(14) An approval of a form mentioned in paragraph (2)(a), or a notice mentioned in subsection (6), 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.

26C Certificates required in relation to patent infringement proceedings

(1) This section applies if:
  (a) a person gives a certificate required under subsection 26B(1) in relation to therapeutic goods; and
  (b) another person (the ***second person***) intends to commence proceedings under the *Patents Act 1990* against the person referred to in paragraph (1)(a) for infringement of a patent

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that has been granted in relation to the therapeutic goods (the ***proceedings***).

(2) The second person, before the date upon which the proceedings are commenced, must give to the Secretary and to the person referred to in paragraph (1)(a) the certificate required by subsection (3).

(3) The certificate required by this subsection is a certificate to the effect that the proceedings:

(a) are to be commenced in good faith; and

(b) have reasonable prospects of success; and

(c) will be conducted without unreasonable delay.

The certificate must be signed by, or on behalf of, the second person and must be in a form approved by the Secretary.

(4) For the purpose of paragraph (3)(b), proceedings have reasonable prospects of success if:

(a) the second person had reasonable grounds in all the circumstances known to the second person, or which ought reasonably to have been known to the second person (in addition to the fact of grant of the patent), for believing that he or she would be entitled to be granted final relief by the court against the person referred to in paragraph (1)(a) for infringement by that person of the patent; and

(b) the second person had reasonable grounds in all the circumstances known to the second person, or which ought reasonably to have been known to the second person (in addition to the fact of grant of the patent), for believing that each of the claims, in respect of which infringement is alleged, is valid; and

(c) the proceedings are not otherwise vexatious or unreasonably pursued.

(5) The person referred to in paragraph (1)(a), with leave of the court, or the Attorney-General, may apply to a prescribed court for an order that the second person pay to the Commonwealth a pecuniary penalty if the second person gives a certificate required under subsection (3) and:

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(a) the certificate is false or misleading in a material particular; or

(b) the second person breaches an undertaking given in the certificate.

(5A) A pecuniary penalty ordered under subsection (5) must not exceed $10,000,000.

(6) When determining the extent of a pecuniary penalty to be ordered pursuant to subsection (5), the court must take into account:

(a) any profit obtained by the second person; and

(b) any loss or damage suffered by any person;

by reason of the second person exploiting the patent during the proceedings.

(7) For the avoidance of doubt, subsection (6) does not limit the matters the court may take into account when determining a pecuniary penalty ordered pursuant to subsection (5).

(8) If:

(a) the second person has sought and obtained in the proceedings an interlocutory injunction restraining the person referred to in paragraph (1)(a) from infringing a patent; and

(b) section 26D does not apply; and

(c) a prescribed court declares that the second person has given a certificate required under subsection (3); and

(d) a prescribed court declares that:

(i) the certificate is false or misleading in a material particular; or

(ii) the second person has breached an undertaking given in the certificate;

the prescribed court may, pursuant to this section, order that the second person pay to the Commonwealth, a State or a Territory compensation for any damages sustained or costs incurred by the Commonwealth, a State or a Territory as a result of the grant of the interlocutory injunction.

(9) In this section:

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prescribed court has the same meaning as in the *Patents Act 1990*.

26D Requirements for interlocutory injunction

(1) This section applies where:

(a) an applicant gives notice to a patentee in accordance with subparagraph 26B(1)(b)(iii); and

(b) the patentee and/or its exclusive licensee (in this section the party or parties is or are referred to as the ***patentee***) applies to a prescribed court for an interlocutory injunction to restrain the applicant from marketing the therapeutic goods the subject of the application on the ground that such conduct will constitute an infringement of its patent.

(2) An application for interlocutory relief in accordance with subsection (1) may not be instituted unless the patentee has first notified the Attorney-General of the Commonwealth, or of a State or of a Territory, in writing of the application.

(3) The Attorney-General of the Commonwealth shall be deemed to be a party to any proceedings commenced in accordance with subsection (1) unless the Attorney-General gives written notice to the prescribed court that he or she does not desire to be a party.

(4) If an interlocutory injunction is granted pursuant to an application made as described in subsection (1) and:

(a) the patentee subsequently discontinues the principal proceedings without the consent of the other parties thereto; or

(b) the principal proceedings are dismissed; and

(c) in either case, the prescribed court declares that:

(i) the patentee did not have reasonable grounds, in all the circumstances known to the patentee or which ought reasonably have been known to the patentee:

(A) to believe that it would be granted final relief by the prescribed court against the applicant referred to in paragraph (1)(a) for infringement by that person of the patent; or

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(B) (in addition to the fact of grant of the patent), for believing that each of the claims, in respect of which infringement is alleged in the proceedings, would have a reasonable prospect of being held to be valid if challenged by the applicant referred to in paragraph (1)(a); or

(ii) the application for the interlocutory injunction was otherwise vexatious or not reasonably made or pursued;

the prescribed court may, in addition to any other relief which it believes should be granted to any person, make any of the orders described in subsection (5).

(5) If the prescribed court makes a declaration pursuant to paragraph (4)(c), the prescribed court may, pursuant to the usual undertaking as to damages given by the patentee to the prescribed court to obtain the interlocutory injunction:

(a) assess and award compensation to the applicant referred to in paragraph (1)(a) against whom the interlocutory injunction was made:

(i) on the basis of an account of the gross profits of the patentee arising from the sale by it in Australia of the therapeutic goods the subject of the interlocutory injunction, during the period of the interlocutory injunction, without requiring the said applicant to establish or quantify its actual loss; or

(ii) on such other basis as the court determines to be appropriate; and

(b) award to the Commonwealth compensation for any damages sustained, or costs incurred, by it as a result of the grant of the interlocutory injunction; and

(c) award to a State or a Territory compensation for any damages sustained, or costs incurred, by it as a result of the grant of the interlocutory injunction.

(6) In this section:

prescribed court has the same meaning as in the *Patents Act 1990*.

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27 Registration or listing number

(1) Where the Secretary includes therapeutic goods (other than grouped therapeutic goods) in the Register, the Secretary is to assign a unique registration or listing number to the goods.

(2) Where the Secretary includes grouped therapeutic goods in the Register, the Secretary is to assign a single, unique registration or listing number to the grouped therapeutic goods.

28 Conditions of registration or listing

(1) The registration or listing of therapeutic goods is subject to the conditions set out in a determination under subsection (2).

(2) The Minister may, by legislative instrument, make a determination setting out conditions for the purposes of subsection (1), being conditions that relate to:

(a) the manufacture of the goods; or

(b) the custody, use, supply, disposal or destruction of the goods; or

(c) the keeping of records relating to the goods; or

(d) matters dealt with in, or matters additional to matters dealt with in, standards applicable to the goods; or

(e) such other matters relating to the goods as the Minister thinks appropriate.

(2A) Without limiting subsection (2), different conditions may be specified for:

(a) the registration of therapeutic goods; and

(aa) the provisional registration of medicine; and

(b) the listing of therapeutic goods; and

(c) different classes of therapeutic goods.

(2B) If the Secretary includes therapeutic goods in the Register in relation to a person, the Secretary may, by notice in writing given to the person, impose conditions on the registration or listing of those goods.

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(3) The Secretary may, by notice in writing given to the person in relation to whom therapeutic goods are registered or listed, impose new conditions on the registration or listing or vary or remove conditions imposed under subsection (2B) or this subsection.

(3A) The Secretary's power under subsection (3) may be exercised at the request of the person concerned or of the Secretary's own motion. A request must be accompanied by the prescribed fee.

(4) The imposition or variation or removal of a condition under subsection (3) 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 28 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 28 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 28 days after the notice is given to the person.

(4A) For the purposes of paragraphs (4)(aa) and (ab), the earlier day must not be earlier than the day the notice is given to the person.

(5) In addition to any conditions imposed under subsection (1), (2B) or (3), the registration or listing of therapeutic goods (the ***subject goods***) is subject to the conditions that the person in relation to whom the subject goods are registered or listed will:

(aa) not supply a batch of the subject goods in Australia, or export a batch of the subject goods from Australia, after the expiry date for the goods; and

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(ab) not, by any means, advertise the subject goods for an indication other than those accepted in relation to the inclusion of the goods in the Register; and

(a) allow an authorised person:

(i) to enter, at any reasonable time, premises at which the person deals with the subject goods, complies with record-keeping requirements covered by paragraph (c) or (ca), or keeps documents that relate to the subject goods; and

(ii) while on those premises, to inspect those premises and any therapeutic goods on those premises and to examine, take measurements of, conduct tests on or take samples of any therapeutic goods on those premises or any thing on those premises that relates to any therapeutic goods; 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

(iv) while on those premises, to inspect, and make copies of, any records kept in compliance with paragraph (c) or (ca); and

(v) while on those premises, to inspect, and make copies of, any documents that relate to the subject goods; and

(b) if requested to do so by an authorised person, produce to the person such documents relating to the subject goods as the person requires and allow the person to copy the documents; and

(c) in relation to each batch of the subject goods—keep a record, at least until the end of the period of 12 months after the expiry date for the goods, of all of the manufacturers involved in the manufacture of that batch; and

(ca) comply, in relation to the subject goods, with any record-keeping requirements that are prescribed; and

(d) if requested to do so by an authorised person, make any record kept in compliance with paragraph (c) or (ca) available to the authorised person for inspection:

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(i) at or before the time the authorised person requests, or (if the authorised person requests) immediately; and

(ii) either in electronic form or in paper form, as the authorised person requests; and

(e) comply, in relation to the subject goods, with any reporting requirements that are prescribed; and

(f) if a manufacturer who was not nominated as a manufacturer of the subject goods in the application for the registration or listing of the goods becomes a manufacturer of the goods—inform the Secretary in writing of that fact, no later than 10 working days after the manufacturer becomes a manufacturer of the goods; and

(g) if premises that were not nominated as premises to be used in the manufacture of the subject goods in the application become premises used in the manufacture of the goods—inform the Secretary in writing of that fact, no later than 10 working days after the premises are first used for that purpose; and

(h) deliver a reasonable number of samples of the subject goods if the Secretary so requests:

(i) within the period specified in the request (which must include at least 10 working days); and

(ii) in accordance with any other requirements specified in the request; and

(i) comply, in relation to the subject goods, with a notice given to the person under subsection 25AA(1B).

(5B) The listing of a medicine under section 26A or 26AE is subject to a condition that:

(a) each step in the manufacture of the medicine that is carried out in Australia is carried out by a person who is the holder of a licence to carry out that step or who is exempt from the operation of Part 3-3 in relation to that step; and

(b) each step in the manufacture of the medicine that is carried out outside Australia is the subject of a certification in force under subsection 26A(3), 26AB(4) or 28A(2).

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(5C) Subsection (5B) does not apply if the medicine is exempt from the operation of Part 3-3.

(6) If in, or in connection with, an application for the listing of therapeutic goods, a claim (other than a claim that is an indication) is made by the applicant in relation to the goods, the listing of the goods is subject to the following conditions:

(a) a condition that the sponsor of the goods had, at the time when the claim was made, information or evidence that supported the claim and complied with the requirements (if any) specified in a determination made under subsection 26A(2B);

(b) a condition that the sponsor retains the information or evidence at all times while the goods remain listed;

(c) a condition that, at any time while the goods remain listed, the sponsor will, if asked to do so by the Secretary, give the information or evidence to the Secretary.

(7) If:

(a) a medicine is listed under section 26A; and

(b) an indication is accepted in relation to the inclusion of the medicine in the Register;

the listing of the medicine is subject to the following conditions:

(c) a condition that the person in relation to whom the medicine is listed has, at all times while the medicine remains listed, information or evidence that supports the indication and complies with the requirements (if any) specified in a determination under subsection 26A(2B);

(d) a condition that, at any time while the medicine remains listed, the person will, if asked to do so by the Secretary, give the information or evidence to the Secretary.

(8) If:

(a) a medicine is listed under section 26AE; and

(b) an indication is accepted in relation to the inclusion of the medicine in the Register;

the listing of the medicine is subject to the following conditions:

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(c) a condition that the person in relation to whom the medicine is listed has, at all times while the medicine remains listed, information or evidence that supports the indication;

(d) a condition that, at any time while the medicine remains listed, the person will, if asked to do so by the Secretary, give the information or evidence to the Secretary.

28A Certification of manufacturing steps outside Australia following application for listing

(1) The person in relation to whom medicine is listed under section 26A or 26AE may apply to the Secretary for a certification under this section of a step in the manufacture of the medicine that is to be carried out outside Australia.

Note: The listing of medicine is subject to the condition that each step in the manufacture of the medicine that is carried out outside Australia is the subject of a certification in force under subsection 26A(3) or subsection (2) of this section: see subsection 28(5B).

(2) If an application is made to the Secretary under this section, the Secretary may, by writing, certify that the manufacturing and quality control procedures used in that step are acceptable. The Secretary must give the person written notice of the certification.

(3) In deciding whether to give the certification:

(a) subsection 26A(4) applies in a way corresponding to the way in which it applies for the purposes of subsection 26A(3); and

(b) subsection 26AB(5) applies in a way corresponding to the way in which it applies for the purposes of subsection 26AB(4).

29 Duration of registration or listing

(1) Subject to this section, if goods are included in the Register in relation to a person, the goods remain so included until their registration or listing is cancelled under this Part.

Note: The goods are taken not to be included in the Register while their registration or listing is suspended: see section 29G.

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Provisionally registered medicine

(2) If:

(a) a person makes an application for provisional registration of a medicine; and

(b) in relation to that application, the Secretary decides under subsection 25(3) to register the medicine; and

(c) the medicine is included in the Register in relation to the person;

then:

(d) the medicine is provisionally registered; and

(e) the medicine remains included in the Register for the provisional registration period, unless the medicine's registration is cancelled under this Part earlier.

Note: The medicine is taken not to be included in the Register while its registration is suspended: see section 29G.

(3) Subject to this section, the ***provisional registration period*** is the 2 years starting on the day the registration commences.

Note: Subsection 25AB(6) provides that registration commences on the day specified in the certificate of registration.

Extension of provisional registration upon application

(4) The person in relation to whom the medicine is provisionally registered may make an application to the Secretary to extend the provisional registration period.

(5) The application must:

(a) be in a form approved, in writing, by the Secretary; and

(b) contain the information that the form requires, and any further information, statement or document the Secretary requires, whether in the form or otherwise; and

(c) be made at least 6 months before the provisional registration of the medicine is due to end; and

(d) be accompanied by the prescribed application fee.

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(6) On receiving the application, the Secretary must decide to grant, or to refuse to grant, an extension of the provisional registration period. In making that decision, the Secretary must have regard to:

(a) whether the Secretary is satisfied with the applicant's plan to submit comprehensive clinical data on the safety and efficacy of the medicine before the end of the 6 years starting on the day the provisional registration commenced; and

(b) such other matters (if any) as the Secretary considers relevant.

(7) As soon as practicable after making the decision, the Secretary must:

(a) give the applicant written notice of the decision; and

(b) if the Secretary decides to extend the provisional registration period—specify in the notice the period of the extension (which must not exceed 2 years and may be less than the period sought by the applicant); and

(c) if the Secretary refuses to extend the provisional registration period—set out the reasons for the refusal in the notice.

Note: At the time of granting an extension, the Secretary may impose new conditions on the provisional registration or vary the existing conditions: see subsection 28(3).

(8) No more than 2 extensions may be granted on applications under subsection (4).

Note: Under subsection (9) the Secretary may extend the provisional registration period on his or her own initiative.

Effect on provisional registration of later section 23 application

(9) If:

(a) before the provisional registration period ends, the person in relation to whom the medicine is provisionally registered makes an application under section 23 for registration of the medicine; and

(b) the application is for the medicine to be included in the part of the Register for goods known as registered goods;

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then the Secretary may, in connection with the application, end or extend the provisional registration period as the Secretary considers appropriate.

Note: At the time of granting an extension, the Secretary may impose new conditions on the provisional registration or vary the existing conditions: see subsection 28(3).

(10) In ending or extending, under subsection (9), the provisional registration period:

(a) the Secretary must have regard to any matters prescribed by the regulations for the purposes of this paragraph; and

(b) the Secretary must ensure the provisional registration period continues while the Secretary is considering the application, unless the medicine's registration is cancelled under this Part; and

(c) the Secretary must not extend the provisional registration period so it would end more than 6 years after the provisional registration commenced, unless the extension is for the purposes of paragraph (b).

29A Criminal offence for failing to notify adverse effects etc. of goods

(1) As soon as a person in relation to whom therapeutic goods are registered or listed becomes aware of information of a kind mentioned in subsection (2) relating to the goods, the person must give the information to the Secretary in writing.

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) The information with which subsection (1) is concerned is information of the following kinds:

(a) information that contradicts information already furnished by the person under this Act;

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(b) information that indicates that the use of the goods in accordance with the recommendations for their use may have an unintended harmful effect;
(c) information that indicates that the goods, when used in accordance with the recommendations for their use, may not be as effective as the application for registration or listing of the goods or information already furnished by the person under this Act suggests;
(d) information that indicates that the quality, safety or efficacy of the goods is unacceptable.

29AA Civil penalty for failing to notify adverse effects etc. of goods

(1) A person contravenes this section if:
(a) therapeutic goods are registered or listed in relation to a person; and
(b) the person becomes aware of information of a kind mentioned in subsection (2) relating to the goods; and
(c) the person does not give the information to the Secretary in writing as soon as he or she becomes aware of it.

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 that contradicts information already given by the person under this Act;
(b) information that indicates that the use of the goods in accordance with the recommendations for their use may have an unintended harmful effect;
(c) information that indicates that the goods, when used in accordance with the recommendations for their use, may not be as effective as the application for registration or listing of the goods or information already given by the person under this Act suggests;

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(d) information that indicates that the quality, safety or efficacy of the goods is unacceptable.

29B Notification of adverse effects etc. where application withdrawn or lapses

(1) If an application for registration or listing of goods 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 29A(2) or 29AA(2) relating to the goods; 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 be given within 14 days after an application is withdrawn or lapses.

(3) A person must comply with the requirements of a notice under subsection (1) within 30 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 must not, in purported compliance with a notice under subsection (1), give information that 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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29C 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 29B(1) within 30 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 the person, in purported compliance with a notice under subsection 29B(1), gives information that 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.

29D Suspension of registration or listing

(1) The Secretary may, by written notice given to a person in relation to whom therapeutic goods are included in the Register, suspend the registration or listing of the goods if:

(a) the Secretary is satisfied that:

(i) there is a potential risk of death, serious illness or serious injury if the therapeutic goods continue 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 therapeutic goods would not cause a potential risk of death, serious illness or serious injury if

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the therapeutic goods 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 registration or listing of the goods under paragraph 30(1)(da), (e), (ea), (f), (fa), (fb) or (g) or subsection 30(1A), (1C), (1D) or (2).

Notice of proposed suspension in some cases

(2) However, before suspending the registration or listing of the goods because of paragraph (1)(b), 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.

(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).

Period of suspension

(4) A notice under subsection (1) must specify the period of the suspension. The period must not exceed 6 months.

Note: Section 29E deals with when the suspension takes effect and extensions of the suspension.

Publication

(5) As soon as practicable after giving a notice under subsection (1), the Secretary must cause to be published in the *Gazette* or on the Department's website a notice setting out particulars of the suspension.

29E When suspension takes effect etc.

(1) A suspension under section 29D takes effect:

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(a) if the notice under subsection 29D(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

(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 29F; or

(b) the end of:

(i) the period specified in the notice under subsection 29D(4); or

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

Extension of suspension

(3) The Secretary may, by written notice given to the person, extend the period specified in the notice under subsection 29D(4) by a further specified period not exceeding 6 months.

Publication

(4) As soon as practicable after giving a notice under subsection (3), the Secretary must cause to be published in the *Gazette* or on the Department's website a notice setting out particulars of the extension.

29F Revocation of suspension

(1) The Secretary must revoke a suspension under section 29D, by written notice given to the person in relation to whom the therapeutic goods are included in the Register, if the Secretary is satisfied that:

(a) the ground on which the registration or listing of the therapeutic goods was suspended no longer applies; and

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(b) there are no other grounds for suspending the registration or listing of the therapeutic goods.

(2) The Secretary's power to revoke the suspension may be exercised:
(a) if the person in relation to whom the therapeutic goods are included in the Register applies in writing to the Secretary; or
(b) on the Secretary's own initiative.

Publication

(3) As soon as practicable after giving a notice under subsection (1), the Secretary must cause to be published in the *Gazette* or on the Department's website a notice setting out particulars of the revocation.

Notice of refusal to revoke suspension

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

29G Effect of suspension

(1) If the registration or listing of therapeutic goods is suspended under section 29D, the goods are taken, for the purposes of this Act (other than sections 28, 29A, 29AA, 29E, 29F, 30 and 31), not to be included in the Register while the suspension has effect.

Note: Dealing in therapeutic goods that are not included in the Register may be an offence or may contravene a civil penalty provision: see Division 1.

(2) While the suspension has effect, the Secretary's power under section 30 to cancel the registration or listing of the therapeutic goods is not affected.

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30 Cancellation of registration or listing

(1) The Secretary may, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if:

(a) it appears to the Secretary that failure to cancel the registration or listing would create an imminent risk of death, serious illness or serious injury; or

(b) the goods become exempt goods; or

(c) the person requests in writing the cancellation of the registration or listing; or

(d) the goods contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; or

(da) the person has refused or failed to comply with the condition to which the inclusion of the goods is subject under paragraph 28(5)(d):

(i) if the person was requested under that paragraph to make the record in question available at or before a requested time—before the end of the period of 24 hours after that time; or

(ii) if the person was requested under that paragraph to make the record in question available immediately—within 24 hours after the request was made; or

(e) in the case of a medicine listed under section 26A, it appears to the Secretary that any of the certifications under paragraph 26A(2)(a), (ca), (cb), (e), (fba), (fd), (fe) or (g) are incorrect or (if applicable) the requirements under subsection 26A(3) or (4A) are not fulfilled; or

(ea) in the case of a medicine listed under section 26AE, it appears to the Secretary that any of the certifications under paragraph 26AB(2)(a), (d), (e), (h) or (n) are incorrect or (if applicable) the requirements under subsection 26AB(4) or (6) are not fulfilled; or

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

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(fa) 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) in relation to the advertising of the goods and the Secretary is satisfied that the contravention is significant; or

(fb) there is a breach, involving the goods, of an applicable provision of the Therapeutic Goods Advertising Code or any other requirement relating to advertising applicable under Part 5-1 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 the goods is misleading to a significant extent; or

(g) the Secretary is satisfied that a statement made in, or in connection with, the application for registration or listing of the goods was false or misleading in a material particular; or

(h) the annual registration or listing charge is not paid within 28 days after it becomes payable.

(1AA) Paragraph (1)(fb) does not apply to medicines that are manufactured in Australia for export only, or are imported into Australia for export only.

(1A) The Secretary may, by notice in writing given to a person in relation to whom a medicine is listed under section 26A or 26AE, cancel the listing of the medicine if:

(a) the medicine is not eligible for listing; or

(b) the medicine is exempt.

(1C) The Secretary may, by notice in writing given to a person in relation to whom a medicine is listed under section 26A, cancel the listing of the medicine if:

(a) the Secretary, under section 31, gives to the person a notice requiring the person to give to the Secretary information or documents relating to the medicine; and

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(b) the notice is given for the purposes of ascertaining whether any of the certifications by the person under subsection 26A(2) or (2A) in relation to the medicine are incorrect; and

(c) the person fails to comply with the notice within 20 working days after the notice is given.

(1D) The Secretary may, by notice in writing given to a person in relation to whom a medicine is listed under section 26AE, cancel the listing of the medicine if:

(a) the Secretary, under section 31, gives to the person a notice requiring the person to give to the Secretary information or documents relating to the medicine; and

(b) the notice is given for the purposes of ascertaining whether any of the certifications by the person under subsection 26AB(2) or (3) in relation to the medicine are incorrect; and

(c) the person fails to comply with the notice within 20 working days after the notice is given.

(2) Subject to subsection (3), the Secretary may, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if:

(a) it appears to the Secretary that the quality, safety or efficacy of the goods is unacceptable; or

(aa) it appears to the Secretary that the presentation of the goods:

(i) in the case of registered goods—is not acceptable; or

(ii) in the case of listed goods—is unacceptable; or

(b) the goods have changed so that they have become separate and distinct from the goods as so included; or

(ba) in the case of a medicine listed under section 26A, it appears to the Secretary that any of the certifications under paragraph 26A(2)(b), (c), (d), (da), (f), (fa), (fb), (fc), (h), (i), (j), (ja) or (k) or subsection 26A(2A) are incorrect; or

(bab) in the case of a medicine listed under section 26AE, it appears to the Secretary that any of the certifications under

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paragraph 26AB(2)(b), (c), (f), (g), (i), (j), (k), (l), (m), (o), (p) or (q) or subsection 26AB(3) are incorrect; or

(c) the sponsor has refused or failed to comply with a condition to which the inclusion of the goods is subject (other than the condition under paragraph 28(5)(d)); or

(caa) all of the following subparagraphs apply:

(i) the Secretary gives the person a notice under section 31 that requires the person to give to the Secretary information, or to produce to the Secretary documents, relating to the goods;

(ii) subsection (1C) of this section does not apply to the notice;

(iii) the person fails to comply with that notice within a further 14 days after the end of the period specified in that notice; or

(ca) the person has contravened subsection 29A(1) or 29AA(1) in relation to the goods; or

(d) the goods become required to be included in the other part of the Register; or

(e) the goods do not conform to a standard applicable to the goods; or

(eaa) the person contravenes a direction, or a condition of a direction, given to the person under subsection 42DV(1) in relation to the advertising of the goods; or

(eab) 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) in relation to the advertising of the goods; or

(ea) either of the following has not been complied with in relation to the goods:

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

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

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(3) Where the Secretary proposes to cancel the registration or listing of goods in relation to a person under subsection (2), the Secretary must:

(a) inform the person in writing that the Secretary proposes to cancel that registration or listing and set out the reasons for that proposed action; and

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

(4) Where a person makes submissions in accordance with paragraph (3)(b), the Secretary is not to make a decision relating to the cancellation until the Secretary has taken the submissions into account.

(4A) The Secretary must, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration of the goods if the Secretary becomes aware that protected information was used when evaluating the goods for registration.

(5) Where the Secretary cancels the registration or listing of goods in relation to a person, the goods cease to be registered or listed:

(a) if the cancellation is effected under subsection (1), (1A), (1C) or (1D)—on the day on which the notice of cancellation is given to the person; or

(b) in any other case—on the day specified in the notice, which must be at least 20 working days after the notice is given to the person.

30A Revocation of cancellation of registration or listing upon request

(1) If:

(a) the Secretary cancels the registration or listing of therapeutic goods because of the request of a person made under paragraph 30(1)(c); and

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(b) before the end of the period of 90 days beginning on the day the goods ceased to be registered or listed, the person requests, in writing, the Secretary to revoke the cancellation; and

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

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.

30AA Revocation of cancellation of registration or listing—payment of annual registration or listing charge

(1) If:

(a) the Secretary cancels the registration or listing of therapeutic goods because the annual registration or listing charge was not paid within 28 days after it became payable (see paragraph 30(1)(h)); and

(b) before the end of the period of 90 days beginning on the day the goods ceased to be registered or listed, the person requests, in writing, the Secretary to revoke the cancellation; and

(c) the annual registration or listing charge has been paid; and

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

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.

30B Publication of cancellation of registration or listing

If the Secretary cancels the registration or listing of therapeutic goods under section 30, the Secretary must, as soon as practicable after the cancellation, cause to be published in the *Gazette*, or on the Department's website, a notice setting out particulars of the cancellation.

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30C Consultation with Gene Technology Regulator

(1) This section applies to an application for listing or registration of a therapeutic good under section 23 if:

(a) the therapeutic good is, or contains, a GM product or a genetically modified organism; and

(b) if the application is for registration—the application has passed preliminary assessment; and

(c) if the application is for the listing of a medicine under section 26AE—the application has passed preliminary assessment.

(2) Subject to subsection (5), the Secretary must give written notice to the Gene Technology Regulator:

(a) stating that the application has been made; and

(b) requesting the Gene Technology Regulator to give advice about the application.

(3) If the Secretary gives the Gene Technology Regulator a notice under subsection (2), the Gene Technology Regulator may give written advice to the Secretary about the application.

(4) The advice is to be given within the period specified in the notice.

(5) If an advice from the Gene Technology Regulator is in force under section 30D in relation to a class of therapeutic goods, the Secretary is not required to notify the Regulator under this section in relation to an application for listing or registration of a therapeutic good belonging to that class.

30D Secretary may seek advice about classes of GM products or genetically modified organisms

(1) The Secretary may request advice from the Gene Technology Regulator in relation to:

(a) therapeutic goods that consist of, or that contain, a GM product belonging to a class of GM products specified in the request; or

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(b) therapeutic goods that consist of, or that contain, a genetically modified organism belonging to a class of genetically modified organisms specified in the request.

(2) A request for advice under subsection (1) must specify the matters to which the advice is to relate.

(3) If the Secretary requests advice from the Gene Technology Regulator under subsection (1), the Gene Technology Regulator may provide written advice in relation to the matters specified in the request.

(4) If the Gene Technology Regulator gives advice to the Secretary under subsection (3), the advice remains in force until it is withdrawn by the Gene Technology Regulator by written notice given to the Secretary.

30E Secretary to take advice into account

If the Secretary receives advice from the Gene Technology Regulator:

(a) in response to a notice under section 30C within the period specified in the notice; or

(b) under section 30D;

the Secretary must:

(c) ensure that the advice is taken into account in making a decision on the application to which the notice relates, or on an application to which the advice under section 30D relates, as the case requires; and

(d) inform the Gene Technology Regulator of the decision on the application.

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Division 2A—Public notification, and recall, of therapeutic goods

30EA Public notification, and recall, of therapeutic goods

(1) The Secretary may, in writing, impose requirements, relating to therapeutic goods, 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 goods; and

(b) the person is referred to in the third column of that item.

Circumstances in which requirements may be imposed

Item	Circumstance relating to therapeutic goods	Person subject to requirements
1.	The goods are supplied while they are registered goods or listed goods, but the Secretary is satisfied that they do not conform with a standard applicable to the goods	The person in relation to whom the goods are included in the Register
2.	The goods are supplied while they are registered goods or listed goods, but the Secretary is satisfied that the manufacturing principles have not been observed in the manufacture of the goods	The person in relation to whom the goods are included in the Register
3.	The goods are supplied while: (a) they are exempt goods; or (b) they are exempt under section 18A; or (c) they are the subject of an approval or authority under section 19; or (d) they are the subject of an approval under section 19A; but the Secretary is satisfied that they do not conform with a standard applicable to the goods	The person supplying the goods

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Circumstances in which requirements may be imposed		
Item	**Circumstance relating to therapeutic goods**	**Person subject to requirements**
4.	The goods are supplied while: (a) they are exempt goods; or (b) they are exempt under section 18A; or (c) they are the subject of an approval or authority under section 19; or (d) they are the subject of an approval under section 19A; but the Secretary is satisfied that the manufacturing principles have not been observed in the manufacture of the goods	The person supplying the goods
5.	The goods are supplied in contravention of subsection 19B(1), (4) or (4A) or 19D(1)	The person supplying the goods
5A.	The goods are supplied while they are registered goods or listed goods, but it appears to the Secretary that: (a) the quality, safety or efficacy of the goods is unacceptable; or (b) in the case of registered goods—the presentation of the goods is not acceptable; or (c) in the case of listed goods—the presentation of the goods is unacceptable	The person in relation to whom the goods are included in the Register
6.	The goods are supplied while they are registered goods or listed goods, but one or more steps in the manufacture of the goods has been carried out by a manufacturer while the manufacturer did not hold a licence that was in force	The person in relation to whom the goods are included in the Register
6A.	The registration or listing of the goods has been suspended under this Part	The person in relation to whom the goods were included in the Register

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Circumstances in which requirements may be imposed		
Item	**Circumstance relating to therapeutic goods**	**Person subject to requirements**
7.	The registration or listing of the goods has been cancelled under this Part	The person in relation to whom the goods were included in the Register
8.	The goods are counterfeit (within the meaning of section 42E)	The person supplying the goods

(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 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 therapeutic goods;

(ba) 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) therapeutic goods;

(ii) the circumstances referred to in paragraph (1)(a) in relation to therapeutic goods;

(c) 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 therapeutic goods;

(d) 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 therapeutic goods have been supplied.

(3) If the circumstances referred to in paragraph (1)(a) apply only to a batch of therapeutic goods, the Secretary may limit the imposition of the requirements to the therapeutic goods included in that batch.

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(4) A requirement to recall therapeutic goods under this section does not apply to therapeutic goods that cannot be recalled because they have been administered to, or applied in the treatment of, a person.

30EB 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 30EA, a notice setting out particulars of the requirement.

30EC Criminal offences for non-compliance with requirements

(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 30EA; 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 30EA.

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

(5) A person commits an offence if:
  (a) the person does an act or omits to do an act; and

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(b) the act or omission breaches a requirement imposed on the person under section 30EA.

Penalty: 100 penalty units.

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

30ECA Civil penalty for non-compliance with requirements

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 requirement imposed on the person under section 30EA.

Maximum civil penalty:

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

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

30ED Powers of suspension and cancellation unaffected

Imposition of a requirement under section 30EA does not affect the Secretary's power to suspend or cancel the registration or listing of therapeutic goods under this Part.

30EE Saving of other laws

This Division 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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Division 2B—Reporting medicine shortages and discontinuation of supply of medicine

30EF Reporting medicine shortages

(1) A person in relation to whom a reportable medicine is included in the Register must notify the Secretary of any shortage of the medicine in Australia. The person must do so:

(a) for a shortage that has a critical impact—as soon as possible, but no later than 2 working days, after the first day the person knows, or ought reasonably to have known, of the shortage; or

(b) in any other case—before the end of 10 working days beginning on the first day the person knows, or ought reasonably to have known, of the shortage.

Note: For ***reportable medicine***, see section 30EH. For ***shortage*** of a medicine in Australia, see section 30EI.

Critical impact

(2) The shortage of a medicine in Australia at a particular time has a ***critical impact*** if, at that time, the medicine is included in an instrument under section 30EJ.

(3) The shortage of a medicine in Australia at a particular time also has a ***critical impact*** if:

(a) either:

(i) at that time, there are no registered goods that could reasonably be used as a substitute for the medicine; or

(ii) at that time, there are other registered goods that could reasonably be used as a substitute for the medicine but the other registered goods are not likely to be available in sufficient quantities to meet the demand for the other registered goods that is likely to arise because of the shortage; and

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(b) the shortage has the potential to have a life-threatening impact on, or a serious impact on the physical or mental health or functioning of, persons who take, or who may need to take, the medicine.

Notification requirements

(4) A notification under subsection (1) must:
(a) be in accordance with a form that is approved, in writing, by the Secretary; and
(b) contain the information required by that form.

(5) 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.

Civil penalty

(6) A person contravenes this subsection if:
(a) the person is subject to a requirement under subsection (1); and
(b) the person contravenes the requirement.

Maximum civil penalty:
(a) for an individual—100 penalty units; and
(b) for a body corporate—1,000 penalty units.

Exception

(7) Subsection (6) does not apply if:
(a) paragraph (1)(a) and subsection (3) apply in relation to the shortage but subsection (2) does not; and
(b) as a result of steps taken by the person, it was reasonable for the person to assume that paragraph (1)(b) applied in relation to the shortage; and
(c) the person complied with paragraph (1)(b) in relation to the shortage.

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30EG Reporting discontinuation of supply of medicine

(1) A person in relation to whom a reportable medicine is included in the Register must notify the Secretary of any decision (the ***discontinuation decision***) of the person to permanently discontinue the supply of the medicine in Australia. The person must do so:

(a) if the discontinuation is likely to be of critical impact:

(i) at least 12 months before the discontinuation is proposed to occur; or

(ii) if the person is unable to comply with subparagraph (i)—as soon as practicable after the decision is made; or

(b) in any other case:

(i) at least 6 months before the discontinuation is proposed to occur; or

(ii) if the person is unable to comply with subparagraph (i)—as soon as practicable after the decision is made.

Note: For ***reportable medicine***, see section 30EH.

Critical impact

(2) The discontinuation of the supply of a medicine in Australia is likely to be of ***critical impact*** if, when the discontinuation decision is made, the medicine is included in an instrument under section 30EJ.

(3) The discontinuation of the supply of a medicine in Australia is also likely to be of ***critical impact*** if:

(a) either:

(i) when the discontinuation decision is made, there are no registered goods that could reasonably be used as a substitute for the medicine; or

(ii) when the discontinuation decision is made, there are other registered goods that could reasonably be used as a substitute for the medicine but the other registered goods are not likely to be available in sufficient

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quantities to meet the demand for the other registered goods that is likely to arise because of the discontinuation; and

(b) the discontinuation has the potential to have a life-threatening impact on, or a serious impact on the physical or mental health or functioning of, persons who take, or who may need to take, the medicine.

Notification requirements

(4) A notification under subsection (1) must:

(a) be in accordance with a form that is approved, in writing, by the Secretary; and

(b) contain the information required by that form.

(5) 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.

Civil penalty

(6) A person contravenes this subsection if:

(a) the person is subject to a requirement under subsection (1); and

(b) the person contravenes the requirement.

Maximum civil penalty:

(a) for an individual—100 penalty units; and

(b) for a body corporate—1,000 penalty units.

Exception

(7) Subsection (6) does not apply if:

(a) paragraph (1)(a) and subsection (3) apply in relation to the discontinuation but subsection (2) does not; and

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(b) as a result of steps taken by the person, it was reasonable for the person to assume that paragraph (1)(b) applied in relation to the discontinuation; and

(c) the person complied with paragraph (1)(b) in relation to the discontinuation.

30EH What is a reportable medicine?

(1) For the purposes of this Act, registered goods are a ***reportable medicine*** if:

(a) the goods are medicine; and

(b) either:

(i) the medicine contains one or more substances included in Schedule 4 or 8 to the current Poisons Standard; or

(ii) the medicine is determined in an instrument under subsection (2).

(2) The Minister may, by legislative instrument, determine medicine for the purposes of subparagraph (1)(b)(ii).

(3) The Minister must not determine a medicine unless the Minister is satisfied of either or both of the following:

(a) the medicine is critical to the health of patients in Australia;

(b) the notification to the Secretary of any shortage of the medicine, or of any decision to permanently discontinue the supply of the medicine, in Australia would be in the interests of public health.

30EI When is there a medicine shortage?

For the purposes of this Act, there is a ***shortage*** of a medicine in Australia at a particular time if, at any time in the 6 months after that particular time, the supply of that medicine in Australia will not, or will not be likely to, meet the demand for the medicine for all of the patients in Australia who take, or who may need to take, the medicine.

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30EJ Medicines Watch List

(1) The Minister may, by legislative instrument, determine medicine for the purposes of subsections 30EF(2) and 30EG(2).

(2) The Minister must not determine a medicine unless the Minister is satisfied that any shortage of the medicine, or any permanent discontinuation of the supply of the medicine, in Australia has the potential to result in:

(a) significant morbidity in patients in Australia; or

(b) the death of one or more patients in Australia.

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Division 3—General

30F Criminal offences for goods exempt under section 18A not conforming to standards etc.

(1) This section applies if:

(a) therapeutic goods of a particular kind are exempt under section 18A; and

(b) a person supplies a batch of goods of that kind; and

(c) the Secretary is satisfied that the goods included in that batch:

(i) do not conform to a standard applicable to goods of that kind; or

(ii) are otherwise not fit to be used for their intended purposes.

(2) The Secretary may, by written notice given to the person, require the person to take steps to recall the goods included in that batch (except any of those goods that cannot be recalled because they have been administered to, or applied in the treatment of, a person).

(3) The notice may specify one or more of the following requirements:

(a) the steps to be taken to recall the goods;

(b) the manner in which the steps are to be taken;

(c) a reasonable period within which the steps are to be taken.

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

Written notice is not a legislative instrument

(4A) A written notice given to a person by the Secretary under this section is not a legislative instrument.

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Offences

(4B) A person commits an offence if:

(a) the Secretary gives a notice to the person under subsection (2); and

(b) the notice specifies a particular requirement mentioned in subsection (3); and

(c) the person fails to comply with that requirement; 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 the person failed to comply with that 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 (5) instead: see section 53A.

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

(5) A person commits an offence if:

(a) the Secretary gives a notice to the person under subsection (2); and

(b) the notice specifies a particular requirement mentioned in subsection (3); and

(c) the person fails to comply with that requirement.

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

(6) A person commits an offence if:

(a) the Secretary gives a notice to the person under subsection (2); and

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(b) the notice specifies a particular requirement mentioned in subsection (3); and
(c) the person fails to comply with that requirement.

Penalty: 100 penalty units.

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

Saving of other laws

(7) This section is not intended to exclude or limit the operation of any other law of the Commonwealth or any law of a State or Territory.

30FA Civil penalty for goods exempt under section 18A not conforming to standards etc.

A person contravenes this section if:
(a) the Secretary gives a notice to the person under subsection 30F(2); and
(b) the notice specifies a particular requirement mentioned in subsection 30F(3); and
(c) the person does not comply with the requirement.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

30G Disposal of unused goods exempt under section 18A

(1) This section applies to particular therapeutic goods if:
(a) an exemption in relation to those goods under section 18A ceases to have effect otherwise than because those goods have become registered goods or listed goods (see paragraph 18A(5)(a)); and
(b) those goods have not been used before the exemption so ceases to have effect.

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(2) The Secretary may arrange for the disposal of any of those goods in accordance with the regulations.

(3) Regulations made for the purposes of subsection (2) may set out the methods by which those goods are 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 those goods.

30H Record for goods exempt under section 18A

(1) A person commits an offence if:
  (a) there are therapeutic goods that are exempt under section 18A; and
  (b) a condition of the exemption:
    (i) requires the person to keep a record about those goods; or
    (ii) specifies the manner in which the person must keep the record; and
  (c) the person does an act or omits to do an act in relation to those goods; and
  (d) the act or omission results in the breach of that condition of the exemption.

  Penalty: 240 penalty units.

(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) there are therapeutic goods that are exempt under section 18A; and
  (b) a condition of the exemption:
    (i) requires the person to keep a record about those goods; or

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(ii) specifies the manner in which the person must keep the record; and

(c) the person does an act or omits to do an act in relation to those goods; and

(d) the act or omission results in the breach of that condition of the exemption.

Penalty: 60 penalty units.

(4) An offence under subsection (3) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

31 Secretary may require information or documents

(1) The Secretary may, by notice in writing given to a person:

(aa) who is an applicant for the registration of therapeutic goods; or

(ab) in relation to whom therapeutic goods are registered; or

(ac) in relation to whom therapeutic goods were, at any time during the previous 5 years, registered;

require the person to give to the Secretary, within such reasonable time as is specified in the notice and in such form as is specified in the notice, information or documents relating to one or more of the following:

(a) the formulation of the goods;

(b) the composition of the goods;

(c) the design specifications of the goods;

(d) the quality of the goods;

(e) the method and place of manufacture or preparation of the goods and the procedures employed to ensure that proper standards are maintained in the manufacture and handling of the goods;

(f) the presentation of the goods;

(g) the safety and efficacy of the goods for the purposes for which they are to be used;

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(ga) whether the goods comply with conditions (if any) on the registration of the goods;

(gb) the conformity of the goods to a standard applicable to the goods;

(h) whether either of the following has not been complied with in relation to the goods:

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

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

(ha) if the goods are registered in relation to the person—whether the goods are being:

(i) supplied in Australia; or

(ii) imported into Australia; or

(iii) exported from Australia;

(j) the regulatory history of the goods in another country;

(ja) if the goods are a reportable medicine and the medicine is registered in relation to the person:

(i) whether or not there is a shortage of the medicine in Australia; or

(ii) if there is a shortage of the medicine in Australia—the shortage; or

(iii) any decision of the person to permanently discontinue the supply of the medicine in Australia;

(k) any other matter prescribed by the regulations for the purposes of this paragraph in relation to goods of that kind.

(1A) If a notice is given under subsection (1) to a person covered by paragraph (1)(ac), then paragraphs (1)(a) to (k) (to the extent to which they are relevant) apply in relation to that part of the period of 5 years before the notice was given during which the therapeutic goods were registered.

(1B) If:

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(a) a person makes an application under section 23 for the registration of therapeutic goods in accordance with a form referred to in paragraph 23B(2)(a); and

(aa) the application has passed preliminary assessment; and

(b) the form is described as a pre-submission planning form; and

(c) the person chooses a number of days specified in the form for the purposes of giving information or documents to the Secretary in the event that the person is given a notice under subsection (1) of this section in relation to the application;

then that number of days must be specified in any such notice as the time within which the person must give the required information or documents to the Secretary. The number of days so specified is taken to be a reasonable time for the purposes of subsection (1).

(1C) If:

(a) the person in relation to whom therapeutic goods are registered makes a request under subsection 9D(3) in accordance with a form referred to in subsection 9D(6); and

(b) the form is described as a pre-submission planning form; and

(c) the person chooses a number of days specified in the form for the purposes of giving information or documents to the Secretary in the event that the person is given a notice under subsection (1) of this section in relation to the request;

then that number of days must be specified in any such notice as the time within which the person must give the required information or documents to the Secretary. The number of days so specified is taken to be a reasonable time for the purposes of subsection (1).

(2) The Secretary may, by notice in writing given to a person:

(aa) who is an applicant for the listing of therapeutic goods; or

(ab) in relation to whom therapeutic goods are listed; or

(ac) in relation to whom therapeutic goods were, at any time during the previous 5 years, listed;

require the person to give to the Secretary, within such reasonable time as is specified in the notice and in such form as is specified in

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the notice, information or documents relating to one or more of the following:

(a) the formulation of the goods;

(b) the composition of the goods;

(c) the design specifications of the goods;

(ca) the quality of the goods;

(d) the method and place of manufacture or preparation of the goods and the procedures employed to ensure that proper standards are maintained in the manufacture and handling of the goods;

(e) the presentation of the goods;

(f) the safety of the goods for the purposes for which they are to be used;

(fa) if the goods are listed under section 26A—any of the matters covered by a certification by the person under subsection 26A(2) or (2A) in relation to the medicine;

(fab) if the goods are or were listed under section 26AE—any of the matters covered by a certification by the person under subsection 26AB(2) or (3) in relation to the medicine;

(fac) if the goods are or were listed under section 26AE—the efficacy of the goods in relation to the purposes for which they are to be used;

(fb) whether the goods comply with conditions (if any) on the listing of the goods;

(g) the conformity of the goods to a standard applicable to the goods;

(gaa) whether either of the following has not been complied with in relation to the goods:

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

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

(ga) if the goods are listed in relation to the person—whether the goods are being:

(i) supplied in Australia; or

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(ii) imported into Australia; or
(iii) exported from Australia;

(h) any other matter prescribed by the regulations for the purposes of this paragraph in relation to goods of that kind.

(2A) If a notice is given under subsection (2) to a person covered by paragraph (2)(ac), then paragraphs (2)(a) to (h) (to the extent to which they are relevant) apply in relation to that part of the period of 5 years before the notice was given during which the therapeutic goods were listed.

(3) 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.

(4) A person commits an offence if:
(a) either:
(i) the person is given a notice under subsection (1) and the person is covered by paragraph (1)(ab) or (ac); or
(ii) the person is given a notice under subsection (2) and the person is covered by paragraph (2)(ab) or (ac); and
(b) the person fails to comply with the notice.

Penalty: 500 penalty units.

(4A) Subsection (4) does not apply if the person has a reasonable excuse.

Note: The defendant bears an evidential burden in relation to the matter in subsection (4A). See subsection 13.3(3) of the *Criminal Code*.

(4B) A person commits an offence if:
(a) either:
(i) the person is given a notice under subsection (1) and the person is covered by paragraph (1)(ab) or (ac); or
(ii) the person is given a notice under subsection (2) and the person is covered by paragraph (2)(ab) or (ac); and
(b) the person fails to comply with the notice.

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Penalty: 100 penalty units.

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

Note: For strict liability, see section 6.1 of the *Criminal Code*.

(5AA) Subsection (4B) does not apply if the person has a reasonable excuse.

Note: A defendant bears an evidential burden in relation to the matter in subsection (5AA): see subsection 13.3(3) of the *Criminal Code*.

(5A) A person commits an offence if:

(a) the person is given a notice under this section in relation to therapeutic goods; and

(b) the person gives information or a document in compliance or purported compliance with the notice; and

(c) the information or document is false or misleading in a material particular; and

(d) either:

(i) the use of the therapeutic 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 therapeutic goods, if the therapeutic goods 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 (6) instead: see section 53A.

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

(6) A person commits an offence if:

(a) the person is given a notice under this section in relation to therapeutic goods; and

(b) the person gives information or 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: Imprisonment for 12 months or 1,000 penalty units, or both.

(7) A person commits an offence if:
(a) the person is given a notice under this section in relation to therapeutic goods; and
(b) the person gives information or 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.

(8) An offence against subsection (7) is an offence of strict liability.

31AAA Civil penalty for providing false or misleading information or documents in relation to therapeutic goods

A person contravenes this section if:
(a) the person is given a notice under section 31 in relation to therapeutic goods; and
(b) the person gives information or 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.

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31A Secretary may require information etc. about goods exempt under section 18

Exempt goods for use for experimental purposes in humans

(1) If therapeutic goods are exempt under subsection 18(1) from the operation of this Part (except this section and sections 31C to 31F) to allow for their use for experimental purposes in humans, the Secretary may give the sponsor of the goods 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 the goods;
  (b) the handling of the goods;
  (c) the monitoring of the supply of the goods;
  (d) the results of the supply of the goods;
  (e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to goods of that kind.

Statement by medical practitioner about medicine

(2) If a medicine is exempt under subsection 18(1) from the operation of this Part (except this section and sections 31C to 31F) because a medical practitioner has signed a statement in accordance with regulation 12A of the *Therapeutic Goods Regulations 1990*, 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 medicine is to be given or is given;
  (b) the supply of the medicine;
  (c) the handling of the medicine;
  (d) the monitoring of the supply of the medicine;
  (e) the results of the supply of the medicine;
  (f) any other matter prescribed by the regulations for the purposes of this paragraph in relation to medicines of that kind.

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Compliance period

(3) A notice under subsection (1) or (2) must specify a reasonable period within which the person to whom the notice is given must comply with it. The period must be at least 14 days starting on the day on which the notice is given.

Information may need to be given in accordance with specified software requirements

(4) A notice under subsection (1) or (2) 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.

31AA Secretary may require information etc. about goods exempt under section 18A

(1) This section applies to a person who is required to comply with a condition of an exemption of therapeutic goods under section 18A.

(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 any of those goods;
  (b) the handling of any of those goods;
  (c) the monitoring of the supply of any of those goods;
  (d) the results of the supply of any of those goods;
  (e) any other matter prescribed by the regulations for the purposes of this paragraph.

Compliance period

(3) The notice must specify a reasonable period within which the person must comply with it. The period must be at least 14 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) 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.

31B Secretary may require information relating to approvals and authorities under section 19

Approval under subsection 19(1)

(1) The Secretary may give to a person who is granted an approval under subsection 19(1) in relation to specified therapeutic goods 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 goods;
  (b) the handling of the goods;
  (c) the monitoring of the supply of the goods;
  (d) the results of the supply of the goods;
  (e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to goods of that kind.

Approval under subsection 19(1)—use by another person

(2) The Secretary may give to a person using specified therapeutic goods that are the subject of an approval granted to someone else under paragraph 19(1)(b) 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 the goods;
  (b) any other matter prescribed by the regulations for the purposes of this paragraph in relation to goods of that kind.

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Authority under subsection 19(5)

(3) The Secretary may give to a person who is granted an authority under subsection 19(5) in relation to specified therapeutic goods, or a specified class of therapeutic goods, 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 goods;

(b) the handling of the goods;

(c) the monitoring of the supply of the goods;

(d) the results of the supply of the goods;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to goods of that kind.

Authority under subsection 19(7A) rules

(3A) If a person is authorised, by subsection 19(7A) rules, to supply therapeutic goods, 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 the goods;

(b) the handling of the goods;

(c) the monitoring of the supply of the goods;

(d) the results of the supply of the goods;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to goods of that kind.

Compliance period

(4) A notice under subsection (1), (2), (3) or (3A) must specify a reasonable period within which the person to whom the notice is given must comply with it. The period must be at least 14 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

(5) A notice under subsection (1), (2), (3) or (3A) 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.

31BA Secretary may require information about therapeutic goods approved under section 19A

(1) The Secretary may give to a person who is granted an approval under subsection 19A(1), (1A) or (2) in relation to specified therapeutic goods a written notice requiring the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to one or more of the following:
  (a) the supply of the goods;
  (b) the handling of the goods;
  (c) the monitoring of the supply of the goods;
  (d) the results of the supply of the goods;
  (e) any other matter prescribed by the regulations.

Compliance

(2) A person given a notice under subsection (1) must give the information, or produce the documents, to the Secretary:
  (a) within the period specified in the notice (which must not be less than 14 days after the day the notice is given); and
  (b) in the form specified in the notice.

(3) The form may require or permit 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.

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31C Criminal offences for failing to give information or documents sought under section 31A, 31AA, 31B or 31BA

(1) A person commits an offence if:

(a) the person is given a notice under section 31A, 31AA, 31B or 31BA; 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 31A, 31AA, 31B or 31BA; 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.

31D False or misleading information

(1) A person to whom a notice is given under section 31A, 31AA, 31B or 31BA commits an offence if:

(a) the person gives information to the Secretary in compliance or purported compliance with the notice; and

(b) the person does so knowing that the information:

(i) is false or misleading; or

(ii) omits any matter or thing without which the information is misleading.

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.

(1A) A person to whom a notice is given under section 31A, 31AA, 31B or 31BA commits an offence if:

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(a) the person gives information to the Secretary in compliance or purported compliance with the notice; and

(b) the information:

(i) is false or misleading; or

(ii) omits any matter or thing without which the information is misleading.

Penalty: 100 penalty units.

(1B) An offence against subsection (1A) is an offence of strict liability.

(2) Subsection (1) or (1A) does not apply as a result of subparagraph (1)(b)(i) or (1A)(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 (2): see subsection 13.3(3) of the *Criminal Code*.

(3) Subsection (1) or (1A) does not apply as a result of subparagraph (1)(b)(ii) or (1A)(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 (3): see subsection 13.3(3) of the *Criminal Code*.

31E False or misleading documents

(1) A person commits an offence if:

(a) the person produces a document to the Secretary; and

(b) the person does so knowing that the document is false or misleading; and

(c) the document is produced in compliance or purported compliance with a notice given under section 31A, 31AA, 31B or 31BA.

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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(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 31A, 31AA, 31B or 31BA.

Penalty: 100 penalty units.

(1B) An offence against subsection (1A) is an offence of strict liability.

(2) 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 (2): see subsection 13.3(3) of the *Criminal Code*.

(3) 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 (3): see subsection 13.3(3) of the *Criminal Code*.

31F Self-incrimination

(1) A person is not excused from giving information or a document under a notice given under section 31, 31A, 31AA, 31B or 31BA on the ground that the giving of the information or document would tend to incriminate the person or expose the person to a penalty.

(2) However, in the case of an individual:

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(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 31(5A), (6) or (7) or section 31D or 31E; or

(e) civil proceedings, except proceedings under section 42Y for a contravention of section 31AAA.

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Part 3-2A—Biologicals

Division 1—Preliminary

32 What this Part is about

This Part regulates biologicals. It does this by providing a process for including biologicals in the Register and providing for enforcement through criminal offences and civil penalties.

This Part provides for the following administrative processes:

(a) exempting biologicals from the requirement to be included in the Register;

(b) making the inclusion of biologicals in the Register subject to conditions;

(c) suspending or cancelling entries of biologicals from the Register;

(d) requiring public notification of problems with biologicals, and recall of biologicals;

(e) obtaining information or documents about biologicals.

32A Meaning of *biological*

(1) Subject to subsection (3), a ***biological*** is a thing that:

(a) either:

(i) comprises, contains or is derived from human cells or human tissues; or

(ii) is specified under subsection (2); and

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(b) is represented in any way to be, or is, whether because of the way in which it is presented or for any other reason, likely to be taken to be:

(i) for use in the treatment or prevention of a disease, ailment, defect or injury affecting persons; or

(ii) for use in making a medical diagnosis of the condition of a person; or

(iii) for use in influencing, inhibiting or modifying a physiological process in persons; or

(iv) for use in testing the susceptibility of persons to a disease or ailment; or

(v) for use in the replacement or modification of parts of the anatomy in persons.

(2) The Secretary may, by legislative instrument, specify things for the purposes of subparagraph (1)(a)(ii).

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

(3) The Secretary may, by legislative instrument, determine that a specified thing is not a biological for the purposes of this Act.

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

32AA Biological classes

The regulations may prescribe different classes of biologicals.

Note 1: The regulations may prescribe the circumstances in which a biological included in a class of biologicals is separate and distinct from other biologicals: see section 32AB.

Note 2: The Secretary may approve different application forms for different classes of biologicals: see section 32DDA.

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32AB When biologicals are separate and distinct from other biologicals

(1) The regulations may prescribe the circumstances in which a biological included in a specified class of biologicals is separate and distinct from other biologicals.

(2) The regulations may make different provision in relation to different classes of biologicals that are prescribed by the regulations for the purposes of section 32AA.

Note: The Secretary may cancel the entry of a biological from the Register if the biological has changed so that it has become separate and distinct from the biological as so included: see subsection 32GC(1).

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Division 2—Main criminal offences and civil penalties

32B What this Division is about

This Division contains criminal offences and civil penalties relating to the import, export, manufacture, supply and use of biologicals.

32BA Criminal offences for importing a biological

(1) A person commits an offence if:

(a) the person imports into Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the importation into Australia of the biological;

(v) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person; and

(c) either:

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

(ii) the use of the biological, if the biological 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 imports into Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the importation into Australia of the biological;

(v) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person.

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

(4A) A person commits an offence if:

(a) the person imports into Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

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(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the importation into Australia of the biological;

(v) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person.

Penalty: 100 penalty units.

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

Defences

(5) Subsection (1), (4) or (4A) does not apply if the defendant proves that the defendant was not the sponsor of the biological at the time of the importation.

Note: A defendant bears a legal burden in relation to the matter in subsection (5): see section 13.4 of the *Criminal Code*.

(6) 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 efficacy of the biological; or

(ii) a matter relating to the labelling or packaging of the biological; or

(iii) the improper use of the biological; or

(b) harm or injury would not, or would not be likely to, directly result from:

(i) the quality, safety or efficacy of the biological; or

(ii) a matter relating to the labelling or packaging of the biological; or

(iii) the improper use of the biological.

Note: A defendant bears an evidential burden in relation to the matters in subsection (6): see subsection 13.3(3) of the *Criminal Code*.

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32BB Criminal offences for exporting a biological

(1) A person commits an offence if:

(a) the person exports from Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the exportation from Australia of the biological; and

(c) either:

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

(ii) the use of the biological, if the biological 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 exports from Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

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(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the exportation from Australia of the biological.

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

(4A) A person commits an offence if:

(a) the person exports from Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the exportation from Australia of the biological.

Penalty: 100 penalty units.

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

Defences

(5) Subsection (1), (4) or (4A) does not apply if the defendant proves that the defendant was not the sponsor of the biological at the time of the exportation.

Note: A defendant bears a legal burden in relation to the matter in subsection (5): see section 13.4 of the *Criminal Code*.

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(6) 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 efficacy of the biological; or

(ii) a matter relating to the labelling or packaging of the biological; or

(iii) the improper use of the biological; or

(b) harm or injury would not, or would not be likely to, directly result from:

(i) the quality, safety or efficacy of the biological; or

(ii) a matter relating to the labelling or packaging of the biological; or

(iii) the improper use of the biological.

Note: A defendant bears an evidential burden in relation to the matters in subsection (6): see subsection 13.3(3) of the *Criminal Code*.

32BBA Treating biologicals as prohibited imports or exports

If:

(a) the importation or exportation of a biological is an offence under subsection 32BA(1), (4) or (4A) or 32BB(1), (4) or (4A); 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 biological 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.

32BC Criminal offences for manufacturing a biological

(1) A person commits an offence if:

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(a) the person manufactures in Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB; and

(c) either:

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

(ii) the use of the biological, if the biological 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 manufactures in Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB.

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

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(4A) A person commits an offence if:

(a) the person manufactures in Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB.

Penalty: 100 penalty units.

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

Defences

(5) Subsection (1), (4) or (4A) does not apply if the defendant proves that the defendant was not the sponsor of the biological at the time of the manufacture.

Note: A defendant bears a legal burden in relation to the matter in subsection (5): see section 13.4 of the *Criminal Code*.

(6) 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 efficacy of the biological; or

(ii) a matter relating to the labelling or packaging of the biological; or

(iii) the improper use of the biological; or

(b) harm or injury would not, or would not be likely to, directly result from:

(i) the quality, safety or efficacy of the biological; or

(ii) a matter relating to the labelling or packaging of the biological; or

(iii) the improper use of the biological.

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Note: A defendant bears an evidential burden in relation to the matters in subsection (6): see subsection 13.3(3) of the *Criminal Code*.

32BD Criminal offences for supplying a biological

(1) A person commits an offence if:

(a) the person supplies in Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the supply in Australia of the biological;

(v) the biological is the subject of an authority under subsection 32CM(1) or (7A) that covers the supply of the biological by the person;

(vi) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person, being an approval covering the supply in Australia of the biological; and

(c) either:

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

(ii) the use of the biological, if the biological 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.

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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 supplies in Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the supply in Australia of the biological;

(v) the biological is the subject of an authority under subsection 32CM(1) or (7A) that covers the supply of the biological by the person;

(vi) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person, being an approval covering the supply in Australia of the biological.

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

(4A) A person commits an offence if:

(a) the person supplies in Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

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(iii) the biological is exempt under section 32CB;
(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the supply in Australia of the biological;
(v) the biological is the subject of an authority under subsection 32CM(1) or (7A) that covers the supply of the biological by the person;
(vi) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person, being an approval covering the supply in Australia of the biological.

Penalty: 100 penalty units.

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

Defences

(5) Subsection (1), (4) or (4A) does not apply if the defendant proves that the defendant was not the sponsor of the biological at the time of the supply.

Note: A defendant bears a legal burden in relation to the matter in subsection (5): see section 13.4 of the *Criminal Code*.

(6) 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 efficacy of the biological; or
(ii) a matter relating to the labelling or packaging of the biological; or
(iii) the improper use of the biological; or
(b) harm or injury would not, or would not be likely to, directly result from:
(i) the quality, safety or efficacy of the biological; or
(ii) a matter relating to the labelling or packaging of the biological; or

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(iii) the improper use of the biological.

Note: A defendant bears an evidential burden in relation to the matters in subsection (6): see subsection 13.3(3) of the *Criminal Code*.

32BE Notice required to adduce evidence in support of exception to offences

(1) If:

(a) a defendant is committed for trial for an offence against subsection 32BA(1), 32BB(1), 32BC(1) or 32BD(1); or

(b) an offence against subsection 32BA(1), 32BB(1), 32BC(1) or 32BD(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 32BA(6), 32BB(6), 32BC(6) or 32BD(6) unless the defendant gives notice of particulars of the exception:

(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.

(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 the defendant gives the notice, any information in the defendant's 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; and

(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 the defendant's 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 under this section 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 an office of the Office of the Director of Public Prosecutions; or

(b) sent by certified mail addressed to the Director of Public Prosecutions at an office of 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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32BF Civil penalties for importing, exporting, manufacturing or supplying a biological

Importing a biological for use in humans

(1) A person contravenes this subsection if:

(a) the person imports into Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the importation into Australia of the biological;

(v) the biological is the subject of an approval under subsection 32CO(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.

Exporting a biological for use in humans

(2) A person contravenes this subsection if:

(a) the person exports from Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

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(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);
(iii) the biological is exempt under section 32CB;
(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the exportation from Australia of the biological.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

Manufacturing a biological for use in humans

(3) A person contravenes this subsection if:
(a) the person manufactures in Australia a biological for use in humans; and
(b) none of the following subparagraphs applies:
(i) the biological is included in the Register in relation to the person;
(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);
(iii) the biological is exempt under section 32CB.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

Supplying a biological for use in humans

(4) A person contravenes this subsection if:
(a) the person supplies in Australia a biological for use in humans; and

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(b) none of the following subparagraphs applies:
(i) the biological is included in the Register in relation to the person;
(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);
(iii) the biological is exempt under section 32CB;
(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the supply in Australia of the biological;
(v) the biological is the subject of an authority under subsection 32CM(1) or (7A) that covers the supply of the biological by the person;
(vi) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person, being an approval covering the supply in Australia of the biological.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

Exception if person was not the sponsor of the biological

(5) Subsection (1), (2), (3) or (4) does not apply if the person proves that he or she was not the sponsor of the biological at the time of the importation, exportation, manufacture or supply, as the case may be.

Civil penalty relating to the supply of biologicals included in the Register

(6) A person contravenes this subsection if:
(a) a biological is included in the Register in relation to the person; and

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(b) the biological is of a kind prescribed by the regulations for the purposes of this paragraph; and
(c) the person supplies the biological in Australia; and
(d) the biological number of the biological is not set out on the label of the biological in the prescribed manner.

Maximum civil penalty:
(a) for an individual—200 penalty units; and
(b) for a body corporate—2,000 penalty units.

Application of the Customs Act 1901

(7) If:
(a) the importation or exportation of a biological contravenes subsection (1) or (2); 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 biological 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.

32BG Criminal offences and civil penalty relating to a failure to notify the Secretary about manufacturing

Criminal offences

(1) A person commits an offence if:
(a) the person:
(i) imports a biological into Australia for use in humans; or
(ii) exports a biological from Australia for use in humans; or

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(iii) manufactures a biological in Australia for use in humans; or

(iv) supplies a biological in Australia for use in humans; and

(b) the person is the sponsor of the biological; and

(c) the person is not exempt under subsection 32CA(1) in relation to the biological and the biological is not exempt under subsection 32CA(2); and

(d) the person has not, at or before the time of the importation, exportation, manufacture or supply, properly notified to the Secretary either or both of the following:

(i) the manufacturer of the biological;

(ii) the premises used in the manufacture of the biological.

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

(1A) A person commits an offence if:

(a) the person:

(i) imports a biological into Australia for use in humans; or

(ii) exports a biological from Australia for use in humans; or

(iii) manufactures a biological in Australia for use in humans; or

(iv) supplies a biological in Australia for use in humans; and

(b) the person is the sponsor of the biological; and

(c) the person is not exempt under subsection 32CA(1) in relation to the biological and the biological is not exempt under subsection 32CA(2); and

(d) the person has not, at or before the time of the importation, exportation, manufacture or supply, properly notified to the Secretary either or both of the following:

(i) the manufacturer of the biological;

(ii) the premises used in the manufacture of the biological.

Penalty: 100 penalty units.

(1B) An offence against subsection (1A) is an offence of strict liability.

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Civil penalty

(2) A person contravenes this subsection if:
  (a) the person:
    (i) imports a biological into Australia for use in humans; or
    (ii) exports a biological from Australia for use in humans; or
    (iii) manufactures a biological in Australia for use in humans; or
    (iv) supplies a biological in Australia for use in humans; and
  (b) the person is the sponsor of the biological; and
  (c) the person is not exempt under subsection 32CA(1) in relation to the biological and the biological is not exempt under subsection 32CA(2); and
  (d) the person has not, at or before the time of the importation, exportation, manufacture or supply, properly notified to the Secretary either or both of the following:
    (i) the manufacturer of the biological;
    (ii) the premises used in the manufacture of the biological.

Maximum civil penalty:
  (a) for an individual—5,000 penalty units; and
  (b) for a body corporate—50,000 penalty units.

Definition

(3) For the purposes of this section:
  (a) a manufacturer is ***properly notified*** to the Secretary if:
    (i) the manufacturer was nominated, as a manufacturer of the biological, in an application for inclusion of the biological in the Register; or
    (ii) the Secretary was subsequently informed in writing that the manufacturer is a manufacturer of the biological; and
  (b) premises are ***properly notified*** to the Secretary if:

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(i) the premises were nominated, as premises used in the manufacture of the biological, in an application for inclusion of the biological in the Register; or

(ii) the Secretary was subsequently informed in writing that the premises are used in the manufacture of the biological.

32BH Criminal offence relating to wholesale supply

A person commits an offence if:

(a) the person supplies a biological in Australia for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the supply in Australia of the biological;

(v) the biological is the subject of an authority under subsection 32CM(1) or (7A) that covers the supply of the biological by the person;

(vi) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person, being an approval covering the supply in Australia of the biological; and

(c) the person to whom the biological is supplied is not the ultimate consumer of the biological.

Penalty: 120 penalty units.

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32BI Criminal offence for using a biological not included in the Register

(1) A person commits an offence if:

(a) the person uses a biological; and

(b) the biological is used:

(i) in the treatment of another person; or

(ii) solely for experimental purposes in humans; and

(c) none of the following subparagraphs applies:

(i) the biological is included in the Register;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2);

(v) the person uses the biological in accordance with an approval under subsection 32CK(1);

(vi) the person uses the biological in accordance with a condition applicable under regulations made for the purposes of section 32CL;

(vii) the person uses the biological in accordance with an authority under subsection 32CM(1) or (7A); and

(d) either:

(i) if the person used the biological in the treatment of that other person—the use of the biological has resulted in, will result in, or is likely to result in, harm or injury to that other person; or

(ii) if the person used the biological solely for experimental purposes in humans—the use of the biological has resulted in, will result in, or is likely to result in, harm or injury to any of those humans.

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

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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:
  (a) the person uses a biological; and
  (b) the biological is used:
    (i) in the treatment of another person; or
    (ii) solely for experimental purposes in humans; and
  (c) none of the following subparagraphs applies:
    (i) the biological is included in the Register;
    (ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);
    (iii) the biological is exempt under section 32CB;
    (iv) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2);
    (v) the person uses the biological in accordance with an approval under subsection 32CK(1);
    (vi) the person uses the biological in accordance with a condition applicable under regulations made for the purposes of section 32CL;
    (vii) the person uses the biological in accordance with an authority under subsection 32CM(1) or (7A).

Penalty: 500 penalty units.

(5) A person commits an offence if:
  (a) the person uses a biological; and
  (b) the biological is used:
    (i) in the treatment of another person; or
    (ii) solely for experimental purposes in humans; and
  (c) none of the following subparagraphs applies:
    (i) the biological is included in the Register;

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(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);
(iii) the biological is exempt under section 32CB;
(iv) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2);
(v) the person uses the biological in accordance with an approval under subsection 32CK(1);
(vi) the person uses the biological in accordance with a condition applicable under regulations made for the purposes of section 32CL;
(vii) the person uses the biological in accordance with an authority under subsection 32CM(1) or (7A).

Penalty: 100 penalty units.

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

32BJ General criminal offences relating to this Part

Including incorrect biological number on containers etc.

(1) A person commits an offence if:
(a) the person sets out or causes to be set out, on a container or package that contains a biological or on a label of a biological, a number that purports to be the biological number of the biological; and
(b) the number is not that biological number.

Penalty: 60 penalty units.

(2) For the purposes of subsection (1), ***number*** includes any combination of one or more of the following:
(a) numbers;
(b) letters;
(c) symbols.

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Advertising biological for an indication

(2A) A person commits an offence if:

(a) the person, by any means, advertises a biological for an indication; and

(b) the biological is included in the Register; and

(c) the indication is not an indication accepted in relation to that inclusion; and

(d) either:

(i) the use of the biological for the advertised indication has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the biological for the advertised indication, if the biological 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.

(2B) A person commits an offence if:

(a) the person, by any means, advertises a biological for an indication; and

(b) the biological is included in the Register; and

(c) the indication is not an indication 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 biological for an indication; and

(b) the biological is included in the Register; and

(c) the indication is not an indication accepted in relation to that inclusion.

Penalty: 100 penalty units.

(3A) An offence against subsection (3) is an offence of strict liability.

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Arranging supply of biological not included in Register

(4) A person commits an offence if:

(a) the person claims, by any means, that the person or another person can arrange the supply of a biological; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register;

(ii) the person or other person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person or other person, being an approval covering the supply in Australia of the biological;

(v) the biological is the subject of an authority under subsection 32CM(1) or (7A) that covers the supply of the biological by the person or other person;

(vi) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person or other person, being an approval covering the supply in Australia of the biological.

Penalty for contravention of this subsection: 60 penalty units.

32BK Civil penalty for making misrepresentations about biologicals

(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:

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(a) representations that a biological is included in the Register;
(b) representations that a person is exempt under subsection 32CA(1) in relation to a biological or that a biological is exempt under subsection 32CA(2);
(c) representations that a biological is exempt under section 32CB;
(d) representations that a biological is the subject of an approval under subsection 32CK(1);
(e) representations that a biological is the subject of an authority under subsection 32CM(1) or (7A);
(f) representations that a biological is the subject of an approval under subsection 32CO(1), (1A) or (2).

32BL Civil penalty for advertising biological for an indication

A person contravenes this section if:

(a) the person, by any means, advertises a biological for an indication; and
(b) the biological is included in the Register; and
(c) the indication is not an indication 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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Division 3—Exemptions

Subdivision A—Preliminary

32C What this Division is about

There are 4 kinds of exemptions in relation to biologicals:

(a) exemptions of biologicals under the regulations; and

(b) exemptions of biologicals to deal with emergencies; and

(c) exemptions of biologicals for special and experimental uses; and

(d) exemptions of biologicals where substitutes are unavailable.

Subdivision B—Exempting biologicals under the regulations

32CA Exempt biologicals

(1) The regulations may exempt specified persons from the operation of Division 4 in relation to specified biologicals.

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

(2) The regulations may exempt specified biologicals from the operation of Division 4.

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

(3) An exemption under this section may be subject to conditions that are prescribed in the regulations.

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(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 results in the breach of a condition of an exemption under this section.

  Penalty: 60 penalty units.

(5) If the regulations revoke an exemption, the revocation takes effect on the day specified in the regulations. The day must not be earlier than 28 days after the day on which the regulations revoking the exemption take effect.

Subdivision C—Exempting biologicals to deal with emergencies

32CB Minister may make exemptions

(1) The Minister may, by writing, exempt specified biologicals from the operation of Division 4.

  Note 1: For specification by class, see subsection 33(3AB) of the *Acts Interpretation Act 1901*.

  Note 2: There are criminal offences and a civil penalty relating to biologicals exempt under this section not conforming to standards etc.: see section 32CJ.

(2) The Minister may make an exemption under subsection (1) only if the Minister is satisfied that, in the national interest, the exemption should be made so that:
  (a) the biologicals may be stockpiled as quickly as possible in order to create a preparedness to deal with a potential threat to public health that may be caused by a possible future emergency; or
  (b) the biologicals 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.

  Period of exemption

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

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(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 32CD deals with variation and revocation of the exemption.

Effect of inclusion of biological in the Register

(5) An exemption under subsection (1) ceases to have effect in relation to a particular biological when that biological becomes included in the Register under Division 4.

Exemption not a legislative instrument

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

32CC Conditions of exemptions

An exemption under section 32CB is subject to conditions specified in the exemption about any of the following:

(a) the quantity of biologicals that are exempt;
(b) the source of those biologicals;
(c) the persons or class of persons who may import, export, manufacture or supply those biologicals;
(d) the supply of those biologicals (including the persons or class of persons to whom biologicals may be supplied for use and the circumstances under which a stockpile of biologicals may be supplied for use);
(e) the storage and security of those biologicals;
(f) the keeping and disclosure of, and access to, records about those biologicals;
(g) the disposal of those biologicals;
(h) the manner in which any of those biologicals is to be dealt with if a condition of the exemption is breached;
(i) any other matters that the Minister thinks appropriate.

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Whether or not biologicals are exempt under section 32CB is not affected by whether or not there is a breach of a condition under this section in relation to those biologicals.

Note 1: There are criminal offences and civil penalties related to the breach of a condition of an exemption: see sections 32CH and 32CI.

Note 2: Section 32CD deals with variation and revocation of the conditions.

32CD Variation or revocation of exemption

Variation of exemption

(1) The Minister may, by writing, vary an exemption made under section 32CB by removing specified biologicals from the exemption.

Note: For specification by class, see subsection 33(3AB) of the *Acts Interpretation Act 1901*.

Revocation of exemption

(2) The Minister may, by writing, revoke an exemption made under section 32CB.

Variation or revocation of conditions

(3) The Minister may, by writing:
(a) vary the conditions of an exemption made under section 32CB (including by imposing new conditions); or
(b) revoke the conditions of an exemption made under section 32CB.

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

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(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).

32CE Informing persons of exemption etc.

If the Minister makes an exemption under section 32CB, the Minister must take reasonable steps to give a copy of the following to each person covered by paragraph 32CC(c):

(a) the exemption;

(b) any variation or revocation of the exemption under section 32CD.

32CF Notification and tabling

Notification

(1) The Secretary must cause a notice setting out particulars of the following:

(a) an exemption made under section 32CB because of paragraph 32CB(2)(b);

(b) a variation or revocation under section 32CD, to the extent that the variation or revocation relates to an exemption made under section 32CB because of paragraph 32CB(2)(b);

to be published in the *Gazette* within 7 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 32CB because of paragraph 32CB(2)(b);

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(b) a variation or revocation under section 32CD, to the extent that the variation or revocation relates to an exemption made under section 32CB because of paragraph 32CB(2)(b);

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.

32CG Disposal of unused biologicals

(1) This section applies to a biological if:

(a) an exemption under section 32CB in relation to that biological ceases to have effect otherwise than because that biological becomes included in the Register under Division 4; and

(b) that biological has not been used before the exemption so ceases to have effect.

(2) The Secretary may arrange for the disposal of the biological in accordance with the regulations.

(3) Regulations made for the purposes of subsection (2) may set out the methods by which the biological 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 biological.

32CH 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 biological; and

(b) the biological is covered by an exemption in force under section 32CB; and

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(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 biological; and

(b) the biological is covered by an exemption in force under section 32CB; 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*.

(5) A person commits an offence if:

(a) the person does an act or omits to do an act in relation to a biological; and

(b) the biological is covered by an exemption in force under section 32CB; 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*.

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32CI 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 biological; and

(b) the biological is covered by an exemption in force under section 32CB; 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.

32CJ Criminal offences and civil penalty for biologicals not conforming to standards etc.

(1) This section applies if:

(a) a biological is exempt under section 32CB; and

(b) a person supplies a batch of the biologicals; and

(c) the Secretary is satisfied that the biologicals included in that batch:

(i) do not conform to a standard applicable to the biologicals; or

(ii) are otherwise not fit to be used for their intended purposes.

(2) The Secretary may, by written notice given to the person, require the person to take steps to recall the biologicals included in that batch (except any of those biologicals that cannot be recalled because they have been administered to, or applied in the treatment of, a person).

(3) The notice may specify one or more of the following requirements:

(a) the steps to be taken to recall the biologicals;

(b) the manner in which the steps are to be taken;

(c) a reasonable period within which the steps are to be taken.

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

Notice is not a legislative instrument

(5) A notice given under subsection (2) is not a legislative instrument.

Offences

(6) A person commits an offence if:
  (a) the Secretary gives a notice to the person under subsection (2); and
  (b) the notice specifies a particular requirement mentioned in subsection (3); and
  (c) the person fails to comply with that requirement; and
  (d) either:
    (i) the use of any of the biologicals has resulted in, will result in, or is likely to result in, harm or injury to any person; or
    (ii) the use of any of the biologicals, if any of the biologicals 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 person failed to comply with that requirement.

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

Note: 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 Secretary gives a notice to the person under subsection (2); and
  (b) the notice specifies a particular requirement mentioned in subsection (3); and
  (c) the person fails to comply with that requirement.

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

(9) A person commits an offence if:
(a) the Secretary gives a notice to the person under subsection (2); and
(b) the notice specifies a particular requirement mentioned in subsection (3); and
(c) the person fails to comply with that requirement.

Penalty: 100 penalty units.

(10) An offence against subsection (9) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

Civil penalty

(11) A person contravenes this subsection if:
(a) the Secretary gives a notice to the person under subsection (2); and
(b) the notice specifies a particular requirement mentioned in subsection (3); and
(c) the person does not comply with the requirement.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

Saving of other laws

(12) This section 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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Subdivision D—Exempting biologicals for certain uses

32CK Approvals for importing, exporting or supplying a biological for special and experimental uses

(1) The Secretary may, by notice in writing, grant an approval to a person for one or more of the following:

(a) the importation into Australia of a specified biological;

(b) the exportation from Australia of a specified biological;

(c) the supply in Australia of a specified biological;

that is:

(d) for use in the treatment of another person; or

(e) for use solely for experimental purposes in humans.

(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) Subsection (1) does not apply if the biological is included in the Register, the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2).

Application for approval

(3) An application for an approval for use of the kind referred to in paragraph (1)(d) must:

(a) be made to the Secretary; and

(aa) be in a form (if any) approved, in writing, by the Secretary; and

(b) be accompanied by such information relating to the biological the subject of the application as is required by the Secretary.

(4) An application for an approval for use of the kind referred to in paragraph (1)(e) must:

(a) be made to the Secretary; and

(b) be made in writing; and

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(c) be accompanied by such information relating to the biological the subject of the application as is required by the Secretary; and

(d) be accompanied by the prescribed evaluation fee.

Secretary's decision

(5) If an application for an approval is made, the Secretary must:

(a) after having considered the application; and

(b) in the case of an application for an approval for use of the kind referred to in paragraph (1)(e)—after having evaluated the information submitted with the application;

notify the applicant of the decision on the application as soon as practicable after making the decision and, in the case of a decision not to grant the approval, of the reasons for the decision.

Conditions

(6) The Secretary may grant an approval under subsection (1) subject to any conditions that are specified in the notice of approval.

(7) Those conditions may include a condition relating to the charges that may be made for the biological to which the approval relates. This subsection does not limit subsection (6).

(8) An approval under subsection (1) for use of the kind referred to in paragraph (1)(e) is subject to the conditions (if any) specified in the regulations. Those conditions (if any) are in addition to any conditions imposed under subsection (6).

(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 results in the breach of a condition of an approval under subsection (1).

Penalty: 60 penalty units.

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Approval not a legislative instrument

(10) An approval under subsection (1) is not a legislative instrument.

32CL Conditions of use of biological for experimental purposes in humans

(1) The use by a person (the ***experimenter***) for experimental purposes in humans of a biological that is the subject of an approval:

(a) that is held by another person under subsection 32CK(1); and

(b) that covers the importation into Australia, or the supply in Australia, of the biological for use solely for experimental purposes in humans;

is subject to the conditions (if any) specified in the regulations relating to one or more of the following:

(c) the preconditions on the use of the biological for those purposes;

(d) the principles to be followed in the use of the biological for those purposes;

(e) the monitoring of the use, and the results of the use, of the biological for those purposes;

(f) the circumstances in which the experimenter must cease the use of the biological for those purposes.

(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 results in the breach of a condition applicable under regulations made for the purposes of this section.

Penalty for contravention of this subsection: 60 penalty units.

32CM Exemptions for health practitioners

(1) The Secretary may, in writing, authorise a specified medical practitioner to supply a specified biological, for use in the treatment of humans, to the class or classes of recipients specified in the authority.

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Note: Section 32CN contains criminal offences relating to the giving an authority to a medical practitioner.

(1A) An application for an authority under subsection (1) must be in a form (if any) approved, in writing, by the Secretary.

(2) The Secretary may give an authority under subsection (1) subject to any conditions that are specified in the authority.

(3) The Secretary may impose conditions (or further conditions) on an authority given to a person under subsection (1) by giving to the person written notice of the conditions (or further 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; or

(b) to a medical practitioner who has the approval of an ethics committee to supply the specified biological.

Paragraph (b) does not apply in the exceptional circumstances (if any) prescribed by the regulations for the purposes of this subsection.

(5) An authority under subsection (1) may only be given in relation to a class or classes of recipients prescribed by the regulations for the purposes of this subsection.

(6) The regulations may prescribe the circumstances in which a biological may be supplied under an authority under subsection (1).

(7) An authority under subsection (1) is not a legislative instrument.

(7A) The Minister may, by legislative instrument, make rules authorising any health practitioner who is included in a specified class of health practitioners to supply a specified biological, for use in the treatment of humans, to the class or classes of recipients specified in those rules, so long as:

(a) the biological is supplied in the circumstances specified in those rules; and

(b) the conditions (if any) specified in those rules are satisfied.

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(7B) In making rules under subsection (7A), 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.

(7C) If:

(a) a person is authorised, by subsection (7A) rules, to supply a biological; and

(b) the person supplies the biological 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.

(7D) A notification under subsection (7C) 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.

(7E) 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.

(7F) A person commits an offence if:

(a) the person is subject to a requirement under subsection (7C); and

(b) the person omits to do an act; and

(c) the omission breaches the requirement.

Penalty: 10 penalty units.

(7G) An offence against subsection (7F) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

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(7GA) Subsection (7F) does not apply in relation to a person and a requirement to notify a supply of a biological 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 (7D).

Note: A defendant bears an evidential burden in relation to the matter in subsection (7GA): see subsection 13.3(3) of the *Criminal Code*.

(7H) In recommending to the Governor-General that regulations should be made for the purposes of paragraph (7D)(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 (7A).

(8) In this section:

medical practitioner means a person who is registered, in a State or internal Territory, as a medical practitioner.

32CN Criminal offences relating to the giving of an authority to a health practitioner

(1) A person commits an offence if:

(a) the Secretary has authorised, under subsection 32CM(1), the person to supply a biological; and

(b) the person supplies the biological; and

(c) any of the following applies:

(i) the supply is not in accordance with the authority;

(ii) the supply is not in accordance with the conditions to which the authority is subject;

(iii) the supply is not in accordance with regulations made for the purpose of subsection 32CM(6); and

(d) either:

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

(ii) the use of the biological, if the biological 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:

(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 32CM(6).

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:

(a) the Secretary has authorised, under subsection 32CM(1), the person to supply a biological; and

(b) the person supplies the biological; and

(c) any of the following applies:

(i) the supply is not in accordance with the authority;

(ii) the supply is not in accordance with the conditions to which the authority is subject;

(iii) the supply is not in accordance with regulations made for the purpose of subsection 32CM(6).

Penalty: 500 penalty units.

(4A) A person commits an offence if:

(a) the Secretary has authorised, under subsection 32CM(1), the person to supply a biological; and

(b) the person supplies the biological; and

(c) any of the following applies:

(i) the supply is not in accordance with the authority;

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(ii) the supply is not in accordance with the conditions to which the authority is subject;

(iii) the supply is not in accordance with regulations made for the purpose of subsection 32CM(6).

Penalty: 100 penalty units.

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

(5) 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 32CM(7A) rules; and

(c) the person supplies a biological 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; and

(e) either:

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

(ii) the use of the biological, if the biological 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.

(7) A person commits an offence if:

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(a) the person is a health practitioner; and
(b) the person is included in a class of health practitioners specified in subsection 32CM(7A) rules; and
(c) the person supplies a biological 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.

(8) 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 32CM(7A) rules; and
(c) the person supplies a biological 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.

(9) An offence against subsection (8) is an offence of strict liability.

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Subdivision E—Exempting biologicals where substitutes are unavailable etc.

32CO Approvals where substitutes for biologicals 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 biological; or

(b) the importation into Australia of a specified biological and the supply in Australia of that biological;

if the Secretary is satisfied that:

(c) therapeutic goods included in the Register that could act as a substitute for the biological are unavailable or are in short supply; and

(d) any of the following conditions is satisfied:

(i) the biological that is the subject of the application for approval is registered or approved for general marketing in at least one foreign country specified by the Secretary under subsection (5);

(ii) an application that complies with section 32DA has been made for inclusion of the biological in the Register;

(iii) an application under section 32DD has been made for inclusion of the biological in the Register, and the application has passed preliminary assessment; and

(e) the biological is of a kind specified by the Secretary in a determination under subsection (6); and

(f) the approval is necessary in the interests of public health.

(1A) The Secretary may, by notice in writing, grant an approval to a person for:

(a) the importation into Australia of a specified biological; or

(b) the importation into Australia of a specified biological and the supply in Australia of that biological;

if the Secretary is satisfied that:

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(c) therapeutic goods included in the Register that could act as a substitute for the biological are unavailable or are in short supply; and

(d) either:

(i) the biological that is the subject of the application for approval is not registered or approved for general marketing in any of the foreign countries specified by the Secretary under subsection (5); or

(ii) the biological that is the subject of the application for approval is registered or approved for general marketing in at least one foreign country specified by the Secretary under subsection (5), but is not readily available for importation into, and supply in, Australia; and

(e) the biological 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 biological are acceptable; and

(g) the biological is of a kind specified by the Secretary in a determination under subsection (6); and

(h) the approval is necessary in the interests of public health.

(2) The Secretary may, by notice in writing, grant an approval to a person for:

(a) the importation into Australia of a specified biological; or

(b) the importation into Australia of a specified biological and the supply in Australia of that biological;

if the Secretary is satisfied that:

(c) there are no therapeutic goods that are included in the Register that could act as a substitute for the biological; and

(d) either:

(i) an application that complies with section 32DA has been made for inclusion of the biological in the Register; or

(ii) an application under section 32DD has been made for inclusion of the biological in the Register, and the application has passed preliminary assessment; and

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(e) the biological is of a kind specified by the Secretary in a determination under subsection (6); and

(f) the approval is necessary in the interests of public health.

Application for approval

(3) An application for an approval must:

(a) be made to the Secretary; and

(b) be accompanied by such information relating to the biological as is required by the Secretary.

Secretary's decision

(4) If an application for an approval is made, the Secretary must, after having considered the application, notify the applicant of the decision on the application as soon as practicable after making the decision and, in the case of a decision not to grant the approval, of 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 the kinds of biologicals 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.

(8) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission results in the breach of a condition of an approval under subsection (1), (1A) or (2).

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Penalty: 60 penalty units.

Period of approval

(9) The Secretary may grant an approval for such period as is specified in the notice of approval.

When approval lapses

(10) The approval lapses if:
(a) the period specified in the notice of approval expires; or
(b) a decision has been made on an application that has been made for inclusion of the biological in the Register.

(11) 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 biological, 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.

(12) 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 biological before that lapsing. The other approval may be expressed to take effect on the expiry of that period.

Approval not a legislative instrument

(13) An approval under subsection (1), (1A) or (2) is not a legislative instrument.

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Division 4—Including biologicals in the Register

Subdivision A—Preliminary

32D What this Division is about

A Class 1 biological can be included in the Register if a proper application is made and the applicant certifies various matters.

A biological other than a Class 1 biological can be included in the Register if a proper application is made and the Secretary is satisfied the biological is suitable for inclusion following an evaluation of the biological.

Subdivision B—Class 1 biologicals

32DA Application for inclusion in the Register

(1) A person may make an application to the Secretary to include a Class 1 biological in the Register.

(2) An application must:
  (a) be made in accordance with a form that is approved, in writing, by the Secretary; and
  (b) be accompanied by a statement certifying the matters mentioned in subsection (3); and
  (c) be delivered to an office of the Department specified in the form; and
  (d) be accompanied by the prescribed application fee.

(3) The applicant must certify that:
  (a) the biological is a Class 1 biological; and
  (b) the biological is safe for the purposes for which it is to be used; and

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(c) the biological conforms to every standard (if any) applicable to it; and

(d) both of the following are complied with in relation to the biological:

(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 under the regulations; and

(e) the biological complies with all prescribed quality or safety criteria that are applicable to it; and

(f) the biological does not contain substances that are prohibited imports for the purposes of the *Customs Act 1901*.

(4) 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.

32DB Inclusion of Class 1 biological in the Register

(1) If an application is made in accordance with section 32DA for a Class 1 biological to be included in the Register in relation to a person, the Secretary must include the biological in the Register in relation to the person.

Biological number

(2) If the Secretary includes the biological in the Register, the Secretary must assign a unique number to the biological. The number assigned may be any combination of numbers and either or both of letters and symbols.

Note: The number assigned is the biological number of the biological.

Certificate

(3) As soon as practicable after the biological has been included in the Register, the Secretary must give to the applicant a certificate of the inclusion of the biological in the Register.

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(4) The certificate must:
  (a) specify the biological number of the biological; and
  (b) specify the day on which the inclusion of the biological in the Register commences.

Duration of inclusion in the Register

(5) The biological remains included in the Register in relation to the person until the Secretary cancels the entry of the biological from the Register under this Part.

Note: The biological is taken not to be included in the Register while it is suspended: see section 32FD.

32DC Refusal to include Class 1 biological in the Register

If:
  (a) an application is made under subsection 32DA(1) to include a Class 1 biological in the Register; and
  (b) the Secretary refuses the application;

the Secretary must, as soon as practicable after the refusal, give the person notice of the refusal and of the reasons for the refusal.

Subdivision C—Biologicals other than Class 1 biologicals

32DD Application for inclusion in the Register

A person may make an application to the Secretary to include a biological, other than a Class 1 biological, in the Register.

32DDA Preliminary assessment of applications

(1) If an application is made under section 32DD for the inclusion of a biological in the Register, the Secretary must carry out an assessment of whether the requirements set out in subsection (2) of this section have been met in relation to the application.

(2) The requirements are as follows:
  (a) the application must be made:

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(i) in accordance with the form approved, in writing, by the Secretary for that class of biological; or

(ii) in such other manner as is approved, in writing, by the Secretary for that class of biological;

(b) the prescribed application fee for that class of biological 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 (9) for that class of biological; and

(ii) in a form determined under subsection (10) for that class of biological;

(e) if the Secretary so requires—the applicant must:

(i) deliver to the Department a reasonable number of samples of the biological; and

(ii) do so in a manner approved, in writing, by the Secretary.

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 passed preliminary assessment, the Secretary must give a written notice to the applicant stating that the application has passed preliminary assessment.

(5) Subsection (4) does not apply if the period within which the Secretary must, under section 32DE, evaluate the biological to which the application relates is prescribed by reference to the prescribed period within which the Secretary is required to consider an application under subsection 9D(3) to vary an entry in the Register.

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(6) If the application has not passed preliminary assessment, the Secretary must, by written notice given to the applicant, refuse the application.

Approval of different forms etc.

(7) For the purposes of paragraph (2)(a), the Secretary may approve different forms and manners for making applications for different classes of biologicals that are prescribed by the regulations for the purposes of section 32AA.

(8) 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.

Determination of kinds and forms of information

(9) The Secretary may, by legislative instrument, determine a kind of information for the purposes of the application of subparagraph (2)(d)(i) to a class of biological that is prescribed by the regulations for the purposes of section 32AA.

(10) The Secretary may, by legislative instrument, determine a form of information for the purposes of the application of subparagraph (2)(d)(ii) to a class of biological that is prescribed by the regulations for the purposes of section 32AA.

32DE Evaluation of biologicals

(1) If an application is made under section 32DD for a biological to be included in the Register in relation to a person, and the application has passed preliminary assessment, the Secretary must evaluate the biological for inclusion in the Register, having regard to:
  (a) whether the quality, safety and efficacy of the biological for the purposes for which it is to be used have been satisfactorily established; and
  (b) whether the presentation of the biological is acceptable; and

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(c) whether the biological conforms to any standard applicable to it; and

(d) whether:

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

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

are complied with in relation to the biological; and

(e) if a step in the manufacture of the biological has been carried out outside Australia and the biological is not exempt from the operation of Part 3-3—whether the manufacturing and quality control procedures used in the step are acceptable; and

(f) if a step in the manufacture of the biological has been carried out in Australia, the biological is not exempt from the operation of Part 3-3 and the person is not exempt from the operation of that Part in relation to that step—whether that step has been carried out in accordance with that Part; and

(g) whether the biological contains substances that are prohibited imports for the purposes of the *Customs Act 1901*; and

(h) whether all of the manufacturers of the biological are nominated as manufacturers of the biological in the application; and

(i) such other matters (if any) as the Secretary considers relevant.

(2) For the purposes of paragraph (1)(e), subsections 25(2), (2E), (2F) and (2G) apply in a way corresponding to the way in which they apply for the purposes of paragraph 25(1)(g).

32DEA Biologicals (priority applicant) determinations

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

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(2) A ***biologicals (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 32DD application that may be made by the person for the inclusion in the Register of a biological specified in the determination.

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

(a) applications for biologicals (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 biologicals (priority applicant) determination;

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

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

(6) A period prescribed under paragraph 63(2)(daa) for the evaluation of a biological covered by a section 32DD application for which the applicant is a priority applicant may be shorter than the period prescribed under that paragraph for the evaluation of a biological covered by a section 32DD application for which the applicant is not a priority applicant.

(7) The regulations may provide that, if:

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(a) a person is a priority applicant in relation to a section 32DD 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 biologicals (priority applicant) determination is in force under the regulations, the determination may be published on the Department's website.

(10) A biologicals (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 biologicals (priority applicant) determination.

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

32DF Inclusion of biological in the Register

(1) If:

(a) an application is made under section 32DD for a biological to be included in the Register in relation to a person; and

(aa) the application has passed preliminary assessment; and

(b) the Secretary decides that it is appropriate to include the biological in the Register after an evaluation under section 32DE; and

(c) no part of an evaluation fee under section 32DI that is due and payable by the person remains unpaid;

the Secretary must include the biological in the Register in relation to the person.

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Biological number

(2) If the Secretary includes the biological in the Register, the Secretary must assign a unique number to the biological. The number assigned may be any combination of numbers and either or both of letters and symbols.

Note: The number assigned is the biological number of the biological.

Certificate

(3) As soon as practicable after the biological has been included in the Register, the Secretary must give to the applicant a certificate of the inclusion of the biological in the Register.

(4) The certificate must:
(a) specify the biological number of the biological; and
(b) specify the day on which the inclusion of the biological in the Register commences.

Duration of inclusion in the Register

(5) The biological remains included in the Register in relation to the person until the Secretary cancels the entry of the biological from the Register under this Part.

Note: The biological is taken not to be included in the Register while it is suspended: see section 32FD.

32DG Refusal to include biological in the Register

If:
(a) an application is made under section 32DD to include a biological in the Register; and
(aa) the application has passed preliminary assessment; and
(b) the Secretary refuses the application;

the Secretary must, as soon as practicable after the refusal, give the person notice of the refusal and of the reasons for the refusal.

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32DH Lapsing of application

(1) An application under section 32DD for inclusion of a biological in the Register lapses if:

(a) any part of the evaluation fee payable in respect of the biological remains unpaid at the end of the period of 42 days after the day on which the part became due and payable; or

(b) 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 32JA, is false or misleading in a material particular; or

(c) the applicant fails to comply with a requirement under section 32JA to give information consisting of patient data in relation to the biological.

(2) In this section:

patient data, in relation to a biological, means information, derived from clinical trials, relating to individuals before, during and after the administration of the biological to those individuals, including, but not limited to, demographic, biochemical and haematological information.

32DI Evaluation fee

(1) If an application is made under section 32DD for a biological to be included in the Register, and the application has passed preliminary assessment, an evaluation fee specified in, or determined in accordance with, the regulations is payable by the applicant in respect of the evaluation of the biological for inclusion in the Register.

(2) The Secretary must notify the applicant in writing of the amount of the evaluation fee.

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32DJ When evaluation fee due for payment

(1) Subject to sections 32DK and 32DM, an evaluation fee payable by an applicant is due and payable on the day on which the applicant is notified of the amount of the evaluation fee.

(2) The evaluation fee is payable in the manner prescribed by the regulations.

32DK Payment of evaluation fee by instalments

(1) The regulations may provide for the payment of an evaluation fee to be made by such instalments and at such times as are ascertained in accordance with the regulations, and the evaluation 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 evaluation fee by instalments if any part of an instalment of that or any other evaluation fee payable by the person was unpaid immediately after the time when it became due for payment.

(3) If:

(a) the regulations make provision as mentioned in subsection (2); and

(b) an instalment of an evaluation fee under section 32DI was unpaid immediately after the time when it became due for payment;

the balance of the evaluation fee becomes due and payable immediately.

(4) Subsection (2) does not limit subsection (1).

32DL Recovery of evaluation fee

An evaluation fee may be recovered by the Commonwealth as a debt due to the Commonwealth.

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32DM Reduction of evaluation fee where evaluation not completed within prescribed period

(1) Nothing in section 32DI, 32DJ or 32DK requires the applicant to pay more than 3/4 of the evaluation fee before the completion of the evaluation if a period is prescribed under paragraph 63(2)(daa) for completing the evaluation.

(2) The Secretary must notify the applicant in writing of the day the evaluation is completed.

(3) If the evaluation is not completed within that period, the evaluation fee is 3/4 of the fee that, apart from this subsection, would have been the evaluation fee.

(4) If:

(a) the evaluation is completed within that period; and

(b) part of the evaluation fee under section 32DI is unpaid when the evaluation is completed;

that part becomes due and payable on the completion of the evaluation.

(5) For the purposes of this section, if a copy of the evaluation report, or a summary of that report, is given to either or both of the following:

(a) the applicant;

(b) a committee established under the regulations to advise the Secretary on applications to include biologicals in the Register where a period for evaluating the biologicals is prescribed under paragraph 63(2)(daa);

then the evaluation is taken to be completed immediately before the first copy or summary is so given.

Note: This subsection has the effect that if the applicant withdraws the application after being given a copy of the evaluation report, or a summary of that report, before the end of that period, the full evaluation fee is due and payable by the applicant.

(6) A notification under subsection (2) is not a legislative instrument.

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Subdivision D—Transitional provisions for existing biologicals

32DN Transitional provisions for existing biologicals

Biologicals currently included in the Register

(1) If, immediately before the commencement of this section, therapeutic goods that are a biological were included in relation to a person:

(a) in the part of the Register for goods known as registered goods; or

(b) in the part of the Register for goods known as listed goods; or

(c) in the part of the Register for medical devices included in the Register under Chapter 4;

then, as soon as practicable after the commencement of this section, the Secretary must:

(d) by writing, cancel the inclusion of the goods in that part; and

(e) include the biological in the Register under this Part in relation to the person; and

(f) vary the Register as a result of that cancellation and inclusion.

Pending applications

(2) If:

(a) before the commencement of this section, an application was made for the registration or listing of therapeutic goods that are a biological or for the inclusion of such goods in the Register under Chapter 4; and

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

(c) the application has not been, and is not, withdrawn either before or after that commencement; and

(d) the application is successful when it is finally determined; and

(e) the goods are included:

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(i) in the part of the Register for goods known as registered goods; or

(ii) in the part of the Register for goods known as listed goods; or

(iii) in the part of the Register for medical devices included in the Register under Chapter 4;

then, as soon as practicable after that inclusion, the Secretary must:

(f) by writing, cancel the inclusion of the goods in that part; and

(g) include the biological in the Register under this Part in relation to the person; and

(h) vary the Register as a result of that cancellation and inclusion.

(3) 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.

Notice of decisions

(4) The Secretary must give the person written notice of the cancellation and inclusion under subsection (1) or (2).

Biological number

(5) If the Secretary includes the biological in the Register under subsection (1) or (2), the Secretary must assign a unique number to the biological. The number assigned may be any combination of numbers and either or both of letters and symbols.

Note: The number assigned is the biological number of the biological.

Certificate

(6) As soon as practicable after the biological has been included in the Register under this Part, the Secretary must give to the person a certificate of the inclusion of the biological in the Register.

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(7) The certificate must:
  (a) specify the biological number of the biological; and
  (b) specify the day on which the inclusion of the biological in the Register under this Part commences.

Duration of inclusion in the Register

(8) The biological remains included in the Register in relation to the person until the Secretary cancels the entry of the biological from the Register under this Part.

Note: The biological is taken not to be included in the Register while it is suspended: see section 32FD.

Annual charge

(9) If, during a financial year, the Secretary includes a biological in the Register under subsection (1) or (2), subsection 4(1AA) of the *Therapeutic Goods (Charges) Act 1989* does not apply in relation to the biological for that financial year.

No review of decisions

(10) A decision under this section is taken not to be an initial decision for the purposes of section 60.

Subdivision E—Criminal offences and civil penalties

32DO Criminal offences for false statements in applications for including biologicals in the Register

(1) A person commits an offence if:
  (a) the person makes a statement; and
  (b) the statement is made in, or in connection with, an application for inclusion of a biological in the Register; and
  (c) the statement is false or misleading in a material particular; and
  (d) either:

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

(ii) the use of the biological, if the biological 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; and

(b) the statement is made in, or in connection with, an application for inclusion of a biological in the Register; and

(c) the statement 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 makes a statement; and

(b) the statement is made in, or in connection with, an application for inclusion of a biological in the Register; 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.

32DP Civil penalty for false statements in applications for including biologicals in the Register

A person contravenes this section if the person in, or in connection with, an application for inclusion of a biological in the Register, makes a statement that is false or misleading in a material particular.

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Maximum civil penalty:

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

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

32DQ Criminal offence and civil penalty for failing to notify adverse effects etc. of biological while it is included in the Register

Criminal offence

(1) A person commits an offence if:

(a) a biological is included in the Register in relation to the person; and

(b) the person knows that particular information is information of a kind to which subsection (3) applies; 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.

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

Civil penalty

(2) A person contravenes this subsection if:

(a) a biological is included in the Register in relation to the person; and

(b) the person knows that particular information is information of a kind to which subsection (3) applies; 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).

Maximum civil penalty:

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(a) for an individual—3,000 penalty units; and
(b) for a body corporate—30,000 penalty units.

Relevant information

(3) This subsection applies to information of the following kinds:
(a) information that contradicts information already given by the person under this Act in relation to the biological (including information given about the quality, safety or efficacy of the biological);
(b) information that indicates that the use of the biological in accordance with the recommendations for its use may have an unintended harmful effect;
(c) information that indicates that the biological, when used in accordance with the recommendations for its use, may not be as effective as the application for inclusion of the biological in the Register or information already given by the person under this Act suggests.

32DR Criminal offences and civil penalties for failing to notify adverse effects etc. of biological where application withdrawn or lapses

(1) If an application for inclusion of a biological in the Register is withdrawn or lapses, the Secretary may, within 14 days after the application is withdrawn or lapses, 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 to which subsection (2) applies; and
(b) if the applicant is aware of such information, to give the information to the Secretary in writing.

(2) This subsection applies to information of the following kinds:
(a) information that contradicts information already given by the person under this Act in relation to the biological (including

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information given about the quality, safety or efficacy of the biological);

(b) information that indicates that the use of the biological in accordance with the recommendations for its use may have an unintended harmful effect;

(c) information that indicates that the biological, when used in accordance with the recommendations for its use, may not be as effective as the application for inclusion of the biological in the Register or information already given by the person under this Act suggests.

Offences

(3) A person commits an offence if:

(a) the Secretary gives a notice to the person under subsection (1); and

(b) the person fails to comply with the notice within 30 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 subsection (1); 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.

Civil penalties

(5) A person contravenes this subsection if:

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(a) the Secretary gives a notice to the person under subsection (1); and
(b) the person fails to comply with the notice within 30 days after 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.

(6) A person contravenes this subsection if:
(a) the person gives information in purported compliance with a notice under subsection (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.

Subdivision F—Advice from Gene Technology Regulator

32DS Consultation with Gene Technology Regulator

(1) This section applies to an application for inclusion of a biological in the Register if the biological is, or contains, a GM product or a genetically modified organism.

(2) Subject to subsection (5), the Secretary must give written notice to the Gene Technology Regulator:
(a) stating that the application has been made; and
(b) requesting the Gene Technology Regulator to give advice about the application.

(3) If the Secretary gives the Gene Technology Regulator a notice under subsection (2), the Gene Technology Regulator may give written advice to the Secretary about the application.

(4) The advice is to be given within the period specified in the notice.

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(5) If an advice from the Gene Technology Regulator is in force under section 32DT in relation to a class of biologicals, the Secretary is not required to notify the Gene Technology Regulator under this section in relation to an application for inclusion in the Register of a biological belonging to that class.

(6) A notice under subsection (2) is not a legislative instrument.

32DT Secretary may seek advice about classes of GM products or genetically modified organisms

(1) The Secretary may request advice from the Gene Technology Regulator in relation to:

(a) biologicals that consist of, or that contain, a GM product belonging to a class of GM products specified in the request; or

(b) biologicals that consist of, or that contain, genetically modified organisms belonging to a class of genetically modified organisms specified in the request.

(2) A request for advice under subsection (1) must specify the matters to which the advice is to relate.

(3) If the Secretary requests advice from the Gene Technology Regulator under subsection (1), the Gene Technology Regulator may provide written advice in relation to the matters specified in the request.

(4) If the Gene Technology Regulator gives advice to the Secretary under subsection (3), the advice remains in force until it is withdrawn by the Gene Technology Regulator by written notice given to the Secretary.

32DU Secretary to take advice into account

If the Secretary receives advice from the Gene Technology Regulator:

(a) in response to a notice under section 32DS within the period specified in the notice; or

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(b) under section 32DT;

the Secretary must:

(c) ensure that the advice is taken into account in making a decision on the application to which the notice relates, or on an application to which the advice under section 32DT relates, as the case requires; and

(d) inform the Gene Technology Regulator of the decision on the application.

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Division 5—Conditions

32E What this Division is about

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

32EA Conditions applying automatically

Entry and inspection powers

(1) The inclusion of a biological in the Register is subject to a condition that the person in relation to whom the biological 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 the biological, complies with record-keeping conditions under paragraph 32EC(2)(c) or keeps documents that relate to the biological; and

(ii) while on those premises, to inspect those premises and any biological on those premises and to examine, take measurements of, conduct tests on or take samples of any biological on those premises or any thing on those premises that relates to any biological; 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

(iv) while on those premises, to inspect, and make copies of, any records kept in compliance with a condition under paragraph 32EC(2)(c); and

(v) while on those premises, to inspect, and make copies of, any documents that relate to the biological; and

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

(c) if requested to do so by an authorised person, make any record kept in compliance with a condition under paragraph 32EC(2)(c) available to the authorised person for inspection:

(i) if the authorised person requires the record to be made available immediately—immediately; and

(ii) if the authorised person requires the record to be made available at or before a time specified by the authorised person—at or before that time; and

(iii) in the form required by the authorised person.

(2) An authorised person is not authorised to enter premises as mentioned in subsection (1) unless the person has shown his or her identity card issued under section 52 if required by the occupier of the premises. For the purposes of this subsection, ***occupier***, in relation to premises, includes a person present at the premises who is in apparent control of the premises.

Delivery of samples

(3) The inclusion of a biological in the Register is subject to a condition that the person in relation to whom the biological is included in the Register will deliver a reasonable number of samples of the biological if the Secretary so requests:

(a) within the period, of not less than 14 days after the day the request is made, specified in the request; and

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

Manufacturing

(4) The inclusion of a biological in the Register is subject to a condition that the person in relation to whom the biological is included in the Register will:

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(a) if a manufacturer who was not nominated as a manufacturer of the biological in the application for inclusion of the biological in the Register is to become a manufacturer of a step in the manufacture of the biological—inform the Secretary in writing of that fact and of the name and address of that manufacturer before that manufacturer begins to carry out that step; and

(b) if premises that were not nominated in the application as premises to be used in the manufacture of the biological are to become premises used in a step in the manufacture of the biological—inform the Secretary in writing of that fact and of the name and address of the new premises before the premises are first so used.

(5) The inclusion of a biological, other than a Class 1 biological, in the Register is subject to a condition that:

(a) each step in the manufacture of the biological that is carried out in Australia is carried out by a person who is the holder of a licence to carry out that step or who is exempt from the operation of Part 3-3 in relation to that step; and

(b) each step in the manufacture of the biological that is carried out outside Australia is the subject of a certification in force under subsection 32EB(2).

(6) Subsection (5) does not apply if the biological is exempt from the operation of Part 3-3.

(7) Paragraph (5)(b) does not apply in relation to a step that was the subject of the evaluation under section 32DE. This subsection ceases to apply in relation to that step if either or both of the following occur:

(a) that step begins to be carried out at premises that are different from the premises in respect of which that evaluation was conducted;

(b) that step begins to be carried out by a manufacturer that is different from the manufacturer in respect of which that evaluation was conducted.

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Expiry date

(8) The inclusion of a biological in the Register is subject to a condition that the person in relation to whom the biological is included in the Register will not supply a batch of the biological in Australia, or export a batch of the biological from Australia, after the expiry date for the biological.

Advertising

(9) The inclusion of a biological in the Register is subject to a condition that the person in relation to whom the biological is included in the Register will not, by any means, advertise the biological for an indication other than an indication accepted in relation to that inclusion.

32EB Certification of manufacturing steps outside Australia

(1) The person in relation to whom a biological, other than a Class 1 biological, is included in the Register may apply to the Secretary for a certification under this section of a step in the manufacture of the biological that is to be carried out outside Australia.

(2) If an application is made to the Secretary under this section, the Secretary may, by writing, certify that the manufacturing and quality control procedures used in that step are acceptable. The Secretary must give the person written notice of the certification.

(3) In deciding whether to give the certification, subsections 25(2), (2E), (2F) and (2G) apply in a way corresponding to the way in which they apply for the purposes of paragraph 25(1)(g).

32EC Imposition of conditions by legislative instrument

(1) The inclusion of a biological in the Register is subject to the conditions set out in a determination under subsection (2).

(2) The Minister may, by legislative instrument, make a determination setting out conditions for the purposes of subsection (1), being conditions that relate to:

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(a) the manufacture of the biological; or
(b) the custody, use, supply, disposal or destruction of the biological; or
(c) the keeping of records relating to the biological; or
(ca) reporting requirements relating to the biological; or
(d) matters dealt with in, or matters additional to matters dealt with in, standards applicable to the biological; or
(e) such other matters relating to the biological as the Minister thinks appropriate.

(3) Without limiting subsection (2), different conditions may be specified for different classes of biologicals.

32ED Imposition of conditions at time biological included in the Register

(1) If the Secretary includes a biological in the Register in relation to a person, the Secretary may, by notice in writing given to the person, impose conditions on the inclusion of the biological in the Register.

(2) A notice under subsection (1) is not a legislative instrument.

32EE Imposition or variation or removal of conditions after biological included in the Register

(1) The Secretary may, by notice in writing given to the person in relation to whom a biological is included in the Register, impose new conditions on the inclusion or vary or remove conditions imposed under section 32ED or this subsection.

(2) The Secretary's power under subsection (1) may be exercised at the request of the person concerned or on the Secretary's own initiative. A request must be accompanied by the prescribed fee.

(3) The imposition or variation or removal of a condition under subsection (1) takes effect:

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(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 28 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 28 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 a later day specified in the notice, being a day not earlier than 28 days after the notice is given to the person.

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

(4) A notice under subsection (1) is not a legislative instrument.

32EF Criminal offences for breach of condition

(1) A person commits an offence if:

(a) a biological 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 biological 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.

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(4) A person commits an offence if:
  (a) a biological 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 biological in the Register.

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

(5) A person commits an offence if:
  (a) a biological 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 biological in the Register.

  Penalty: 100 penalty units.

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

32EG Civil penalty for breach of condition

A person contravenes this section if:
  (a) a biological 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 biological in the Register.

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—Suspension from the Register

32F What this Division is about

The Secretary may suspend biologicals from the Register in certain circumstances. A biological that is suspended is taken not to be included in the Register for most purposes.

32FA Suspension of biological from the Register

(1) The Secretary may, by written notice given to a person in relation to whom a biological is included in the Register, suspend the biological 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 biological 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 biological would not cause a potential risk of death, serious illness or serious injury if the biological 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 biological from the Register under Division 7 (other than because of paragraph 32GA(1)(a), (d) or (g)).

Notice of proposed suspension in some cases

(2) However, before suspending a biological from the Register because it is likely that there are grounds for cancelling the entry of the biological from the Register under section 32GC, the Secretary must:

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

(b) invite the person to make written submissions to the Secretary in relation to the proposed suspension within the period specified in the notice (being not less than 28 days after the day the notice is given).

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

Period of suspension

(4) A notice under subsection (1) must specify the period of the suspension (which must not exceed 6 months).

Note: Section 32FB deals with when the suspension takes effect and extensions of the suspension.

Publication

(5) As soon as practicable after giving a notice under subsection (1), the Secretary must cause to be published in the *Gazette* or on the Department's website a notice setting out particulars of the suspension.

Notice not a legislative instrument

(6) A notice under subsection (1) is not a legislative instrument.

32FB When suspension takes effect etc.

(1) A suspension under section 32FA takes effect:

(a) if the notice under subsection 32FA(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

(b) in any other case—on a later day specified in the notice, being a day not earlier than 28 days after the notice is given to the person.

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(2) The suspension has effect until:
  (a) the Secretary revokes it under section 32FC; or
  (b) the end of:
    (i) the period specified under subsection 32FA(4); or
    (ii) if the period is extended under subsection (3) of this section—the period as so extended.

Extension of suspension

(3) The Secretary may, by written notice given to the person, extend the period specified under subsection 32FA(4) by a further specified period not exceeding 6 months.

Publication

(4) As soon as practicable after giving a notice under subsection (3), the Secretary must cause to be published in the *Gazette* or on the Department's website a notice setting out particulars of the extension.

Notice not a legislative instrument

(5) A notice under subsection (3) is not a legislative instrument.

32FC Revocation of suspension

(1) The Secretary must revoke a suspension under section 32FA, by written notice given to the person in relation to whom the biological is included in the Register, if the Secretary is satisfied that:
  (a) the ground on which the biological was suspended from the Register no longer applies; and
  (b) there are no other grounds for suspending the biological from the Register.

(2) The Secretary's power to revoke the suspension may be exercised:
  (a) if the person in relation to whom the biological is included in the Register applies in writing to the Secretary; or

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(b) on the Secretary's own initiative.

Publication

(3) As soon as practicable after giving a notice under subsection (1), the Secretary must cause to be published in the *Gazette* or on the Department's website a notice setting out particulars of the revocation.

Notice of refusal to revoke suspension

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

Notice not a legislative instrument

(5) A notice under subsection (1) is not a legislative instrument.

32FD Effect of suspension

(1) If a biological is suspended from the Register under section 32FA, the biological is taken, for the purposes of this Act (other than section 32DQ, Division 5, sections 32FB and 32FC and Divisions 7 and 9), not to be included in the Register while the suspension has effect.

Note: Dealing in a biological that is not included in the Register may be a criminal offence or may contravene a civil penalty provision: see Division 2.

(2) While the suspension has effect, the Secretary's power under Division 7 to cancel the entry of the biological from the Register is not affected.

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Division 7—Cancellation from the Register

32G What this Division is about

The Secretary may cancel inclusions of biologicals in the Register in certain circumstances.

32GA Immediate cancellation of biological from the Register in various circumstances

(1) The Secretary may, by written notice given to the person in relation to whom a biological is included in the Register, cancel the entry of the biological 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 biological continued to be included in the Register; or

(b) the biological ceases to be a biological or the biological becomes covered by an order under section 7 declaring goods not to be therapeutic goods; or

(c) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2); or

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

(e) the biological contains substances that are prohibited imports for the purposes of the *Customs Act 1901*; or

(f) the Secretary is satisfied that a statement made in, or in connection with, the application for including the biological in the Register was false or misleading in a material particular; or

(g) the annual charge payable under the *Therapeutic Goods (Charges) Act 1989* in respect of the inclusion of the biological in the Register is not paid within 28 days after it becomes payable; or

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(h) the person has failed to comply with a condition mentioned in subsection 32EA(1) or (3); or

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

(k) there is a breach, involving the biological, of an applicable provision of the Therapeutic Goods Advertising Code or any other requirement relating to advertising applicable under Part 5-1 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 the biological is misleading to a significant extent.

(2) A notice under subsection (1) is not a legislative instrument.

32GB Immediate cancellation of biological from the Register after failure to comply with information gathering notice

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

(a) the Secretary gives to the person a notice under section 32JA requiring the person to give to the Secretary information, or to produce to the Secretary documents, relating to the biological; and

(b) the notice under section 32JA is given for the purposes of ascertaining whether any of the certifications by the person under subsection 32DA(3) in relation to the biological are incorrect; and

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(c) the person fails to comply with the notice under section 32JA within a further 14 days after the end of the period specified in that notice.

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

(a) the Secretary gives to the person a notice under section 32JA requiring the person to give to the Secretary information, or to produce to the Secretary documents, relating to whether the biological is 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 the biological is not being supplied in Australia, imported into Australia or exported from Australia; or

(ii) the person fails to comply with the notice under section 32JA within a further 14 days after the end of the period specified in that notice.

(3) A notice under subsection (1) or (2) is not a legislative instrument.

32GC Cancellation of biological from the Register after notice of proposed cancellation

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

(a) it appears to the Secretary that the quality, safety or efficacy of the biological is unacceptable or that the presentation of the biological is not acceptable; or

(b) the biological has changed so that it has become separate and distinct from the biological as so included; or

Note: Section 32AB deals with when a biological is separate and distinct from other biologicals.

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(c) the person has failed to comply with a condition to which the inclusion of the biological is subject (except a condition mentioned in subsection 32EA(1) or (3)); or

(d) the Secretary gives to the person a notice under section 32JA:

(i) that requires the person to give to the Secretary information, or to produce to the Secretary documents, relating to the biological; and

(ii) in respect of which section 32GB does not apply;

and the person fails to comply with that notice within a further 14 days after the end of the period specified in that notice; or

(e) the person contravenes subsection 32DQ(1) or (2) in relation to the biological; or

(f) the biological does not conform to a standard applicable to it; or

(fa) the person contravenes a direction, or a condition of a direction, given to the person under subsection 42DV(1) in relation to the advertising of the biological; or

(fb) 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) in relation to the advertising of the biological; or

(g) either of the following has not been complied with in relation to the biological:

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

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

(2) However, before cancelling the entry of the biological 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) invite the person to make written submissions to the Secretary in relation to the proposed cancellation within the

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period specified in the notice (being not less than 28 days after the day the notice is given).

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

(4) A notice under subsection (1) is not a legislative instrument.

32GD Revocation of cancellation of biological upon request

(1) If:

(a) the Secretary cancels the entry of a biological from the Register because of the request of a person made under paragraph 32GA(1)(d); and

(b) before the end of the period of 90 days beginning on the day the biological 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;

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.

32GDA Revocation of cancellation of biological upon request—payment of annual charge

(1) If:

(a) the Secretary cancels the entry of a biological from the Register because the annual charge payable under the *Therapeutic Goods (Charges) Act 1989* in respect of the inclusion of the biological in the Register was not paid within 28 days after it becomes payable; and

(b) before the end of the period of 90 days beginning on the day the biological ceased to be included in the Register, the

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person requests, in writing, the Secretary to revoke the cancellation; and

(c) the annual charge payable under the *Therapeutic Goods (Charges) Act 1989* in respect of the inclusion of the biological in the Register has been paid; and

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

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.

32GE 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 of a biological from the Register, a notice setting out particulars of the cancellation.

32GF Date of effect of cancellation of entries from Register

If the Secretary cancels an entry of a biological from the Register, the cancellation has effect on the day on which the notice of cancellation is given to the person in relation to whom the biological was included in the Register.

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Division 8—Public notification, and recall, of biologicals

32H What this Division is about

The Secretary may require a person to recall biologicals, or to inform the public about biologicals, that do not comply with requirements or cannot lawfully be supplied. There are criminal offences and a civil penalty for breaching such a requirement.

32HA Public notification, and recall, of biologicals

(1) The Secretary may, by notice in writing, impose requirements, relating to a biological, on a person if:

(a) any of the circumstances referred to in the 2nd column of an item in the following table occur in relation to the biological; and

(b) the person is referred to in the 3rd column of that item.

Circumstances in which requirements may be imposed

Item	Circumstance relating to biological	Person subject to requirements
1	It is supplied while it is included in the Register, but the Secretary is satisfied that it does not conform with a standard applicable to it	The person in relation to whom it is included in the Register
2	It is a biological, other than a Class 1 biological, and it is supplied while it is included in the Register, but the Secretary is satisfied that the manufacturing principles have not been observed in its manufacture	The person in relation to whom it is included in the Register

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Circumstances in which requirements may be imposed

Item	Circumstance relating to biological	Person subject to requirements
3	It is supplied while: (a) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2); or (b) it is exempt under section 32CB; or (c) it is the subject of an approval under subsection 32CK(1); or (d) it is the subject of an authority under subsection 32CM(1) or (7A); or (e) it is the subject of an approval under subsection 32CO(1), (1A) or (2); but the Secretary is satisfied that it does not conform with a standard applicable to it	The person supplying it
4	It is a biological, other than a Class 1 biological, and it is supplied while: (a) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2); or (b) it is exempt under section 32CB; or (c) it is the subject of an approval under subsection 32CK(1); or (d) it is the subject of an authority under subsection 32CM(1) or (7A); or (e) it is the subject of an approval under subsection 32CO(1), (1A) or (2); but the Secretary is satisfied that the manufacturing principles have not been observed in its manufacture	The person supplying it

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Circumstances in which requirements may be imposed		
Item	**Circumstance relating to biological**	**Person subject to requirements**
5	It is supplied while: (a) it is not included in the Register; and (b) the person is not exempt under subsection 32CA(1) in relation to the biological and the biological is not exempt under subsection 32CA(2); and (c) it is not exempt under section 32CB; and (d) it is not the subject of an approval under subsection 32CK(1); and (e) it is not the subject of an authority under subsection 32CM(1) or (7A); and (f) it is not the subject of an approval under subsection 32CO(1), (1A) or (2)	The person supplying it
6	It is supplied while it is exempt under section 32CB, and the Secretary is satisfied that it is not fit to be used for its intended purpose	The person supplying it
7	It is counterfeit goods (within the meaning of section 42E)	The person supplying it
8	It is a biological, other than a Class 1 biological, and it is supplied while it is included in the Register, but the Secretary is satisfied that there is a breach of the condition set out in subsection 32EA(5)	The person in relation to whom it is included in the Register
9	It appears to the Secretary that the quality, safety or efficacy of the biological is unacceptable or that the presentation of the biological is not acceptable	The person in relation to whom the biological is included in the Register
10	It has been suspended from the Register	The person in relation to whom it is included in the Register
11	Its entry has been cancelled from the Register	The person in relation to whom it is included in the Register

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(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 the biological that has been 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 the circumstances referred to in paragraph (1)(a) have occurred in relation to the biological;

(ba) 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) the biological;

(ii) the circumstances referred to in paragraph (1)(a);

(c) 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 supply of the biological;

(d) 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 the biological has been supplied.

(3) If the circumstances referred to in paragraph (1)(a) apply only to a batch of the biological, the Secretary may limit the imposition of the requirements to that batch.

(4) A requirement to recall a biological under this section does not apply to a biological that cannot be recalled because it has been administered to, or applied in the treatment of, a person.

(5) A notice under subsection (1) is not a legislative instrument.

32HB 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

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requirement under section 32HA, a notice setting out particulars of the requirement.

32HC Criminal offences for non-compliance with requirements

(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 32HA; 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 32HA.

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

(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 32HA.

Penalty: 100 penalty units.

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

32HD Civil penalty for non-compliance with requirements

A person contravenes this section 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 requirement imposed on the person under section 32HA.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

32HE Powers of suspension and cancellation unaffected

Imposition of a requirement under section 32HA does not affect the Secretary's power to suspend a biological, or cancel the entry of a biological, from the Register under this Part.

32HF Saving of other laws

This Division 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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Division 9—Obtaining information or documents

Subdivision A—Preliminary

32J What this Division is about

The Secretary may by written notice seek information or documents relating to:

- applications for inclusion of biologicals in the Register; or
- biologicals included in the Register; or
- the supply of, and other matters relating to, biologicals covered by exemptions under Division 3.

There are criminal offences for failing to comply with a notice and for giving false or misleading information or documents and civil penalties for giving false or misleading information or documents.

Subdivision B—Obtaining information or documents for biologicals included or proposed to be included in the Register

32JA Secretary may require information or documents

(1) The Secretary may, by written notice given to a person:
  (a) who is an applicant for the inclusion of a biological in the Register; or
  (b) in relation to whom a biological is included in the Register; or
  (c) in relation to whom a biological was, at any time during the previous 5 years, included in the Register;

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require the person to give to the Secretary information, or to produce to the Secretary documents, that are relevant to one or more of the following:

(d) the formulation of the biological;

(e) the composition of the biological;

(f) the design specifications of the biological;

(g) the quality of the biological;

(h) the method and place of manufacture or preparation of the biological and the procedures employed to ensure that proper standards are maintained in the manufacture and handling of the biological;

(i) the presentation of the biological;

(j) the safety and efficacy of the biological for the purposes for which it is to be used;

(k) whether the biological conforms with a standard applicable to it;

(l) whether the biological complies with conditions (if any) on the inclusion of the biological in the Register;

(m) whether either of the following has not been complied with in relation to the biological:

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

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

(n) if the biological is included in the Register in relation to the person—whether the biological is being:

(i) supplied in Australia; or

(ii) imported into Australia; or

(iii) exported from Australia;

(o) the regulatory history of the biological in another country;

(p) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

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(2) 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; and
  (b) in the form specified in the notice.

Note: Section 32JB contains criminal offences for failing to comply with the notice and for giving false or misleading information or documents and section 32JC contains a civil penalty for giving false or misleading information or documents.

(3) The form may require or permit 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.

(4) If a notice is given under subsection (1) to a person covered by paragraph (1)(c), then paragraphs (1)(d) to (p) (to the extent to which they are relevant) apply in relation to that part of the period of 5 years before the notice was given during which the biological was included in the Register.

32JB 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 32JA; and
  (aa) the person is covered by paragraph 32JA(1)(b) or (c); 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 cancellation of the entry of a biological in the Register (see Divisions 6 and 7).

(1A) Subsection (1) does not apply if the person has a reasonable excuse.

Note: A defendant bears an evidential burden in relation to the matter in subsection (1A): see subsection 13.3(3) of the *Criminal Code*.

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(1B) A person commits an offence if:

(a) the person is given a notice under section 32JA; and

(b) the person is covered by paragraph 32JA(1)(b) or (c); and

(c) the person fails to comply with the notice.

Penalty: 100 penalty units.

(1C) An offence against subsection (1B) is an offence of strict liability.

(1D) Subsection (1B) does not apply if the person has a reasonable excuse.

Note: A defendant bears an evidential burden in relation to the matter in subsection (1D): see subsection 13.3(3) of the *Criminal Code*.

(2) A person commits an offence if:

(a) the person is given a notice under section 32JA in relation to a biological; 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; and

(d) either:

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

(ii) the use of the biological, if the biological 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 (5) instead: see section 53A.

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

(5) A person commits an offence if:

(a) the person is given a notice under section 32JA; 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: Imprisonment for 12 months or 1,000 penalty units, or both.

(6) A person commits an offence if:
(a) the person is given a notice under section 32JA; 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: 100 penalty units.

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

32JC 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 32JA; 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.

32JD Self-incrimination

(1) A person is not excused from giving information or producing a document under section 32JA on the ground that the information or

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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 32JB(1), (1B), (2), (5) or (6); or

(e) in civil proceedings, except proceedings under section 42Y for a contravention of section 32JC.

Subdivision C—Obtaining information or documents for biologicals covered by exemptions

32JE Secretary may require information etc. about biologicals exempt under the regulations

(1) If a person is exempt under subsection 32CA(1) in relation to a biological, the Secretary may give the person a written notice requiring the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to one or more of the following:

(a) the supply of the biological;

(b) the handling of the biological;

(c) the monitoring of the supply of the biological;

(d) the results of the supply of the biological;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

(2) If a biological is exempt under subsection 32CA(2), the Secretary may give the sponsor of the biological a written notice requiring the sponsor to give to the Secretary specified information, or to

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produce to the Secretary specified documents, relating to one or more of the following:

(a) the supply of the biological;
(b) the handling of the biological;
(c) the monitoring of the supply of the biological;
(d) the results of the supply of the biological;
(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

Compliance

(3) A person given a notice under subsection (1) or (2) 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; and
(b) in the form specified in the notice.

Note: Section 32JI contains criminal offences for failing to comply with the notice and for giving false or misleading information or documents and section 32JJ 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:
(a) on a specified kind of data processing device; or
(b) by way of a specified kind of electronic transmission.

32JF Secretary may require information etc. about biologicals exempt to deal with emergencies

(1) This section applies to a person who is required to comply with a condition of an exemption of a biological under section 32CB.

(2) The Secretary may, by written notice given to the person, require the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to one or more of the following:

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(a) the supply of the biological;
(b) the handling of the biological;
(c) the monitoring of the supply of the biological;
(d) the results of the supply of the biological;
(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

(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; and
(b) in the form specified in the notice.

Note: Section 32JI contains criminal offences for failing to comply with the notice and for giving false or misleading information or documents and section 32JJ 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:
(a) on a specified kind of data processing device; or
(b) by way of a specified kind of electronic transmission.

32JG Secretary may require information etc. about biologicals exempt for special and experimental uses

Approval under subsection 32CK(1)

(1) The Secretary may give to a person who is granted an approval under subsection 32CK(1) in relation to a biological a written notice requiring the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to one or more of the following:
(a) the supply of the biological;
(b) the handling of the biological;
(c) the monitoring of the supply of the biological;

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(d) the results of the supply of the biological;
(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

Approval under subsection 32CK(1)—use by another person

(2) The Secretary may give to a person (the ***experimenter***) using a biological that is the subject of an approval:
(a) that is held by another person under subsection 32CK(1); and
(b) that covers the importation into Australia, or the supply in Australia, of the biological for use solely for experimental purposes in humans;

a written notice requiring the experimenter to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to either or both of the following:
(c) the use of the biological;
(d) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

Authority under subsection 32CM(1)

(3) The Secretary may give to a person who is granted an authority under subsection 32CM(1) in relation to a biological a written notice requiring the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to one or more of the following:
(a) the supply of the biological;
(b) the handling of the biological;
(c) the monitoring of the supply of the biological;
(d) the results of the supply of the biological;
(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

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Authority under subsection 32CM(7A) rules

(3A) If a person is authorised, by subsection 32CM(7A) rules, to supply a biological, the Secretary may give the person a written notice requiring the person to give the Secretary specified information, or to produce to the Secretary specified documents, relating to one or more of the following:

(a) the supply of the biological;

(b) the handling of the biological;

(c) the monitoring of the supply of the biological;

(d) the results of the supply of the biological;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

Compliance

(4) A person given a notice under subsection (1), (2), (3) or (3A) 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; and

(b) in the form specified in the notice.

Note: Section 32JI contains criminal offences for failing to comply with the notice and for giving false or misleading information or documents and section 32JJ contains a civil penalty for giving false or misleading information or documents.

(5) The form may require or permit 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.

32JH Secretary may require information etc. about biologicals exempt where substitutes are unavailable etc.

(1) The Secretary may give to a person who is granted an approval under subsection 32CO(1), (1A) or (2) in relation to a biological a

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written notice requiring the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to one or more of the following:

(a) the supply of the biological;
(b) the handling of the biological;
(c) the monitoring of the supply of the biological;
(d) the results of the supply of the biological;
(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

Compliance

(2) A person given a notice under subsection (1) 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; and
(b) in the form specified in the notice.

Note: Section 32JI contains criminal offences for failing to comply with the notice and for giving false or misleading information or documents and section 32JJ contains a civil penalty for giving false or misleading information or documents.

(3) The form may require or permit 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.

32JI 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 32JE, 32JF, 32JG or 32JH; and
(b) the person fails to comply with the notice.

Penalty: 500 penalty units.

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(1A) A person commits an offence if:

(a) the person is given a notice under section 32JE, 32JF, 32JG or 32JH; and

(b) the person fails to comply with the notice.

Penalty: 100 penalty units.

(1B) An offence against subsection (1A) is an offence of strict liability.

(2) A person commits an offence if:

(a) the person is given a notice under section 32JE, 32JF, 32JG or 32JH; 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.

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

(3) A person commits an offence if:

(a) the person is given a notice under section 32JE, 32JF, 32JG or 32JH; 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: 100 penalty units.

(4) An offence against subsection (3) is an offence of strict liability.

32JJ Civil penalty for giving false or misleading information or document in compliance with a notice

A person contravenes this section if:

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(a) the person is given a notice under section 32JE, 32JF, 32JG or 32JH; 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.

32JK Self-incrimination

(1) A person is not excused from giving information or producing a document under section 32JE, 32JF, 32JG or 32JH 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 32JI(1), (1A), (2) or (3); or
(e) in civil proceedings, except proceedings under section 42Y for a contravention of section 32JJ.

Subdivision D—Inspecting, copying and retaining documents

32JL Secretary may inspect and copy documents

The Secretary may inspect a document produced under section 32JA, 32JE, 32JF, 32JG or 32JH and may make and retain copies of the whole or a part of the document.

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32JM Secretary may retain documents

(1) The Secretary may take possession of a document produced under section 32JA, 32JE, 32JF, 32JG or 32JH, and retain it for as long as is reasonably necessary.

(2) The person otherwise entitled to possession of the document 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 3-3—Manufacturing of therapeutic goods

33A Application of this Part to medical devices

This Part does not apply to a medical device unless Part 3-2 applies to the device.

Note: Section 15A sets out when Part 3-2 applies to a medical device.

33B Application of this Part to biologicals

This Part does not apply to a Class 1 biological.

34 Exempt goods and exempt persons

(1) The regulations may exempt therapeutic goods or a class of therapeutic goods identified in the regulations from the operation of this Part.

(2) The regulations may exempt a person identified in the regulations from the operation of this Part in relation to the manufacture or a step in the manufacture of therapeutic goods or a class of therapeutic goods identified in the regulations.

(3) Where the regulations revoke an exemption, the revocation takes effect on the day, not being earlier than 28 days after the day on which the regulations are made, as is specified in the regulations.

35 Criminal offences relating to manufacturing therapeutic goods

(1) A person commits an offence if:
  (a) the person, at premises in Australia, carries out a step in the manufacture of therapeutic goods (other than goods exempt under section 18A or 32CB); and
  (b) the goods are for supply for use in humans; and
  (c) none of the following applies:
    (i) the goods are exempt goods;

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(ii) the person is an exempt person in relation to the manufacture of the goods;

(iii) the person is the holder of a licence that is in force that authorises the carrying out of that step in relation to the goods at those premises; 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 the person carried out the step in the manufacture of the goods.

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, at premises in Australia, carries out a step in the manufacture of therapeutic goods (other than goods exempt under section 18A or 32CB); and

(b) the goods are for supply for use in humans; and

(c) none of the following applies:

(i) the goods are exempt goods;

(ii) the person is an exempt person in relation to the manufacture of the goods;

(iii) the person is the holder of a licence that is in force that authorises the carrying out of that step in relation to the goods at those premises.

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

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Section 35

(4A) A person commits an offence if:

(a) the person, at premises in Australia, carries out a step in the manufacture of therapeutic goods (other than goods exempt under section 18A or 32CB); and

(b) the goods are for supply for use in humans; and

(c) none of the following applies:

(i) the goods are exempt goods;

(ii) the person is an exempt person in relation to the manufacture of the goods;

(iii) the person is the holder of a licence that is in force that authorises the carrying out of that step in relation to the goods at those premises.

Penalty: 100 penalty units.

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

(5) A person commits an offence if:

(a) the person, at premises in Australia, carries out a step in the manufacture of therapeutic goods; and

(b) the goods are for supply for use in humans; and

(c) the goods are exempt under section 18A or 32CB; and

(d) the person is not the holder of a licence that:

(i) is in force; and

(ii) authorises the carrying out of that step in relation to the goods at those premises; and

(e) 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

(f) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because the person carried out the step in the manufacture of the goods.

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 (9) instead: see section 53A.

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

(9) A person commits an offence if:

(a) the person, at premises in Australia, carries out a step in the manufacture of therapeutic goods; and

(b) the goods are for supply for use in humans; and

(c) the goods are exempt under section 18A or 32CB; and

(d) the person is not the holder of a licence that:

(i) is in force; and

(ii) authorises the carrying out of that step in relation to the goods at those premises.

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

(10) A person commits an offence if:

(a) the person, at premises in Australia, carries out a step in the manufacture of therapeutic goods; and

(b) the goods are for supply for use in humans; and

(c) the goods are exempt under section 18A or 32CB; and

(d) the person is not the holder of a licence that:

(i) is in force; and

(ii) authorises the carrying out of that step in relation to the goods at those premises.

Penalty: 100 penalty units.

(11) An offence against subsection (10) is an offence of strict liability.

35A Civil penalties relating to manufacturing therapeutic goods

(1) A person contravenes this subsection if:

(a) the person carries out a step in the manufacture of therapeutic goods at premises in Australia; and

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(b) the goods are for supply for use in humans; and
(c) the goods are not exempt under section 18A or 32CB; and
(d) none of the following applies:
(i) the goods are exempt goods;
(ii) the person is an exempt person in relation to the manufacture of the goods;
(iii) the person is the holder of a licence that is in force that authorises the carrying out of that step in relation to the goods at those premises.

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) the person carries out a step in the manufacture of therapeutic goods at premises in Australia; and
(b) the goods are for supply for use in humans; and
(c) the goods are exempt under section 18A or 32CB; and
(d) the person is not the holder of a licence that:
(i) is in force; and
(ii) authorises the carrying out of that step in relation to the goods at those premises.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

35B Criminal offences relating to breaching a condition of a licence

(1) A person commits an offence if:
(a) the person holds a licence; and
(b) the person does an act or omits to do an act; and
(c) the act or omission breaches a condition of the licence; and
(d) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

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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:
(a) the person holds a licence; and
(b) the person does an act or omits to do an act; and
(c) the act or omission breaches a condition of the licence.

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

(5) A person commits an offence if:
(a) the person holds a licence; and
(b) the person does an act or omits to do an act; and
(c) the act or omission breaches a condition of the licence.

Penalty: 100 penalty units.

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

35C Civil penalty relating to breaching a condition of a licence

A person contravenes this section if:
(a) the person holds a licence; and
(b) the person does an act or omits to do an act; and
(c) the act or omission breaches a condition of the licence.

Maximum civil penalty:
(a) for an individual—5,000 penalty units; and
(b) for a body corporate—50,000 penalty units.

36 Manufacturing principles

(1) The Minister may, from time to time, determine written principles to be observed in the manufacture of therapeutic goods for use in humans.

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(2) The manufacturing principles may relate to:

(a) the standards to be maintained, and the equipment to be used, at premises used for the manufacturing of therapeutic goods for use in humans; or

(b) procedures for quality assurance and quality control to be employed in the manufacturing of therapeutic goods for use in humans; or

(c) the qualifications and experience required of persons employed in the manufacture of therapeutic goods for use in humans; or

(d) the manufacturing practices to be employed in the manufacturing of therapeutic goods for use in humans; or

(e) other matters relevant to the quality, safety and efficacy of therapeutic goods for use in humans that are manufactured in Australia;

and may include codes of good manufacturing practice.

(4) Manufacturing principles are legislative instruments.

37 Application for licence

(1) An application for a licence must:

(a) be made in accordance with a form approved by the Secretary; and

(b) identify the therapeutic goods or classes of therapeutic goods that the applicant proposes to manufacture; and

(c) in accordance with subsections (1A) and (1B), identify one or more manufacturing sites that will be used in the manufacture of those goods; and

(d) identify the steps in the manufacture of those goods that the applicant proposes to carry out under the licence; and

(da) if the applicant proposes to carry out steps in the manufacture of blood or blood components under the licence—contain information relating to those steps set out in regulations made for the purposes of this paragraph; and

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(e) state the names, qualifications and experience of the persons who are to have control of the production of the goods and of the quality control measures that are to be employed; and

(f) be delivered to an office of the Department specified in the form; and

(g) be accompanied by the prescribed application fee.

Manufacturing sites

(1A) Subject to subsection (1B), an application under subsection (1) must relate to one manufacturing site only. This does not prevent other applications from relating to other manufacturing sites.

(1B) If an applicant is of the view that, having regard to the guidelines under section 38A, a licence could be granted covering 2 or more manufacturing sites, the applicant may:

(a) identify those sites in the application; and

(b) state the applicant's reasons for the applicant's view.

Further information

(2) The Secretary may, by notice in writing given to an applicant for a licence, require the applicant:

(a) 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; or

(b) to allow an authorised person, at any reasonable time specified in the notice, to inspect each manufacturing site identified in the application and the equipment, processes and facilities that will be used in the manufacture of the goods, or other goods at that site.

Applications or information may be given electronically

(3) An approval of a form mentioned in paragraph (1)(a), or a notice mentioned in subsection (2), 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.

38 Grant of licence

(1) Where:
(a) a person has made an application to carry out steps in the manufacture of therapeutic goods at one or more manufacturing sites; and
(b) the prescribed application fee has been paid; and
(c) any applicable prescribed inspection fees have been paid; and
(d) the applicant has complied with any requirements made by the Secretary under subsection 37(2) in relation to the application;

the Secretary must grant the applicant a licence covering one or more manufacturing sites specified in the licence unless the Secretary is satisfied that:

(e) the applicant will be unable to comply with the manufacturing principles; or
(f) one or more of the manufacturing sites identified in the application are not satisfactory for the manufacture of the goods; or
(g) at least one of the following persons:
(i) the applicant;
(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

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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 manufacturing licence; or

(ix) had a manufacturing licence 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

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

Interpretation

(1A) A reference in paragraph (1)(g) 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.

(1AA) Paragraph (1)(g) does not limit paragraph (1)(h).

(1B) In paragraph (1)(g):

manufacturing licence means:

(a) a licence granted under this Part; or

(b) a licence, granted under a law of a State or Territory relating to therapeutic goods, relating to manufacturing therapeutic goods.

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Special circumstances justifying grant of licence

(2) Notwithstanding paragraph (1)(g), the Secretary may grant a licence to an applicant who, apart from this subsection, could not be granted a licence because of that paragraph if, in the opinion of the Secretary, special circumstances make it appropriate to do so.

Guidelines

(2A) The Secretary must have regard to the guidelines under section 38A in granting licences under this section.

What the licence authorises

(2B) For each manufacturing site covered by a licence, the Secretary must authorise, in the licence, the holder of the licence to carry out specified steps in the manufacture of specified therapeutic goods at that manufacturing site.

Note 1: For specification by class, see subsection 33(3AB) of the *Acts Interpretation Act 1901*.

Note 2: Sections 40A and 40B deal with variation of authorisations.

Notice of decision

(3) Where the Secretary grants or refuses to grant a licence to an applicant, the Secretary must:

(a) give the applicant written notice of the decision; and

(b) in the case of a refusal—include in the notice the reasons for the refusal.

Publication

(4) Where the Secretary grants a licence, the Secretary must cause particulars of the decision to be published in the *Gazette* or on the Department's website as soon as is practicable after the decision is made.

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38A Guidelines for multi-site licences

The Secretary must, by legislative instrument, make guidelines setting out the circumstances in which a licence may cover 2 or more manufacturing sites.

38B Splitting multi-site licences

(1) This section applies if a licence (the ***old licence***):

(a) either:

(i) was in force under this Part immediately before the commencement of this section; or

(ii) was suspended under this Part immediately before that commencement; and

(b) related to premises that comprise 2 or more sites (the ***old sites***).

(2) As soon as practicable after the commencement of this section, the Secretary must:

(a) by writing, revoke the old licence; and

(b) on the day that the Secretary revokes the old licence, grant new licences (each of which is a ***new licence***) to the holder of the old licence which, when considered together, cover the old sites.

The Secretary must give the holder written notice of the revocation and grant.

Note: Subsections (5) and (6) deal with when each new licence commences and when the old licence ends.

Guidelines

(3) The Secretary must have regard to the guidelines under section 38A in granting licences under this section.

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Application of this Part

(4) Subject to this section, subsections 38(2B) and (4) and sections 39 to 41A apply to a new licence in the same way as they apply to a licence granted under section 38.

Note: This means, for example, that:

(a) the Secretary must give a manufacturing site authorisation under subsection 38(2B) in relation to each manufacturing site covered by a new licence; and

(b) the Secretary may impose conditions on a new licence under subsection 40(1) and the statutory conditions under subsection 40(4) will apply to a new licence; and

(c) the Secretary may revoke or suspend a new licence under section 41.

Commencement of new licence

(5) The day specified under subsection 39(1) for the commencement of each new licence granted to the holder of the old licence must be the day (the ***transition day*)** after the day each new licence is granted.

Note: Subsection (7) deals with suspending a new licence from the transition day.

When revocation of old licence takes effect

(6) The revocation of the holder's old licence takes effect immediately before the start of the transition day.

Suspension of new licence

(7) If:

(a) subparagraph (1)(a)(ii) applies in relation to an old licence; and

(b) the period of suspension of the old licence is due to end at the end of a day (the ***relevant day***) after the transition day;

the Secretary may, on the day that the Secretary grants a new licence to the holder of the old licence and by notice in writing given to the holder, suspend the new licence for a period starting on the transition day and ending at the end of the relevant day.

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(8) Subsection 41(2) does not apply in relation to a suspension under subsection (7) of this section. However, subsections 41(4) to (6) do apply in relation to the suspension.

(9) To avoid doubt, subsection (7) does not prevent subsection 41(1) from applying in relation to a new licence.

Licence charges

(10) Subsection 4(2) of the *Therapeutic Goods (Charges) Act 1989* does not apply in relation to a new licence for the financial year in which the new licence is granted.

No review of revocation of old licence

(11) The revocation of the old licence is taken not to be an initial decision for the purposes of section 60.

39 Term of licence

(1) A licence commences on the day specified in the licence and remains in force until it is revoked or suspended.

(2) If:

(a) the licence covers therapeutic goods that are exempt under section 18A; and

(b) those goods cease to be exempt under that section before the licence is revoked;

the licence ceases to be in force in relation to those goods when those goods cease to be exempt under that section.

Note: An exemption under section 18A may cease to have effect only in relation to some of the goods covered by the exemption, see subsection 18A(5).

(3) If:

(a) the licence covers a biological that is exempt under section 32CB; and

(b) the biological ceases to be exempt under that section before the licence is revoked;

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the licence ceases to be in force in relation to the biological when the biological ceases to be exempt under that section.

Note: An exemption under section 32CB may cease to have effect only in relation to some of the biologicals covered by the exemption: see subsections 32CB(5) and 32CD(1).

40 Conditions of licences

(1) A licence may be granted subject to such conditions relating to the manufacture of the goods as the Secretary thinks appropriate.

(2) The Secretary may, by notice in writing given to the holder of a licence, impose new conditions on the licence or vary or remove existing conditions.

(3) The imposition, variation or removal of a condition under subsection (2) 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

(b) in any other case—on the day specified in the notice, which must be at least 28 days after the notice is given to the person, unless the person has agreed to an earlier day.

(3A) For the purposes of paragraph (3)(b), the earlier day must not be earlier than the day the notice is given to the person.

(4) In addition to any conditions imposed under subsection (1) or (2), each licence is, except as otherwise specified in the licence, subject to the conditions that the holder of the licence will:

(a) ensure that:

(i) the goods conform to any standard applicable to the goods; and

(ii) the holder of the licence observes the manufacturing principles in carrying out any steps in the manufacture of the goods under the licence;

unless:

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(iii) the goods are a biological and are for supply after the circumstances prescribed by the regulations for the purposes of paragraphs 14(9A)(b) and 14A(2A)(b) have occurred; or

(iv) the goods are a biological and are for export after the circumstances prescribed by the regulations for the purposes of paragraphs 14(13A)(b) and 14A(3A)(b) have occurred; and

(aa) if:

(i) the holder of the licence carries out, or proposes to carry out, steps in the manufacture of blood or blood components under the licence; and

(ii) regulations made for the purposes of this paragraph set out particular information relating to those steps;

comply with a request by the Secretary to provide such information, in accordance with those regulations; and

(ab) as soon as the holder of the licence becomes aware of information of a kind mentioned in subsection (5), give the information to the Secretary in writing; and

(ac) give the Secretary the information specified in a notice under subsection (6) within the period, and in the manner, specified in the notice; and

(b) allow an authorised person:

(i) to enter, at any reasonable time, each manufacturing site covered by the licence; and

(ii) while at such a site, to inspect the site, any therapeutic goods at the site and the processes relating to the manufacture of therapeutic goods at the site and to examine, take measurements of, conduct tests on or take samples of any therapeutic goods at the site or any thing at the site that relates to any therapeutic goods; and

(iii) while at such a site, to make any still or moving image or any recording of that site or those goods or processes; and

(c) where an authorised person enters a site as mentioned in subparagraph (b)(i), require the holder or his or her

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employees at that site to answer questions relating to procedures carried out at that site; and

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

(i) produce to the person such documents relating to the manufacture of therapeutic goods manufactured at that site as the person requires and allow the person to copy the documents; or

(ii) produce to the person for examination any batch samples kept by the holder; and

(e) comply with such other conditions (if any) as are specified in the regulations for the purposes of this section.

(5) The information with which paragraph (4)(ab) is concerned is information of the following kinds:

(a) information that indicates that the use of the goods in accordance with the recommendations for their use may have an unintended harmful effect;

(b) information that indicates that the goods, when used in accordance with the recommendations for their use, may not be as effective as was suggested by:

(i) the application for registration or listing of the goods; or

(ii) information already furnished by the holder of the licence under this Act; or

(iii) if the holder of the licence is not the sponsor of the goods—information already furnished by the sponsor of the goods under this Act;

(c) information that indicates that the quality, safety or efficacy of the goods is unacceptable.

(6) The Secretary may, by notice in writing given to the holder of a licence, require the holder to give the Secretary, within the specified period and in the specified manner, specified information to be used by the Secretary in deciding whether to revoke or suspend the licence under section 41 in the circumstances referred to in paragraph 41(1)(a).

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(7) The period specified in a notice given under subsection (6) must be at least 14 days after the notice is given.

40A Variation of manufacturing site authorisations—Secretary's own initiative

(1) The Secretary may, on his or her own initiative and by notice in writing given to the holder of a licence, vary a manufacturing site authorisation in relation to the licence.

(2) A variation under subsection (1) takes effect:
  (a) if the notice states that the variation is necessary to prevent imminent risk of death, serious illness or serious injury—on the day on which the notice is given to the holder; or
  (b) in any other case—on the day specified in the notice (which must not be earlier than 28 days after the notice is given to the holder).

40B Variation of licences—application by licence holder

Addition of manufacturing sites

(1) If the holder of a licence is of the view that, having regard to the guidelines under section 38A, the licence could cover one or more additional manufacturing sites, the holder may apply to the Secretary for a variation of the licence so that it covers one or more additional manufacturing sites specified in the application.

(2) An application under subsection (1) must:
  (a) be made in accordance with a form approved by the Secretary; and
  (b) identify the therapeutic goods or classes of therapeutic goods that the holder proposes to manufacture at each additional manufacturing site specified in the application; and
  (c) identify the steps in the manufacture of those goods that the holder proposes to carry out under the licence; and
  (d) if the holder proposes to carry out steps in the manufacture of blood or blood components under the licence—contain

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information relating to those steps set out in regulations made for the purposes of paragraph 37(1)(da); and

(e) state the names, qualifications and experience of the persons who are to have control of the manufacture of the goods and of the quality control measures that are to be employed; and

(f) be delivered to an office of the Department specified in the form; and

(g) be accompanied by the prescribed application fee.

(3) If an application is made under subsection (1) and any applicable prescribed inspection fees have been paid, the Secretary may, by notice in writing given to the holder of the licence, vary the licence so that the licence covers each additional manufacturing site specified in the notice.

(4) For each manufacturing site specified under subsection (3), the Secretary must, in the notice under that subsection, vary the licence to authorise the holder of the licence to carry out specified steps in the manufacture of specified therapeutic goods at that manufacturing site.

Note 1: For specification by class, see subsection 33(3AB) of the *Acts Interpretation Act 1901*.

Note 2: Section 40A and subsections (6) to (9) of this section deal with variation of authorisations.

(5) A variation under subsection (3) or (4) takes effect on the day on which the notice is given to the holder.

Variation of manufacturing site authorisations

(6) The holder of a licence may apply to the Secretary for a variation of a manufacturing site authorisation in relation to the licence.

(7) An application under subsection (6) must:

(a) be made in accordance with a form approved by the Secretary; and

(b) set out the variation sought; and

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(c) be delivered to an office of the Department specified in the form; and

(d) be accompanied by the prescribed application fee.

(8) If an application is made under subsection (6) and any applicable prescribed inspection fees have been paid, the Secretary may, by notice in writing given to the holder of the licence, vary the manufacturing site authorisation.

(9) A variation under subsection (8) takes effect on the day on which the notice is given to the holder.

Removal of manufacturing sites

(9A) The holder of a licence may apply to the Secretary for a variation of the licence so that it ceases to cover one or more manufacturing sites specified in the application.

(9B) An application under subsection (9A) must:

(a) be made in accordance with a form approved by the Secretary; and

(b) be delivered to an office of the Department specified in the form; and

(c) be accompanied by the prescribed application fee.

(9C) If an application is made under subsection (9A), the Secretary may, by notice in writing given to the holder of the licence, vary the licence so that the licence does not cover each manufacturing site specified in the notice.

(9D) A variation under subsection (9C) takes effect on the day specified in the notice.

Further information

(10) The Secretary may, by notice in writing given to the holder of a licence who has made an application under subsection (1), (6) or (9A), require the holder:

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(a) 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; or

(b) for an application under subsection (1) or (6)—to allow an authorised person, at any reasonable time specified in the notice, to inspect each manufacturing site identified in the application and the equipment, processes and facilities that will be used in the manufacture of therapeutic goods at that site.

Applications or information may be given electronically

(11) An approval of a form mentioned in paragraph (2)(a), (7)(a) or (9B)(a), or a notice mentioned in subsection (10), 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.

41 Revocation and suspension of licences

(1) Subject to subsection (2), the Secretary may, by notice in writing given to the holder of a licence, revoke the licence, or suspend the licence for a period specified in the notice, if:

(a) at least one of the following persons:

(i) the holder;

(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 manufacturing licence; or

(ix) had a manufacturing licence 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

(d) the holder requests in writing that the licence be revoked or suspended, as the case may be; or

(e) the holder ceases to carry on the business of manufacturing the goods to which the licence relates; or

(ea) the holder contravenes a manufacturing site authorisation in relation to the licence; or

(f) the annual licensing charge, or any applicable prescribed inspection fees, have not been paid within 28 days after they become payable; or

(g) the goods are exempt under section 18A and the holder has breached a condition of the exemption in relation to those goods; or

(ga) the licence covers a biological that is exempt under section 32CB and the holder has breached a condition of the exemption in relation to the biological; or

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

(1A) A reference in paragraph (1)(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:

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(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)(a) does not limit paragraph (1)(h).

(1C) In paragraph (1)(a):

manufacturing licence means:
(a) a licence granted under this Part; or
(b) a licence, granted under a law of a State or Territory relating to therapeutic goods, relating to manufacturing therapeutic goods.

(2) Where the Secretary proposes to revoke a licence or suspend a licence otherwise than at the request of the holder of the licence, the Secretary must, unless the Secretary considers that failure to revoke or suspend the licence immediately would create an imminent risk of death, serious illness or serious injury:
(a) by notice in writing given to the holder, inform the holder of the action that the Secretary proposes to take and of the reasons for that proposed action; and
(b) except where the proposed action is to be taken as a result of a failure to pay the annual licensing charge or an applicable prescribed inspection fee—give the holder an opportunity to make, within such reasonable time as is specified in the notice, submissions to the Secretary in relation to the proposed action.

(3) Where the holder makes submissions in accordance with paragraph (2)(b), the Secretary is not to make a decision relating to the revocation or suspension of the licence before taking into account the submissions.

(4) A licence may be revoked notwithstanding that the licence is suspended.

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(5) Where a licence is suspended, the Secretary may, by notice in writing given to the holder of the licence, revoke the suspension.

(6) Where the Secretary revokes or suspends a licence, the Secretary must cause particulars of the decision to be published in the *Gazette* or on the Department's website as soon as is practicable after the decision is made.

41AAAA Withdrawal of revocation of licence upon request

(1) If:

(a) the Secretary revokes a licence because of the request of a person made under paragraph 41(1)(d); and

(b) before the end of the period of 90 days beginning on the day the licence was revoked, the person 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 person, withdraw the revocation.

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

41AA Spent convictions scheme

Nothing in section 40 or 41 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).

41AB Secretary may require information or documents

(1) If:

(a) a person is the holder of a licence; and

(b) the person has carried out, or is carrying out, one or more steps in the manufacture of therapeutic goods;

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the Secretary may, by written notice given to the person, require the person to:

(c) give the Secretary information, or produce to the Secretary documents, relating to one or more of the following:

(i) the therapeutic goods;

(ii) if the therapeutic goods consist of a mixture of ingredients—those ingredients;

(iii) if the therapeutic goods consist of a mixture of ingredients—the suppliers of those ingredients;

(iv) if the therapeutic goods consist of a combination of component parts—those component parts;

(v) if the therapeutic goods consist of a combination of component parts—the suppliers of those component parts;

(vi) the containers or packages used, or proposed to be used, to contain the therapeutic goods;

(vii) the batch numbers of the therapeutic goods;

(viii) the expiry dates of the therapeutic goods;

(ix) the distribution of the therapeutic goods;

(x) the conformity of the therapeutic goods to a standard applicable to the goods;

(xi) the step or steps that the person has carried out, or is carrying out, in the manufacture of the therapeutic goods;

(xii) the premises used to carry out one or more steps in the manufacture of the therapeutic goods;

(xiii) the observance of the manufacturing principles;

(xiv) the names, qualifications and experience of individuals who have control of any of the steps that have been carried out, or are being carried out, in the manufacture of the therapeutic goods;

(xv) the measures for quality assurance and quality control employed in the taking of any of the steps that have been carried out, or are being carried out, in the manufacture of the therapeutic goods;

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(xvi) compliance with the conditions of the licence;

(xvii) whether there are grounds for revoking or suspending the licence;

(xviii) any other matter that is prescribed by the regulations and that relates to the manufacture of the therapeutic goods; and

(d) do so:

(i) within such reasonable time as is specified in the notice; and

(ii) in such form as is specified in the notice.

(2) The time specified in the notice must not be shorter than 14 days after the notice is given.

(3) The rule in subsection (2) does not apply if the Secretary is satisfied that, because of circumstances of urgency, the time specified in the notice should be shorter than 14 days after the notice is given.

(4) An approval of a form may require or permit 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.

41AC Criminal offence for contravening a requirement in a notice under section 41AB

A person commits an offence if:

(a) the person has been given a notice under section 41AB; and

(b) the person omits to do an act; and

(c) the omission contravenes a requirement in the notice.

Penalty: 400 penalty units.

41AD False or misleading information—offence

(1) A person commits an offence if:

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(a) the person is given a notice under section 41AB; and
(b) the person gives information to the Secretary in compliance, or purported compliance, with the notice; and
(c) the person does so knowing that the information:
(i) is false or misleading; or
(ii) omits any matter or thing without which the information is misleading.

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

(2) Subsection (1) does not apply as a result of subparagraph (1)(c)(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 (2).

(3) Subsection (1) does not apply as a result of subparagraph (1)(c)(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 (3).

41AE False or misleading documents—offence

(1) A person commits an offence if:
(a) the person produces a document to the Secretary; and
(b) the person does so knowing that the document is false or misleading; and
(c) the document is produced in compliance, or purported compliance, with a notice given under section 41AB.

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

(2) Subsection (1) 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 (2).

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(3) Subsection (1) 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 (3).

41AF False or misleading information or documents—civil penalty

(1) A person contravenes this section if:

(a) the person is given a notice under section 41AB; 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.

(2) Subsection (1) 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.

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41AG Self-incrimination

(1) A person is not excused from giving information or a producing a document under a section 41AB notice on the ground that the giving of the information or the production of the document 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 the document produced; or

(b) the giving of the information or the production of the document; or

(c) any information, document or thing obtained as a direct or indirect consequence of giving the information or producing the document;

is not admissible in evidence in:

(d) criminal proceedings against the individual, except proceedings under, or arising out of, section 41AD or 41AE; or

(e) proceedings for a pecuniary penalty order against the individual for a contravention of a civil penalty provision.

41AAA Transfer of licences

(1) The regulations may make provision for and in relation to the transfer of licences.

(2) Regulations made for the purposes of subsection (1) may make provision for and in relation to:

(a) the making of an application for the transfer of a licence; and

(b) the payment of a fee in respect of an application; and

(c) the assessment of an application; and

(d) the conditions of a licence upon the transfer of the licence; and

(e) the review of decisions made under the regulations.

(3) Subsection (2) does not limit subsection (1).

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41A Publication of list of manufacturers etc.

The Secretary may, from time to time and in such manner as the Secretary determines, publish a list of the persons who are licensed under this Part, the classes of goods to which the licences relate, the steps of manufacture that the licences authorise and the addresses of the manufacturing sites to which the licences relate.

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Chapter 4—Medical devices

Note: This Chapter does not apply, and Chapter 3 (Medicines and other therapeutic goods that are not medical devices) still applies, to medical devices that are registered or listed goods. Section 9B automatically cancels the registration or listing of those goods over time.

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:

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(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

(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, 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, 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 process;

(iv) control of conception;

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, material or other article specified under subsection (2A); or

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

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

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, material or other article (the ***main***

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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, material or other article for the purposes of paragraph (1)(aa). The notice is not a legislative instrument.

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

(3) The Secretary may, by order published in the *Gazette* or on the Department's website, declare that a particular instrument, apparatus, appliance, material or other article, or that a particular class of instruments, apparatus, appliances, 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.

(4) A declaration under this section takes effect on the day on which the declaration is published in the *Gazette* or on the Department's website or on such later day as is specified in the order.

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

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(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.

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

(1) A package and therapeutic goods in the package are a ***system or procedure pack*** if:
(a) the package and the therapeutic goods are for use as a unit, either in combination as a system or in a medical or surgical procedure; and
(b) the package contains at least one medical device; and
(c) the package and the therapeutic goods do not constitute a composite pack.

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(2) To avoid doubt, a system or procedure pack is a medical device.

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;
    (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;

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(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.

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.

(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.

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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 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.

(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).

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(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

41BJ Application of this Chapter to medical devices covered by Part 3-2

(1) This Chapter does not apply to a medical device if section 15A applies to the device, except for purposes connected with:

(a) applications for including the medical device in the Register under this Chapter; or

(b) including the medical device in the Register under this Chapter.

Note: Section 15A sets out the circumstances in which Part 3-2 applies or continues to apply to medical devices.

(2) However, if an exemption under section 34 applied to a medical device, or the manufacturer of the device, immediately before the commencement of this Chapter:

(a) Parts 4-3 and 4-4, and Division 2 of Part 4-11, apply in relation to the device after the end of the period of 2 years after that commencement; and

(b) Parts 4-8, 4-9 and 4-10, and Divisions 3 and 4 of Part 4-11, apply in relation to the device, to the extent that they relate to any of the provisions referred to in paragraph (a), after the end of that period.

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.

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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.

(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,

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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.

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***.

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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).

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

(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:

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(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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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).

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

(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;

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(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 under the regulations; and

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(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

(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

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.

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 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

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

(iii) has procedures in place, including a written agreement with the manufacturer of the kind of devices setting out

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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

(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.

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.

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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.

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:

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(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

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.

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

(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

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(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) 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) in relation to the 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 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

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(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 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.

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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.

(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.

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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;

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;

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(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) 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) 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 the regulations.

(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.

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(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.

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).

(2) The Minister may make an exemption under subsection (1) only if the Minister is satisfied 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 public health that may be caused by a possible future emergency; or

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(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.

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.

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;

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(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;
(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.

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

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(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):

(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);

(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);

to be published in the *Gazette* within 5 working days after the day on which the exemption, variation or revocation is made. However,

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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);

(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);

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.

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.

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.

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Note: Breach of the conditions may be an offence: see subsection 41MN(9).

(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 Exemptions 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.

(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 subsection 41MN(9).

(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 made in writing; 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;
(c) the monitoring of the use, and the results of the use, of devices of those kinds for those purposes;

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(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 subsection 41MN(9).

41HC Exemptions 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 exceptional 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 class of health practitioners to supply a specified kind of medical

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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

(b) the person omits to do an act; and

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(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).

(7) In this section:

medical practitioner means a person who is registered, in a State or internal Territory, as a medical practitioner.

41HD Approvals if substitutes for medical devices are unavailable or in short supply

(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:

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(c) the kinds of medical devices included in the Register that could act as a substitute for the medical device are unavailable or are 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 are unavailable or are 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 available for importation into, and supply in, Australia; and

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(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

(b) be accompanied by such information relating to the medical device as is required by the Secretary.

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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 subsection 41MN(9).

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
  (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:

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(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 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;

(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 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

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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).

(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.

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(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*.

(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*.

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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.

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

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(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.

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 4-9—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

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Circumstances in which requirements may be imposed		
Item	**Circumstance relating to a kind of medical device**	**Person subject to requirements**
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
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

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(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 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

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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.

(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.

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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.

41MB Exceptions

(1) Sections 41MA and 41MAA do not apply if:
(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.

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(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.

(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:

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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.

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
(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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41MM Claims about arranging supplies of medical devices

A person commits an offence if:

(a) the person claims, by any means, that the person or another person can arrange the supply of a medical device; and

(b) none of the following subparagraphs applies in relation to the device:

(i) the device is of a kind included in the Register;

(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 that covers the supply of the device by the person or other person;

(v) the device is the subject of an approval under subsection 41HD(1), (1A) or (2) that covers the supply of the device by the person or other person.

Penalty: 60 penalty units.

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.

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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) 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.

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.

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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.

(8B) An offence against subsection (8A) is an offence of strict liability.

Offence relating to breaching a condition of an exemption or approval, 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

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(iv) a condition of an approval under subsection 41HD(1), (1A) or (2).

Penalty: 60 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
(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

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(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.

(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 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) medical practitioners, psychologists, dentists, pharmacists, optometrists, chiropractors, physiotherapists, nurses, midwives, dental hygienists, dental prosthetists, dental therapists or osteopaths; or

(b) persons who are:

(i) engaged in the business of wholesaling therapeutic goods; or

(ii) purchasing officers in hospitals; or

(c) herbalists, homoeopathic practitioners, naturopaths, nutritionists, practitioners of traditional Chinese medicine or podiatrists 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

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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) 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.

42B Definitions

In this Part, unless the contrary intention appears:

approval number means the distinguishing number allocated to an approved advertisement by the Secretary under regulation 5J of the Therapeutic Goods Regulations.

approved advertisement means an advertisement:

(a) approved under regulation 5G, or taken to be approved by the Secretary under subregulation 5H(2), or approved by the Minister on review under regulation 5M, of the Therapeutic Goods Regulations; and

(b) the approval of which has not been withdrawn.

broadcaster, in relation to an advertisement for therapeutic goods, means a person (other than a person who is required to enter those

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goods on the Register) who undertakes, as a business activity in its own right:

(a) the broadcasting of the advertisement in broadcast media; or

(b) the placement of the advertisement for such broadcasting.

broadcast media, in relation to an advertisement or generic information, means any means (other than a means declared in the regulations to be an exempted means) by which the information is disseminated electronically in a visible or audible form or a combination of such forms.

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.

mainstream media means any magazine or newspaper for consumers containing a range of news, public interest items, advertorials, advertisements or competitions.

prohibited representation means a representation referred to in subsection 42DJ(1).

publisher, in relation to an advertisement for therapeutic goods, means a person (other than a person who is required to enter those goods on the Register) who undertakes, as a business activity in its own right:

(a) the publishing of the advertisement in specified media other than broadcast media; or

(b) the placement of the advertisement for such publication.

publishing, in relation to an advertisement, includes inserting material within the pages of an item of mainstream media.

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required representation means a representation referred to in subsection 42DJ(2).

restricted representation means a representation referred to in section 42DD.

specified media, in relation to an advertisement or generic information, means:

(a) mainstream media; or

(b) broadcast media; or

(c) cinematograph films; or

(d) displays about goods, including posters:

(i) in shopping malls (except inside an individual shop); and

(ii) in or on public transport; and

(iii) on billboards.

visual broadcast media means broadcast media that is intended to be viewed by its audience.

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 2—Therapeutic goods advertisements for which an approval is required

42BA Application of Division

This Division applies only to advertisements to which Part 2 of the Therapeutic Goods Regulations applies.

42C Offences relating to publication of advertisements

(1) A person commits an offence if:

(a) the person:

(i) publishes or broadcasts; or

(ii) causes to be published or broadcast;

in specified media, an advertisement that is required by the Therapeutic Goods Regulations to be an approved advertisement; and

(b) the advertisement is not an approved advertisement.

Penalty: 60 penalty units.

Note: Advertising that requires approval under Part 2 of the *Therapeutic Goods Regulations 1990* must also comply with the Therapeutic Goods Advertising Code.

(2) A person commits an offence if:

(a) the person:

(i) publishes or broadcasts; or

(ii) causes to be published or broadcast;

an advertisement in specified media; and

(b) the advertisement is not an approved advertisement in that it differs, in any respect, from the advertisement that was approved.

Penalty: 60 penalty units.

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Note: Advertising that requires approval under Part 2 of the *Therapeutic Goods Regulations 1990* must also comply with the Therapeutic Goods Advertising Code.

(3) It is a defence to a prosecution under subsection (2) if:

(a) the person prosecuted is a publisher or broadcaster who received the advertisement to which the prosecution relates for publication or broadcasting in specified media in the ordinary course of business; or

(b) the particular advertisement to which the prosecution relates differs only in respect of a matter mentioned in paragraph 5C(2)(b), (e) or (f) of the Therapeutic Goods Regulations.

Note: A defendant bears an evidential burden in relation to the matters in subsection (3) (see subsection 13.3 of the *Criminal Code*).

(4) A person commits an offence if:

(a) the person:

(i) publishes or broadcasts; or

(ii) causes to be published or broadcast;

a particular advertisement in specified media referred to in paragraph (a), (c) or (d) of the definition of ***specified media***; and

(b) the advertisement:

(i) does not display its approval number; or

(ii) displays a number purporting to be its approval number but that is not its approval number; or

(iii) displays an approval number that has expired.

Penalty: 30 penalty units.

Note: Advertising that requires approval under Part 2 of the *Therapeutic Goods Regulations 1990* must also comply with the Therapeutic Goods Advertising Code.

(5) It is a defence to a prosecution under subsection (4) if the person prosecuted:

(a) is a publisher who received the advertisement to which the prosecution relates for publication in specified media referred

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to in paragraph (a), (c) or (d) of the definition of ***specified media***; or

(b) is a broadcaster who received the advertisement to which the prosecution relates for broadcasting in visual broadcast media;

in the ordinary course of business.

Note: A defendant bears an evidential burden in relation to the matters in subsection (5) (see subsection 13.3 of the *Criminal Code*).

(6) A person commits an offence if:

(a) the person:

(i) publishes or broadcasts; or

(ii) causes to be published or broadcast;

in specified media, an approved advertisement; and

(b) the person's action is in contravention of a condition to which the approval of the advertisement is subject.

Penalty: 60 penalty units.

Note: Advertising that requires approval under Part 2 of the *Therapeutic Goods Regulations 1990* must also comply with the Therapeutic Goods Advertising Code.

(7) It is a defence to a prosecution under subsection (6) if the person prosecuted is a publisher or broadcaster who received the advertisement to which the prosecution relates for publication or broadcasting in specified media in the ordinary course of business.

Note: A defendant bears an evidential burden in relation to the matters in subsection (7) (see subsection 13.3 of the *Criminal Code*).

(8) An offence against this section is an offence of strict liability.

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Division 3—General provisions about advertising therapeutic goods

42DA Simplified outline

The following is a simplified outline of this Division:

This Division has 2 kinds of application.

First, Part 2 of the *Therapeutic Goods Regulations 1990* deals with the Secretary approving certain advertisements and it refers to provisions of this Division.

Second, the offences in Division 3A of this Part refer to provisions of this Division.

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:
  (a) any recommendation of the Therapeutic Goods Advertising Code Council; and
  (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 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—Therapeutic goods advertisements for which an approval is not required

42DKA Application of Division

This Division applies to advertisements about therapeutic goods other than advertisements for which an approval is required under Part 2 of the *Therapeutic Goods Regulations 1990*.

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

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(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:

(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.

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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;

(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

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(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.

(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.

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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:

(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.

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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

(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

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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.

(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

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government authority (not including a foreign government or foreign government authority).

Exception

(10) Subsection (1) does not apply if:

(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.

(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:

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

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

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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

(ii) causes the advertising, by any means, of therapeutic goods; and

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(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:

(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

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(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.

(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 5-2—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

(1) A person to whom an infringement notice has been given may apply to the Secretary for an extension of the period referred to in paragraph 42YKA(1)(h).

(2) If the application is made before the end of that period, the Secretary may, in writing, extend that period. The Secretary may do so before or after the end of that period.

(3) If the Secretary extends that period, a reference in this Part, or in a notice or other instrument under this Part, to the period referred to in paragraph 42YKA(1)(h) is taken to be a reference to that period so extended.

(4) If the Secretary does not extend that period, a reference in this Part, or in a notice or other instrument under this Part, to the period referred to in paragraph 42YKA(1)(h) is taken to be a reference to the period that ends on the later of the following days:

(a) the day that is the last day of the period referred to in paragraph 42YKA(1)(h);

(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 extend the period more than once under subsection (2).

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:

(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.

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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.

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 referred to in paragraph 42YKA(1)(h):
  (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

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(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

(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 Court 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 Court 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 Court 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 Court 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 Court 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 Court 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 Court 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 Court 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 Court 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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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 Appeals 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 6-2—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.

seize includes secure against interference.

thing includes a substance, and a thing in electronic or magnetic form.

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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 on the premises or any thing on the premises that relates to any therapeutic goods;
  (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.

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(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, 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:
    (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
    (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

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(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 or listing of the therapeutic goods; 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

(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:

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(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.

(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:

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(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 on the premises or any thing on the premises that relates to any therapeutic goods;

(c) to make any still or moving image or any recording of the premises or any thing on the premises;

(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;

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(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.

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.

(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 magistrate who issued the warrant.

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48AA Completing execution of warrant under section 50 after temporary cessation

(1) This section applies if an authorised person who is executing a warrant under section 50 in relation to premises temporarily ceases its execution and leaves the premises.

(2) The authorised person may complete the execution of the warrant if:

(a) the warrant is still in force; and

(b) the authorised person is 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 a magistrate 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 may apply to a magistrate 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 believes on reasonable grounds that the authorised person will not be able to return to the premises within that period.

(4) If it is practicable to do so, before making the application, 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) A magistrate 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

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(b) the magistrate 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.

(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:

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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.

(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.

(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 a magistrate for an extension of the 24-hour period if the authorised person believes on

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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:

(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

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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.

(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 a magistrate 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.

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(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.

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

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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 an authorised person executing the warrant with all reasonable facilities and assistance for the effective exercise of the authorised person's powers.

(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.

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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 90 days after its seizure ends;

whichever first occurs, unless the thing is forfeited or forfeitable to the Commonwealth.

(2) At the end of the 90 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 90 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

(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.

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48J Magistrate may permit a thing to be retained

(1) An authorised person may apply to a magistrate for an order that he or she may retain the thing for a further period if:

(a) before the end of 90 days after the seizure; or

(b) before the end of a period previously specified in an order of a magistrate under this section;

proceedings in respect of which the thing may afford evidence have not commenced.

(2) If the magistrate 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 magistrate 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

(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.

49 Monitoring warrants

(1) An authorised person may apply to a magistrate for a warrant under this section in relation to premises.

(2) Subject to subsection (3), the magistrate may issue the warrant if the magistrate is satisfied, by information on oath, that it is

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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 magistrate must not issue the warrant unless the authorised person or some other person has given to the magistrate, either orally or by affidavit, such further information (if any) as the magistrate 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.

50 Offence and civil penalty provision related warrants

(1) An authorised person may apply to a magistrate for a warrant under this section in relation to premises.

(2) Subject to subsection (3), the magistrate may issue the warrant if the magistrate 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 magistrate must not issue the warrant unless the authorised person or some other person has given to the magistrate, either

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orally or by affidavit, such further information (if any) as the magistrate 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 a magistrate by telephone for a warrant under section 50 in relation to premises.

(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 magistrate is satisfied:

(a) after having considered the terms of the information; and

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(b) after having received such further information (if any) as the magistrate requires concerning the grounds on which the issue of the warrant is being sought;

that there are reasonable grounds for issuing the warrant, the magistrate may complete and sign the same warrant that the magistrate would issue under section 50 if the application had been made under that section.

(5) If the magistrate completes and signs the warrant:

(a) the magistrate 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 magistrate 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 magistrate; and

(ii) write on the form the name of the magistrate and the day on which and the time at which the warrant was signed.

(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 magistrate:

(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 magistrate receives those documents, the magistrate must:

(a) attach them to the warrant that the magistrate completed and signed; and

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(b) deal with them in the way in which the magistrate 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 magistrate 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 magistrate 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 a magistrate 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.

(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:

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(a) state in a document that purports to be a form of warrant under section 51 the name of a magistrate unless that magistrate 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 magistrate; 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 a magistrate under that section; or

(ii) to depart in a material particular from the terms authorised by a magistrate under that section; or

(d) give to a magistrate 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.

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 6-3—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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52EB Compensation for acquisition of property

(1) If the operation of section 52EA would result in an acquisition of property from a person otherwise than on just terms, the Commonwealth is liable to pay a reasonable amount of compensation to the person.

(2) If the Commonwealth and the person do not agree on the amount of the compensation, the person may institute proceedings in the Federal Court for the recovery from the Commonwealth of such reasonable amount of compensation as the court determines.

(3) In this section:

acquisition of property has the same meaning as in paragraph 51(xxxi) of the Constitution.

just terms has the same meaning as in paragraph 51(xxxi) of the Constitution.

52EC Review of scheduling regime

(1) The Minister must cause an independent review of the operation of this Part to be conducted, with particular reference to the amendments to this Part made by the *Therapeutic Goods Amendment (2009 Measures No. 2) Act 2009* (***the amendments***).

(2) The review must:
  (a) start not later than 1 July 2013; and
  (b) be completed within 6 months.

(3) The review must report on:
  (a) the system of access controls for goods containing scheduled substances established by this Part;
  (b) the outcomes of the administration of scheduled substances by the Secretary and by the committees established by this Part;
  (c) the effect of the amendments on the therapeutic goods industry and on individual parties within the industry;

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(d) whether there are adequate avenues for review of decisions made by the Secretary and by the committees established by this Part;

and may make recommendations for further changes to the scheduling regime.

(4) The review must be conducted by a panel which must comprise not less than three, and not more than five, persons with relevant expertise.

(5) As part of the review, the panel must invite and consider public submissions.

(6) The panel must give the Minister a written report of the review.

(7) The Minister must cause a copy of the report to be laid before each House of the Parliament within 15 sitting days of that House after the day on which the Minister receives the report.

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Chapter 7—Miscellaneous

53 Retention of material on withdrawal of application

Where a person withdraws an application for:

(a) registration; or

(b) listing; 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:

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)

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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...**
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)
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)
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)

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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...**
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)
31A	subsection 41MN(10)	subsection 41MN(11)
32	subsection 41MO(1)	subsection 41MO(4)
32A	subsection 41MO(4A)	subsection 41MO(4C)
33	subsection 41MO(5)	subsection 41MO(8)
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)
34	subsection 42V(6)	subsection 42V(6C)

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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, 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.

(5) Goods forfeited under an order referred to in subsection (3) are to be disposed of in such manner as the Secretary directs.

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.

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(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.

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

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(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.

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:

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(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
(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.

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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) or (7AB)
6	Subsection 22A(1)
7	Subsection 29A(1)
8	Subsection 29B(3) or (4)
9	Subsection 30EC(1)
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 32CH(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)

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Corporate offences for which executive officers may be personally liable	
Item	**Provisions of this Act**
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)
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) or (10)
41	Subsection 41MNB(1)
42	Subsection 41MP(1)
43	Subsection 41MQ(3) or (4)
43A	Subsection 42DL(1)
43B	Subsection 42DLA(1)
43C	Subsection 42DM(1)
43D	Subsection 42DW(1)
44	Subsection 42E(1)
45	Subsection 42T(1) or (2)
46	Subsection 42V(6)
47	Subsection 42W(1) or (2)
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.

(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.

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:

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(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.

(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;

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(d) requiring information to be given by delegates to the Secretary.

(6) The powers of the Secretary under subsection 19(5), 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) may be delegated only to the Secretary.

(10A) The power of the Minister under subsection 32CB(1) may be delegated only to the Secretary.

(11) The power of the Minister under subsection 41GS(1) may be delegated only to the Secretary.

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.

(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 Appeals Tribunal Act 1975*.

initial decision means a decision of the Secretary or of a delegate of the Secretary:
  (a) under the definition of ***therapeutic devices*** in subsection 3(1) or under subsection 7(1) or 41BD(3); or
  (aa) under subsection 7C(3); or
  (ab) under section 9C, 9D or 9F; or
  (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); 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

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(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
(i) under Part 4-8 (obtaining information); 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
(l) under section 42DF, 42DH or 42DI or subsection 42DV(1) or (2).

reviewable decision means a decision of the Minister under subsection (3).

(1A) For the avoidance of doubt, the following are not initial decisions for the purposes of this section or section 60A:
(aa) a preliminary assessment under section 23B, 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.

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(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 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

(c) makes a decision under section 23B in relation to an application for provisional registration of a medicine; 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.

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(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 26BE(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) 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;

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.

(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

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(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.

(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, except where subsection 28(4) of the *Administrative Appeals Tribunal Act 1975* applies, apply for a statement setting out the reasons for the decision on reconsideration and may, subject to that Act, make an application to the Administrative Appeals 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.

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(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 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 Appeals Tribunal Act 1975*, if the person is dissatisfied with the decision upon reconsideration, make an application to the Administrative Appeals 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 Appeals 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:

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(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 Appeals 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 Appeals Tribunal for review of the decision on reconsideration and lodges initial new information in support of that application; and

(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 Appeals 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

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(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:

(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

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(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.

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

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(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 or the EFTA Mutual Recognition Agreement).

(2) The Secretary may:

(a) release to the World Health Organisation therapeutic goods information relating to:

(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.

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(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.

(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

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(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;

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);

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(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.

(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)

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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).

(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:

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(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.

(8) Subject to section 25A, therapeutic goods information provided to 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; and

(b) be provided to a committee appointed to advise the Minister or the Secretary on matters relating to therapeutic goods, including a committee of the National Health and Medical Research Council.

Note: The Secretary may also disclose therapeutic goods information provided to 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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(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.

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);

(d) a member of a committee established under this Act or the regulations;

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(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);
(h) a person assisting a person (a ***primary person***) referred to in paragraph (a), (b), (c), (d), (e), (f) or (g) 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.

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.

(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 by the Department in the sampling and testing of therapeutic 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

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(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 evaluations under section 26BE in relation to recommendations to vary a section 26BB determination are to be completed; 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

(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, the inspection of manufacturing operations or the evaluation of

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data concerning therapeutic goods by the Department at the request of persons; 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

(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) The regulations may make provision for a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument:

(a) as that instrument is in force at the time when the regulations take effect; or

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(b) as that instrument is in force 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 the amendment to be made. If, despite the misdescription, the amendment can

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be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation "(md)" added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation "(md not incorp)" is added to the details of the amendment included in the amendment history.

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Endnote 2—Abbreviation key

ad = added or inserted

am = amended

amdt = amendment

c = clause(s)

C[x] = Compilation No. x

Ch = Chapter(s)

def = definition(s)

Dict = Dictionary

disallowed = disallowed by Parliament

Div = Division(s)

ed = editorial change

exp = expires/expired or ceases/ceased to have effect

F = Federal Register of Legislation

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)

o = order(s)

Ord = Ordinance

orig = original

par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)

pres = present

prev = previous

(prev…) = previously

Pt = Part(s)

r = regulation(s)/rule(s)

reloc = relocated

renum = renumbered

rep = repealed

rs = repealed and substituted

s = section(s)/subsection(s)

Sch = Schedule(s)

Sdiv = Subdivision(s)

SLI = Select Legislative Instrument

SR = Statutory Rules

Sub-Ch = Sub-Chapter(s)

SubPt = 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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Endnote 3—Legislation history

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): *(h)*	—
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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Endnote 3—Legislation history

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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Endnote 3—Legislation history

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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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 Sch 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, 6 (items 1–51) and 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), Sch 6 (item 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)	—

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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; Nos. 12, 56, 120 and 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
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
s. 4	rs. No. 204, 1991; No. 76, 1993; No. 3, 1999
	am. No. 24, 2002
s. 5	am. No. 39, 2006
s. 5A	ad. No. 111, 2001
	rs. No. 39, 2006
	am No 7, 2018
s. 6	am. No. 76, 1993
s. 6AA	ad. No. 6, 1996
	am. No. 111, 2001

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Endnote 4—Amendment history

Provision affected	How affected
	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
s 6C	ad. No. 76, 1993
s. 7	am. No. 76, 1993; No. 24, 2002; No. 141, 2010; No 4, 2014
s 7AA	ad No 4, 2014
	am No 126, 2015
s. 7A	ad. No. 76, 1993
s. 7B	ad. No. 76, 1993
	am. No. 24, 2002; No. 54, 2010; No 4, 2014
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
s. 9	am. No. 54, 2010
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
s. 9B	ad. No. 24, 2002
	am. No. 140, 2007
s. 9C	ad. No. 24, 2002

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Provision affected	How affected
	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 3	
Part 2 heading	rep. No. 24, 2002
Chapter 3 heading	ad. No. 24, 2002
Chapter 3	am No. 24, 2002; No 140, 2007
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
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
s. 14A	ad. No. 39, 2006
	am. No. 54, 2010; No 4, 2014
s. 14B	ad. No. 39, 2006
	am No 41, 2015; No 7, 2018
s. 15	am. No. 6, 1996; No. 111, 2001

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Endnote 4—Amendment history

Provision affected	How affected
	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
s. 15B	ad. No. 54, 2010
s. 16	am. No. 141, 1990; No. 84, 1991; No. 76, 1993; No. 14, 2001; No. 24, 2002
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
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
s. 19A	ad. No. 6, 1996
	am. No. 76, 2009; No 4, 2014; No 47, 2017; No 7, 2018
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
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

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Endnote 4—Amendment history

Provision affected	How affected
s. 21	am. No. 204, 1991; No. 6, 1996; No. 111, 2001; No. 23, 2002; No. 38, 2009
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
s. 22	am. No. 204, 1991; No. 6, 1996; No. 120, 2000; Nos. 14 and 111, 2001; No. 23, 2002; No. 39, 2003; No. 39, 2006; No. 180, 2012; Nos. 38 and 96, 2009; No 4, 2016; No 7, 2018
s. 22AA	ad. No. 39, 2006
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 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
s 23A	ad No 7, 2018
s 23B	ad No 7, 2018
s 23C	ad No 7, 2018
s. 24	am. Nos. 84 and 204, 1991; No. 77, 2011; No 7, 2018

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Endnote 4—Amendment history

Provision affected	How affected
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. Nos. 84 and 204, 1991; No. 76, 1993; No 6, 1996; No. 116, 1997; No 34, 1998; No. 12, 2000; Nos. 24 and 56, 2002; No. 39, 2003; No. 120, 2004; No. 2, 2006; Nos. 54 and 141, 2010; No 4, 2014; No 7, 2018
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
s 25AC	ad No 4, 2014
	am No 7, 2018
s. 25A	ad. No. 34, 1998
	am. No. 54, 2010
s. 25B	ad. No. 116, 1997 (as am. by No. 3, 1999)
	am. No. 56, 2002; No 7, 2018
s. 26	am. No. 76, 1993; No. 6, 1996; 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. 26AA	ad. No. 116, 1997
	am. No. 56, 2002; No 7, 2018
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

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Endnote 4—Amendment history

Provision affected	How affected
s 26AB	ad No 7, 2018
s 26AC	ad No 7, 2018
s 26AD	ad No 7, 2018
s 26AE	ad No 7, 2018
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
s. 26BE	ad. No. 76, 2009
	rep. No. 141, 2010
	ad No 47, 2017
	am No 7, 2018
s 26BF	ad No 7, 2018
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

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Endnote 4—Amendment history

Provision affected	How affected
	am No 7, 2018
s. 28A	ad. No. 76, 2009
	am No 7, 2018
s 29	am No. 76, 2009; No 7, 2018
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
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; Nos. 14 and 111, 2001; No. 39, 2003; No. 39, 2006; No. 76, 2009; No. 141, 2010; No 4, 2014; No 47, 2017; No 7, 2018
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

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Provision affected	How affected
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
s. 30EB	ad. No. 39, 2003
	am No 4, 2014
s. 30EC	ad. No. 39, 2003
	rs. No. 39, 2006
	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
s 30EG	ad No 104, 2018
s 30EH	ad No 104, 2018
s 30EI	ad No 104, 2018
s 30EJ	ad No 104, 2018
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

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Endnote 4—Amendment history

Provision affected	How affected
s. 30H	ad. No. 23, 2002
	am. No. 38, 2009
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
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
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

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Provision affected	How affected
	ad. No. 54, 2010
	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
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
s. 32BK	ad. No. 54, 2010
	am No 47, 2017; No 7, 2018

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Endnote 4—Amendment history

Provision affected	How affected
s 32BL	ad No 7, 2018
Division 3	
Subdivision A	
s. 32C	ad. No. 54, 2010
Subdivision B	
s. 32CA	ad. No. 54, 2010
	am No 126, 2015
Subdivision C	
s. 32CB	ad No 54, 2010
	am No 46, 2011
s 32CC	ad No 54, 2010
s 32CD	ad No 54, 2010
	am No 46, 2011
s. 32CE	ad. No. 54, 2010
s. 32CF	ad. No. 54, 2010
s. 32CG	ad. No. 54, 2010
s. 32CH	ad. No 54, 2010
	am No 180, 2012
s. 32CI	ad. No. 54, 2010
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
s 32CL	ad. No. 54, 2010
s 32CM	ad. No. 54, 2010
	am No 47, 2017; No 7, 2018; No 104, 2018
s 32CN	ad. No. 54, 2010
	am No 47, 2017; No 7, 2018

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Provision affected	How affected
Subdivision E	
s. 32CO	ad. No. 54, 2010
	am No 47, 2017; No 7, 2018
Division 4	
Subdivision A	
s. 32D	ad. No. 54, 2010
Subdivision B	
s. 32DA	ad. No. 54, 2010
	am No 4, 2014
s. 32DB	ad. No. 54, 2010
s. 32DC	ad. No. 54, 2010
Subdivision C	
s. 32DD	ad. No. 54, 2010
	am No 7, 2018
s 32DDA	ad No 7, 2018
s. 32DE	ad. No. 54, 2010
	am No 4, 2014; No 7, 2018
	ed C69
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

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Endnote 4—Amendment history

Provision affected	How affected
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
s 32DU	ad. No. 54, 2010
Division 5	
s. 32E	ad. No. 54, 2010
s. 32EA	ad. No. 54, 2010
	am No 7, 2018
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

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Provision affected	How affected
	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
s. 32GB	ad. No. 54, 2010
	am No 4, 2014
s. 32GC	ad. No. 54, 2010
	am No 4, 2014; No 7, 2018
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
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

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Endnote 4—Amendment history

Provision affected	How affected
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
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
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

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Endnote 4—Amendment history

Provision affected	How affected
s. 33A	ad. No. 24, 2002
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
s. 37	am. No. 76, 1993; No. 56, 2002; No. 96, 2006; No. 76, 2009
	am No 4, 2014
s. 38	am. No. 76, 1993; No. 34, 1998; No. 39, 2003; No. 39, 2006; Nos. 38 and 76, 2009; No 46, 2011; No 4, 2014
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; Nos. 38 and 76, 2009; No. 54, 2010; No 4, 2014
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

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Endnote 4—Amendment history

Provision affected	How affected
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
Part 4-1	
Division 1	
s. 41B	ad. No. 24, 2002 am. No. 39, 2006
s. 41BA	ad. No. 24, 2002 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
s. 41BE	ad. No. 24, 2002 am. No. 76, 2009
s. 41BEA	ad. No. 96, 2009
s. 41BF	ad. No. 24, 2002
s. 41BG	ad. No. 24, 2002 am. No. 76, 2009
s 41BH	ad No 24, 2002
s 41BI	ad No 24, 2002
s 41BIA	ad No 7, 2018

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Provision affected	How affected
s 41BIB	ad No 7, 2018
Division 3	
s. 41BJ	ad. No. 24, 2002
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
Division 1	
s. 41CA	ad. No. 24, 2002
Division 2	
s. 41CB	ad. No. 24, 2002
	am. No. 76, 2009; No 126, 2015
s. 41CC	ad. No. 24, 2002
	am. No. 38, 2009; No. 46, 2011; No 4, 2014
s. 41CD	ad. No. 24, 2002
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
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

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Endnote 4—Amendment history

Provision affected	How affected
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
	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

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Provision affected	How affected
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
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

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Endnote 4—Amendment history

Provision affected	How affected
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
s 41FDA	ad No 7, 2018
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

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Provision affected	How affected
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
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
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

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Endnote 4—Amendment history

Provision affected	How affected
s. 41GH	ad. No. 24, 2002
	am No 4, 2014; No 7, 2018
Subdivision C	
s. 41GI	ad. No. 24, 2002
	am No 39, 2006
s. 41GJ	ad. No. 24, 2002
Division 2	
s. 41GK	ad. No. 24, 2002
s. 41GL	ad. No. 24, 2002
	am. No. 39, 2003; No 4, 2014; No 7, 2018
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
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
s 41GT	ad No 38, 2009
s 41GU	ad No 38, 2009
s 41GV	ad No 38, 2009
s 41GW	ad No 38, 2009
s 41GX	ad. No. 38, 2009
	rep. No. 54, 2010

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Provision affected	How affected
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
s. 41HA	ad. No. 24, 2002
	am. No. 39, 2006
s. 41HB	ad. No. 24, 2002
	am. No. 39, 2006; No 7, 2018
s. 41HC	ad. No. 24, 2002
	am. No. 54, 2010; No 47, 2017; No 7, 2018; No 104, 2018
s. 41HD	ad. No. 141, 2010
	am No 126, 2015; No 47, 2017; No 7, 2018
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; Nos. 38 and 76, 2009; No 4, 2014; No 7, 2018
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
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

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Endnote 4—Amendment history

Provision affected	How affected
	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 4-9	
Part 4-9 heading	rs No 47, 2017
s. 41K	ad. No. 24, 2002
	am No 47, 2017
s. 41KA	ad. No. 24, 2002
	am. No. 38, 2009; Nos. 54, and 141, 2010; No 47, 2017; No 7, 2018
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

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Provision affected	How affected
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. 41MB	ad. No. 24, 2002
	am. No. 39, 2006
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

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Endnote 4—Amendment history

Provision affected	How affected
	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
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

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Provision affected	How affected
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
s. 41MNA	ad. No. 39, 2006
	am No 7, 2018
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
	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 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

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Endnote 4—Amendment history

Provision affected	How affected
	rs. No. 39, 2003
Division 1	
Division 1 of	ad. No. 39, 2003
s. 42AA	ad. No. 39, 2003
	am. No. 76, 2009
s. 42AB	ad. No. 39, 2003
s. 42AC	ad. No. 39, 2003
	am. No. 38, 2009; No 7, 2018
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
s. 42BAA	ad. No. 76, 2009
	am No 104, 2018
Division 2	
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

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Provision affected	How affected
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
s 42DK	ad No 39, 2003
	am No 8, 2010
	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
s 42DLC	ad No 7, 2018
s. 42DM	ad. No. 39, 2003
	am No 4, 2016
	rs No 7, 2018

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Endnote 4—Amendment history

Provision affected	How affected
s 42DMA	ad No 7, 2018
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
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 5-2	
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

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Provision affected	How affected
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
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

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Endnote 4—Amendment history

Provision affected	How affected
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
s 42YKC	ad No 7, 2018
s 42YKD	ad No 7, 2018
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
s 42YN	ad No 7, 2018
s 42YO	ad No 7, 2018
s 42YP	ad No 7, 2018
s 42YQ	ad No 7, 2018
s 42YR	ad No 7, 2018
Chapter 6	
Part 5 heading	rep. No. 24, 2002

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Provision affected	How affected
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
s. 44	am. No. 84, 1991; No. 24, 2002
	rs. No. 96, 2008
	am No 7, 2018
s. 44A	ad. No. 96, 2008
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 6-2	
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
s. 46	rs. No. 6, 1996
	am No 7, 2018
s. 46A	ad. No. 6, 1996
	am. Nos. 23 and 24, 2002; Nos. 38 and 76, 2009; Nos. 54 and 141, 2010; No 47, 2017; No 7, 2018
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; Nos. 38 and 76, 2009; No 7, 2018

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Endnote 4—Amendment history

Provision affected	How affected
s 48A	ad. No. 6, 1996
s 48AA	ad No 7, 2018
s 48B	ad. No. 6, 1996
s 48BA	ad No 7, 2018
s. 48C	ad. No. 6, 1996
	am. No. 39, 2006; No 7, 2018
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
s 48G	ad No 6, 1996
s 48H	ad No 6, 1996
s. 48J	ad. No. 6, 1996
	am. No. 39, 2006
s. 49	am. No. 6, 1996; No 7, 2018
s. 50	am No 6, 1996; No. 39, 2006; No 7, 2018
s. 51	am No 6, 1996; No 39, 2006
s. 51A	ad. No. 76, 1993
	am No 7, 2018
s. 51B	ad. No. 6, 1996
	am. No. 38, 2009
s. 52	am. No. 6, 1996; No. 111, 2001; No. 38, 2009
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

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Provision affected	How affected
	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
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
s. 52EC	ad. No. 96, 2009
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
s 52G	ad. No. 3, 1999
	rep. No. 76, 2009
Chapter 7	
Part 6 heading	ad. No. 6, 1996
	rep. No. 24, 2002
Chapter 7 heading	ad. No. 24, 2002
s. 53	rs. No. 24, 2002
	am. No. 54, 2010
s. 53A	ad. No. 39, 2006

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Endnote 4—Amendment history

Provision affected	How affected
	am. No. 54, 2010; No 4, 2014; No 47, 2017; No 7, 2018
s. 54	am. No. 204, 1991; No. 76, 1993; No. 6, 1996; No. 24, 2002; No. 39, 2006; No 4, 2014; No 7, 2018
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
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; Nos. 38 and 76, 2009; Nos. 54 and 141, 2010; No 4, 2014; No 47, 2017; No 7, 2018
s. 57	am. Nos. 84 and 204, 1991; No. 88, 1992; No. 6, 1996; No. 146, 1999; Nos. 23 and 24, 2002; No. 5, 2006; Nos. 38 and 96, 2009; Nos. 54 and 141, 2010; No 47, 2017
s. 58	am. No. 76, 1993; No. 76, 2009
s. 59	am. No. 54, 2010
s. 60	am. No. 6, 1996; No. 24, 2002; No. 39, 2003; No. 39, 2006; No. 76, 2009; Nos. 54 and 141, 2010; No 4, 2014; No 47, 2017; No 7, 2018
s. 60A	ad. No. 6, 1996
	am. No. 24, 2002; No. 54, 2010
s. 61	am. No. 84, 1991; No. 88, 1992; No. 76, 1993; No. 116, 1997; No. 34, 1998; Nos. 12 and 120, 2000; No. 24, 2002; No. 39, 2006; Nos. 38 and 76, 2009; No. 54, 2010; No 197, 2012; No 47, 2017; No 7, 2018; No 121, 2019
s. 61A	ad. No. 54, 2010
s. 62	rep. No. 136, 2012

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Endnote 4—Amendment history

Provision affected	How affected
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
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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