



# Therapeutic Goods Act 1989

## Act No. 21 of 1990 as amended

This compilation was prepared on 12 January 2011  
taking into account amendments up to Act No. 141 of 2010

The text of any of those amendments not in force  
on that date is appended in the Notes section

The operation of amendments that have been incorporated may be affected  
by application provisions that are set out in the Notes section

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# An Act relating to therapeutic goods

## Chapter 1—Preliminary

### 1 Short title [see Note 1]

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

### 2 Commencement [see Note 1]

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.

***advertisement***, in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.

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***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.

***authorised person*** means:

- (a) in relation to any provision of this Act, 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.

***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.

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

**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).

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

**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*.

**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).

***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.

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**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.

**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 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*.



**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.

**included in the Register**, in relation to a medical device to which Chapter 4 applies, means included in the Register under Chapter 4.

Note: For medical devices to which Chapter 4 applies, see section 41BJ.

**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* 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).

**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 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.

***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.

***National Manager of the Therapeutic Goods Administration*** means:

- (a) the person holding the position of National Manager of the Therapeutic Goods Administration; or
- (b) if the position of National Manager of the Therapeutic Goods Administration ceases to exist, or ceases to be referred to by that name—the person holding a position determined in writing by the Secretary.

***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.

**penalty unit**, in relation to a civil penalty provision, has the meaning given by section 42YB.

**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.

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

**registered goods** means therapeutic goods included in the part of the Register for goods known as registered goods.

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

**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 to the Department.

**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
- (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 Pharmacopoeia-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 Pharmacopoeia-National Formulary.

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 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 Secretary, by order published in the *Gazette*, 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 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.

***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.
- (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* 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 or an annual licensing 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.

**3A Declaration—member of European Community**

- (1) The Minister may declare, in writing, that a country specified in the declaration is a member of:
- (a) the European Community; or
  - (b) the European Free Trade Association.

- (2) A declaration under subsection (1) must be published in the *Gazette*.

### **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*.

### **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 Pharmacopoeia-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 *Legislative Instruments 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 Pharmacopoeia-National Formulary are exempt for the purposes of paragraph (b), (c) or (d) of the definition of **standard** in subsection 3(1).

## **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

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- (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 subsections 21A(1), (2) and (4) and sections 22A, 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 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).

*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 (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:

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- (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:

- (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:
  - (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 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.

**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*, 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 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.

**7A Authorised persons**

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

- (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) A package and therapeutic goods in the package together constitute a kit for the purposes of this Act if:
  - (a) the package and the therapeutic goods are for use as a unit; and
  - (b) each item of the therapeutic goods consists of goods that are registered or listed or are exempt goods in relation to Part 3-2; and
  - (c) the package and therapeutic goods do not constitute a composite pack or a system or procedure pack.
- (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.
- (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.

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

## 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 3 parts:
  - (a) a part for goods to be known as registered goods; and
  - (b) a part for goods to be known as listed goods; 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:
    - (i) goods that are included in the part of the Register relating to registered goods may be transferred, or may be required to be transferred, to the part of the Register for listed goods; and
    - (ii) goods that are included in the part of the Register relating to listed goods may be transferred, or may be required to be transferred, to the part of the Register for registered goods; 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
  - (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*:
- (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 *Gazette* 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:

<b>Time of cancellation of registration or listing</b>	
<b>Circumstances</b>	<b>Time</b>
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

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**Time of cancellation of registration or listing**

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Circumstances	Time
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: <ul style="list-style-type: none"> <li>(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);</li> <li>(b) the time the application is finally determined, if the application is unsuccessful when it is finally determined;</li> </ul> or, if the application lapses, the later of the following times (or either of them if they are the same): <ul style="list-style-type: none"> <li>(c) the time the application lapses;</li> <li>(d) the start of 4 October 2007</li> </ul>
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:

- (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.

**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.
- (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.

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(2A) Subsection (2), to the extent to which it relates to subparagraph (2)(b)(i), 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
- (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.

(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;

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
- (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 the part for goods to be known as registered goods or to the part for goods to be known as listed goods (whichever 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).

*Approved forms for requests*

- (6) The Secretary may, by writing, approve a form for particular kinds of requests under this section.
- (7) If the Secretary has approved a form for a particular kind of request under this section, then any request of that kind must be in accordance with that form.

*Fees*

- (8) A request under this section must be accompanied by any prescribed application fee or prescribed evaluation fee or both.

**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.

## **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 or the United States Pharmacopoeia-National Formulary).

Note: Section 12 of the *Legislative Instruments Act 2003* deals with when a legislative instrument takes effect.

- (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 or the United States Pharmacopoeia-National Formulary; or
    - (v) a monograph in another publication approved by the Minister for the purposes of this subsection; or
    - (vi) such a monograph as modified in a manner specified in the order establishing the standard; or
    - (vii) a standard published by the Standards Australia International Limited; 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 *Legislative Instruments Act 2003* deals with when a legislative instrument takes effect.
- (4) The Minister must not make an order under subsection (1), or vary or revoke an order made under subsection (1), unless the Minister has consulted with respect to the proposed action with a committee established by the regulations to advise the Minister on standards.

## 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.

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

## 13 Special provisions relating to 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 Pharmacopoeia-National Formulary 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 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
  - (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*, 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.

#### **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; and
  - (d) either:
    - (i) the use of the goods has resulted in, or will result in, harm or injury to any person; or
    - (ii) the use of the goods, if the goods were used, would result in harm or injury to any person; and
  - (e) the harm or injury has resulted, will result, or would result, because the goods do not conform with the standard.

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.

- (2) 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; and

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- (d) the use of the goods, if the goods were used, would be likely to result in harm or injury to any person; and
- (e) the harm or injury would be likely to result because the goods do not conform with the standard.

Penalty: 2,000 penalty units.

- (3) Subsection (2) is an offence of strict liability.

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

- (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.

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

*Exception*

- (5) Paragraphs (1)(a), (2)(a) and (4)(a) do not apply to goods that do not conform with a standard applicable to the goods by reason only of matters relating to labelling or packaging.

Note: A defendant bears an evidential burden in relation to the matters in subsection (5): 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:
- (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, or will result in, harm or injury to any person; or
    - (ii) the use of the goods, if the goods were used, would result in harm or injury to any person; and



- (e) the harm or injury has resulted, will result, or would result, because the goods do not conform with the standard.

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 (9) instead: see section 53A.

- (7) 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; and
  - (d) the use of the goods, if the goods were used, would be likely to result in harm or injury to any person; and
  - (e) the harm or injury would be likely to result because the goods do not conform with the standard.

Penalty: 2,000 penalty units.

- (8) Subsection (7) is an offence of strict liability.

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

- (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.

*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

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- (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, or will result in, harm or injury to any person; or
  - (ii) the use of the goods, if the goods were used, would result in harm or injury to any person; and
- (e) the harm or injury has resulted, will result, or would result, because the goods do not conform with the standard.

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 (13) instead: see section 53A.

- (11) 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) the use of the goods, if the goods were used, would be likely to result in harm or injury to any person; and
  - (e) the harm or injury would be likely to result because the goods do not conform with the standard.

Penalty: 2,000 penalty units.

- (12) Subsection (11) is an offence of strict liability.

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

- (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.

*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*.
- (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.

*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

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

*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.

*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*.
- (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), (2), (4), (10), (11) or (13) or a contravention of subsection 14A(1) or (3); and
- (b) the Secretary notifies the Chief Executive Officer 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:
- (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, or will result in, harm or injury to any person.

Penalty: 2,000 penalty units.

Note: 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.

- (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 breaches a condition of a consent; and
  - (c) the act or omission is likely to result in harm or injury to any person.

Penalty: 1,000 penalty units.

- (4) Subsection (3) is an offence of strict liability.

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; and
  - (b) the act or omission breaches a condition of a consent.

Penalty: 500 penalty units.

## **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.

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Maximum civil penalty:

- (a) for an individual—3,000 penalty units; and
- (b) for a body corporate—30,000 penalty units.

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

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*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.

*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.

## **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).
- (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.

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- (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.

**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 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

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- (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*.

*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 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 special and experimental 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.

(1A) An approval for the purpose mentioned in paragraph (1)(b) is subject to the conditions (if any) specified in the regulations. 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:

- (a) in the case of an application for use of the kind referred to in paragraph (1)(a)—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;
  - (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.

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- (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).
- (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 that complies with section 23 has been made under that section for registration of the goods; 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.
- (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 that complies with section 23 has been made under that section for registration of the goods; 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 this section.
- (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.
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- (8) The approval lapses if:
  - (a) the period specified in the notice of approval expires; or
  - (b) a decision has been made under section 25 in relation to the goods.
  
- (9) The approval lapses if:
  - (a) the Secretary is satisfied that paragraph (1)(a), (b), (c) or (d), or paragraph (2)(a), (b), (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.

**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;
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- (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, or will result in, harm or injury to any person; or
  - (ii) the use of the goods, if the goods were used, would 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:** 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.

(2) 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

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- (c) the use of the goods, if the goods were used, would be likely to result in harm or injury to any person.

Penalty: 2,000 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.

- (3) Subsection (2) is an offence of strict liability.

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

- (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.

*Defence if person was not the sponsor of the goods*

- (5) It is a defence to a prosecution under subsection (1), (2) or (4) 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, or will not, 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; or
  - (b) harm or injury would not 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), (2) or (4); and
  - (b) the Secretary notifies the Chief Executive Officer 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

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- (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:
  - (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.

- (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;
    - (iv) supplies in Australia therapeutic goods for use in humans; and
  - (b) none of the following subparagraphs applies in relation to the goods:

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- (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.

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 Chief Executive Officer 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 is guilty of 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:

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- (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.

(1C) For the purposes of paragraph (1B)(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.

(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:
- (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.

## **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); and
  - (c) the statement is false or misleading in a material particular; and
  - (d) either:
    - (i) the use of the medicine has resulted in, or will result in, harm or injury to any person; or
    - (ii) the use of the medicine, if the medicine were used, would 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.

- (2) 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); and

- (c) the statement is false or misleading in a material particular;  
and
- (d) the use of the medicine, if the medicine were used, would be likely to result in harm or injury to any person.

Penalty: 2,000 penalty units.

- (3) Subsection (2) is an offence of strict liability.

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

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

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

*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, or will 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.

- (6) 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

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- (d) the act or omission is likely to result in harm or injury to any person.

Penalty: 2,000 penalty units.

- (7) Subsection (6) is an offence of strict liability.

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

- (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.

*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:
  - (i) the use of the goods has resulted in, or will result in, harm or injury to any person; or
  - (ii) the use of the goods, if the goods were used, would result in harm or injury to any person; and
- (e) the harm or injury has resulted, will result, or would 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.

Note: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection 22(7A) instead: see section 53A.

- (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; 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) the use of the goods, if goods were used, would be likely to result in harm or injury to any person; and
  - (e) the harm or injury 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: 2,000 penalty units.

- (11) Subsection (10) is an offence of strict liability.

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

*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

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- (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, or will 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, or will result in, harm or injury to any of those persons.

**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 22(8) instead: see section 53A.

- (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); and



(e) either:

- (i) if the person used the goods in the treatment of another person—the use of the goods, if the goods were used, 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, if the goods were used, is likely to result in harm or injury to any of those persons.

Penalty: 2,000 penalty units.

(14) Subsection (13) is an offence of strict liability.

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

## **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), 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
  - (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.

**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.

- (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: 60 penalty units.

- (6) A person must not make a claim, by any means, that the person or another person can arrange the supply of therapeutic goods (not being exempt goods or goods exempt under section 18A) that are not registered goods or listed goods.

Penalty: 60 penalty units.

- (7) A person is guilty of 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
  - (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.

(7AC) Strict liability applies to paragraph (7AB)(b).

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

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(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*.

(7A) A person to whom an authority under subsection 19(5) has been granted must not supply the therapeutic goods to which the authority relates except in accordance with:

- (a) the authority; and
- (aa) the conditions (if any) to which the authority is subject; and
- (b) any regulations made for the purpose of subsection 19(7).

Penalty: 500 penalty units.

(8) A person must not use therapeutic goods, other than exempt goods, listed goods, registered goods, goods exempt under section 18A or goods that are the subject of an approval under section 19A:

- (a) for use in the treatment of another person; or
  - (b) for use solely for experimental purposes in humans;
- except in accordance with an approval or authority under section 19 or a condition applicable under regulations made for the purposes of subsection 19(4A).

Penalty: 500 penalty units.

**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:

- (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, or will result in, harm or injury to any person; or
    - (ii) the use of the goods, if the goods were used, would 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.

- (2) 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) the use of the goods, if the goods were used, would be likely to result in harm or injury to any person.

Penalty: 2,000 penalty units.

- (3) Subsection (2) is an offence of strict liability.

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

- (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.

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

**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.

## **Division 2—Registration and listing**

### **23 Applications generally**

- (1) An application for registration or listing of therapeutic goods 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.
- (2) An application is not effective unless:
  - (a) the prescribed application fee has been paid; and
  - (b) 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
  - (ba) if the application is for the registration of restricted medicine—the application is accompanied by product information, in relation to the medicine, that is in the form approved under section 7D in relation to the medicine; and
  - (c) 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.
- (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.

### **24 Applications for registration**

- (1) Where an application is made for the registration of therapeutic goods in accordance with section 23 and the goods are goods that are required to be registered, 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.

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- (2) Subject to section 24D, 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 sections 24B and 24D, 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.

**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 Reduction 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) Nothing in section 24, 24A or 24B requires the applicant to pay more than three-quarters of the evaluation fee before the completion of the evaluation of the goods.
- (3) If the evaluation is not completed within the period referred to in subsection (1), this Act has effect as if the evaluation fee were reduced to three-quarters of the fee that, under the regulations, would have been the evaluation fee.
- (4) If:
  - (a) the evaluation is completed within the period referred to in subsection (1); and
  - (b) part of the evaluation fee under section 24 is unpaid when the evaluation is completed;that part becomes due and payable on the completion of the evaluation.
- (5) For the purposes of subsections (2), (3) and (4), the evaluation is to be taken to be completed when the applicant is notified according to subsection 25(3) or (4) of the Secretary's decision on the application.
- (6) Despite subsection (5), if:

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- (a) the Secretary has given the applicant all evaluation reports relating to the application; and
- (b) the Secretary has given those reports, or proposes to give those reports, to a committee established under the regulations to advise the Secretary on applications to register therapeutic goods to which subsection (1) applies; and
- (c) the applicant withdraws the application after being given the reports, and before the end of the period mentioned in subsection (1);

the evaluation is taken for the purposes of subsections (2), (3) and (4) to be completed immediately before the time of withdrawal.

**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 and registration of therapeutic goods**

- (1) If an application is made for the registration of therapeutic goods in relation to a person in accordance with section 23, the Secretary must evaluate the goods for registration having regard to:

- (d) whether the quality, safety and efficacy of the goods for the purposes for which they are to be used have been satisfactorily established; 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, or any requirements relating to advertising applicable under Part 5-1 or under the regulations; and
- (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 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.
- (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) If:
- (a) the therapeutic goods are therapeutic devices; and
  - (b) the evaluation of the goods for registration has been completed;
- the Secretary must:
- (c) notify the applicant in writing of his or her decision on the evaluation within 28 days of the making of the decision and, in the case of a decision not to register the goods, of the reasons for the decision; and
  - (d) if the decision is to register the goods—include the goods in the Register and give the applicant a certificate of registration.
- (4) If:
- (a) the therapeutic goods are not therapeutic devices; and
  - (b) the evaluation of the goods for registration has been completed;
- the Secretary must:
- (c) notify the applicant in writing of his or her decision on the evaluation within 28 days of the making of the decision and,

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in the case of a decision not to register the goods, of the reasons for the decision; and

- (d) if the decision is to register the goods:
  - (i) notify the applicant in writing that the goods will be included in the Register if the applicant gives the Secretary either the certificate required under subsection 26B(1) or 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
  - (ia) if the goods are restricted medicine or the goods are medicine in respect of which the applicant has been given a notice of the kind referred to in subparagraph (1)(da)(ii)—notify the applicant in writing of the product information that is approved in relation to the medicine; and
  - (ii) include the goods in the Register and give the applicant a certificate of registration if the applicant gives the Secretary either the certificate required under subsection 26B(1) or 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.

To avoid doubt, if the applicant gives the Secretary the certificate required under subsection 26B(1) or a notice that a certificate under that subsection is not required in relation to the application, the Secretary must include the goods in the Register under subparagraph (d)(ii) without inquiring into the correctness of the certificate or the notice.

- (5) The registration of therapeutic goods commences on the day specified for the purpose in the certificate of registration.

**25AA Approved product information for medicine**

- (1) If:
  - (a) the Secretary includes restricted medicine in the Register in relation to a person under subparagraph 25(4)(d)(ii); or
  - (b) an applicant for the registration of medicine (other than restricted medicine) is given a notice of the kind referred to in subparagraph 25(1)(da)(ii) and the Secretary includes the

medicine in the Register in relation to the applicant under subparagraph 25(4)(d)(ii);  
the product information that is approved under this section in relation to the medicine is the product information referred to in subparagraph 25(4)(d)(ia).

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) 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) 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 under subparagraph 25(4)(d)(ii);
- 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.

Note: Subsection (4) deals with variation of the product information.

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*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.
- (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.

**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.

### **25B Registration of therapeutic device to which EC/EFTA attestation of conformity applies**

- (1) If:
- (a) an application is made in accordance with section 23 for the registration of a therapeutic device in relation to a person; 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 in accordance with section 23; and
- (aa) if goods are not therapeutic devices—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 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;

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 to a requirement relating to advertising applicable under Part 5-1 or under 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:
  - (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
  - (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 in accordance with section 23; 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 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:
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- (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.
- (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.

#### **26AA Listing of therapeutic device to which EC/EFTA attestation of conformity applies**

- (1) If:
- (a) an application is made in accordance with section 23 for the listing of a therapeutic device in relation to a person; 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

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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 in accordance with section 23; 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 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
  - (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
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- (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 to every requirement (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
- (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
- (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

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- (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) the applicant holds information or evidence to support any claim that the applicant makes relating to the medicine; 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.
- (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.
- (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.
- (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.

## **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:

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- (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 is guilty of 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.

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 25(4), 26(1) or 26A(1) 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 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.
- (3) The requirements referred to in paragraph (1)(b) may relate to permitted concentrations or permitted total amounts of ingredients.
- (4) Subsections (2) 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.

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- (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 *Legislative Instruments 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.

**26BD Variation of determination under section 26BB —application by person**

- (1) A person may apply to the Minister for a variation of a determination under subsection 26BB(1).
- (2) An application under subsection (1) must:
- (a) be made in accordance with a form approved by the Secretary; and
  - (b) set out the variation sought; and
  - (c) be delivered to an office of the Department specified in the form; and
  - (d) be accompanied by the prescribed application fee.
- (3) If an application is made under subsection (1) and any applicable prescribed evaluation fee has been paid, the Minister may, by legislative instrument, vary the determination.
- (3A) In deciding whether to vary the determination, the Minister must have regard to the quality and safety of the ingredients concerned. This subsection does not limit the matters to which the Minister may have regard to in deciding whether to vary the determination.

*Further information*

- (4) The Minister may, by notice in writing given to the person, require the person to give to the Minister, 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*

- (5) An approval of a form mentioned in paragraph (2)(a), or a notice mentioned in subsection (4), 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 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:
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- (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:
- (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:

*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.

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- (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
      - (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*.

## **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
  - (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.
- (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
  - (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.
- (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
  - (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; 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
- (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
- (d) if requested to do so by an authorised person, make any such record available to the authorised person for inspection:
- (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.
- (5A) In addition to any conditions imposed under subsection (1), (2B), (3) or (5), the listing of a medicine under section 26A is subject to a condition that the person in relation to whom the medicine is listed will deliver a reasonable number of samples of the medicine if the Secretary so requests:
- (a) within the period specified in the request; and

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- (b) in accordance with any other requirements specified in the request.  
The period specified in the request must include at least 10 working days.
- (5B) The listing of a medicine under section 26A 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) or 28A(2).
- (5C) Subsection (5B) does not apply if the medicine is exempt from the operation of Part 3-3.
- (6) If:
  - (a) in, or in connection with, an application for the listing of therapeutic goods, a claim is made by the applicant in relation to the goods; and
  - (b) the claim is included in the Register in respect of the goods; the listing of the goods is subject to the following conditions:
    - (c) 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) of the regulations;
    - (d) a condition that the sponsor retains the information or evidence at all times while the goods remain listed;
    - (e) 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) The regulations may prescribe the amount, standard or type of information or evidence required for the purposes of paragraph (6)(c).

## **28A Certification of manufacturing steps outside Australia following application for listing**

- (1) The person in relation to whom medicine is listed under section 26A 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, subsection 26A(4) applies in a way corresponding to the way in which it applies for the purposes of subsection 26A(3).

## **29 Duration of registration or listing**

Where 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.

## **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.

- (2) The information with which subsection (1) is concerned is information of the following kinds:

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- (a) information that contradicts information already furnished 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 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;
    - (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.

- (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.

**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.

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*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 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) or (f) or subsection 30(1A), (1C) 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 in Gazette*

- (5) As soon as practicable after giving a notice under subsection (1), the Secretary must cause to be published in the *Gazette* a notice setting out particulars of the suspension.

**29E When suspension takes effect etc.**

- (1) A suspension under section 29D takes effect:
- (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.

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*Publication in Gazette*

- (4) As soon as practicable after giving a notice under subsection (3), the Secretary must cause to be published in the *Gazette* 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
  - (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 in Gazette*

- (3) As soon as practicable after giving a notice under subsection (1), the Secretary must cause to be published in the *Gazette* 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.

### **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) or (g) are incorrect or (if applicable) the requirements under subsection 26A(3) or (4A) are not fulfilled; or
  - (f) both of the following apply:
    - (i) under the regulations, an authority constituted by or under the regulations gives a direction to, or makes a requirement of, the person in relation to an

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advertisement of the goods to ensure that advertising complies with the Therapeutic Goods Advertising Code;

- (ii) the person does not comply with the direction or requirement.

(1A) 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 medicine is not eligible for listing; or
- (b) the medicine is exempt; or
- (c) there is a serious breach, involving the medicine, of the requirements 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 medicine is misleading to a significant extent.

(1B) However, paragraph (1A)(c) does not apply to medicines that are manufactured in Australia for export only, or are imported into Australia for export only.

(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
- (b) the notice is given for the purposes of ascertaining whether the medicine should have been listed; 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
- (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), (f), (fa), (fb), (fc), (h), (i), (j) or (k) or subsection 26A(2A) 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
  - (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 to a requirement relating to advertising applicable to the goods under Part 5-1 or under the regulations; or
  - (f) the annual registration or listing charge is not paid within 28 days after it becomes payable.
- (3) Where the Secretary proposes to cancel the registration or listing of goods in relation to a person under subsection (2) otherwise than as a result of a failure to pay the annual registration or listing charge, 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:
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- (a) if the cancellation is effected under subsection (1), (1A) or (1C)—on the day on which the notice of cancellation is given to the person; or
- (b) in any other case—on such later day as is specified in the notice.

**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
  - (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.

**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 the therapeutic good 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.

- (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
  - (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

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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 recovery of therapeutic goods**

### **30EA Public notification and recovery 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.

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<b>Circumstances in which requirements may be imposed</b>		
<b>Item</b>	<b>Circumstance relating to therapeutic goods</b>	<b>Person subject to requirements</b>
1.	The goods are supplied while they are registered goods or listed goods, but 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 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 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**

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<b>Item</b>	<b>Circumstance relating to therapeutic goods</b>	<b>Person subject to requirements</b>
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 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), (2) or (4), 19D(1) or 42E(1) or section 42EA	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 the quality, safety or efficacy of the goods is unacceptable or that 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
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

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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 recover 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
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paragraph (1)(a) have occurred 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.
- (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.
- (4) A requirement to recover therapeutic goods under this section does not apply to therapeutic goods that cannot be recovered 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*, 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, or will 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.

- (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 requirement imposed on the person under section 30EA; and
  - (c) the act or omission is likely to result in harm or injury to any person.

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Penalty: 2,000 penalty units.

- (3) Subsection (2) is an offence of strict liability.

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

- (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.

**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.

## **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 recover the goods included in that batch (except any of those goods that cannot be recovered 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 recover 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*.

*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 for the purposes of the *Legislative Instruments Act 2003*.

*Offences*

- (4B) 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; and
- (d) either:
  - (i) the use of the goods has resulted in, or will result in, harm or injury to any person; or
  - (ii) the use of the goods, if the goods were used, would result in harm or injury to any person; and
- (e) the harm or injury has resulted, will result, or would result, because the person failed to comply with that requirement.

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 (5) instead: see section 53A.

- (4C) 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) the use of the goods, if the goods were used, would be likely to result in harm or injury to any person; and
  - (e) the harm or injury would be likely to result because the person failed to comply with that requirement.

Penalty: 2,000 penalty units.

- (4D) Subsection (4C) is an offence of strict liability.

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

- (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) For the purposes of an offence against subsection (5), strict liability applies to the following physical elements of circumstances:
- (a) that the notice concerned is given under subsection (2);
  - (b) that the particular requirement concerned is a requirement mentioned in subsection (3).

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

**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.
- (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
    - (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**

- (1) The Secretary may, by notice in writing given to a person:
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- (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;
  - (ga) whether the goods comply with conditions (if any) on the registration of the goods;
  - (h) the conformity of the goods to a requirement relating to advertising applicable under Part 5-1 or under 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;
  - (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.

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(1B) If:

- (a) a person makes an application under section 23 for the registration of therapeutic goods in accordance with a form referred to in paragraph 23(1)(a); and
- (b) the form is described as a pre-submission 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 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 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 medicine—the matters covered by a certification by the person under paragraph 26A(2)(j) in relation to the medicine;
  - (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, or to a requirement relating to advertising applicable to the goods under Part 5-1 or under the regulations;
  - (ga) if the goods are listed in relation to the person—whether the goods are being:
    - (i) supplied in Australia; or
    - (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:

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- (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*.

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

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

- (5A) A person commits an offence if:

- (a) a medicine is listed under section 26A in relation to the person; and
- (b) the person provides information in purported compliance with a notice under section 31 relating to the medicine; and
- (c) the information is false or misleading in a material particular; and
- (d) either:
  - (i) the use of the medicine has resulted in, or will result in, harm or injury to any person; or
  - (ii) the use of the medicine, if the medicine were used, would 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 (6) instead: see section 53A.

- (5B) A person commits an offence if:

- (a) a medicine is listed under section 26A in relation to the person; and
- (b) the person provides information in purported compliance with a notice under section 31 relating to the medicine; and
- (c) the information is false or misleading in a material particular; and

- (d) the use of the medicine, if the medicine were used, would be likely to result in harm or injury to any person.

Penalty: 2,000 penalty units.

- (5C) Subsection (5B) is an offence of strict liability.

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

- (6) A person in relation to whom a medicine is listed under section 26A must not, in purported compliance with a notice under this section relating to the medicine, provide information that is false or misleading in a material particular.

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

### **31AAA Civil penalty for providing false or misleading information in relation to medicines listed under section 26A**

A person contravenes this section if:

- (a) a medicine is listed under section 26A in relation to the person; and
- (b) the person provides information in purported compliance with a notice under section 31 relating to the medicine; 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.

### **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;

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- (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.

*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.

*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;

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- (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.

*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.

*Compliance period*

- (4) A notice under subsection (1), (2) or (3) 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*

- (5) A notice under subsection (1), (2) or (3) 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.

### **31C Criminal offence for failing to give information or documents sought under section 31A, 31AA or 31B**

A person commits an offence if:

- (a) the person is given a notice under section 31A, 31AA or 31B;  
and
- (b) the person fails to comply with the notice.

Penalty: 400 penalty units.

Note: The privilege against self incrimination is not a reasonable excuse for the purposes of this section. However, the information given, and the fact that a document was given under this section (and other information, documents or things obtained because of giving the information or document) generally cannot be used in a prosecution (see section 31F).

### **31D False or misleading information**

- (1) A person to whom a notice is given under section 31A, 31AA or 31B is guilty of 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.

- (2) Subsection (1) does not apply as a result of subparagraph (1)(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).

- (3) Subsection (1) does not apply as a result of subparagraph (1)(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).

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**31E False or misleading documents**

- (1) A person is guilty of 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 or 31B.

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).

- (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).

**31F Self-incrimination**

- (1) A person is not excused from giving information or a document under a notice given under section 31A, 31AA or 31B 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:
  - (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 31D or 31E; or
  - (e) proceedings for a pecuniary penalty order against the individual for a contravention of a civil penalty provision.

## **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.

### **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); 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; and

- (d) either:
  - (i) the use of the goods has resulted in, or will result in, harm or injury to any person; or
  - (ii) the use of the goods, if the goods were used, would result in harm or injury to any person; and
- (e) the harm or injury has resulted, will result, or would 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: 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.

- (2) 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); 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; and
  - (d) the use of the goods, if the goods were used, would be likely to result in harm or injury to any person; and
  - (e) the harm or injury would be likely to result because the person carried out the step in the manufacture of the goods.

Penalty: 2,000 penalty units.

- (3) Subsection (2) is an offence of strict liability.

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

- (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); and
  - (b) the goods are for supply for use in humans; and

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- (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.

- (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; 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, or will result in, harm or injury to any person; or
    - (ii) the use of the goods, if the goods were used, would result in harm or injury to any person; and
  - (f) the harm or injury has resulted, will result, or would 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: 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.

- (6) Strict liability applies to paragraph (5)(c).

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

- (7) 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; 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) the use of the goods, if the goods were used, would be likely to result in harm or injury to any person; and
- (f) the harm or injury would be likely to result because the person carried out the step in the manufacture of the goods.

Penalty: 2,000 penalty units.

- (8) Subsection (7) is an offence of strict liability.

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

- (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; 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) Strict liability applies to paragraph (9)(c).

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

### **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
- (b) the goods are for supply for use in humans; and
- (c) the goods are not exempt under section 18A; and
- (d) 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.

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; 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, or will 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.

- (2) 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 is likely to result in harm or injury to any person.

Penalty: 2,000 penalty units.

- (3) Subsection (2) is an offence of strict liability.

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

- (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.

### **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.
- (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

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- (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.
- (3) The Minister may, before taking action under subsection (1) in relation to the manufacturing principles, obtain advice from a committee established by the regulations on the action that should be taken under that subsection as to the principles to be observed in the manufacture of therapeutic goods for use in humans.
  - (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
  - (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:
  - (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

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- (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
- (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.

*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 46(3) of the *Acts Interpretation Act 1901*.

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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 in Gazette*

- (4) Where the Secretary grants a licence, the Secretary must cause particulars of the decision to be published in the *Gazette* as soon as is practicable after the decision is made.

**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.

*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;

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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.

- (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).

**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 or variation 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 for the purpose in the notice, being a day not earlier than 28 days after 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; 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

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- (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 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).
- (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

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- (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 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 46(3) 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

- (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.

*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) or (6), require the holder:
- (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 therapeutic goods at that site.

*Applications or information may be given electronically*

- (11) An approval of a form mentioned in paragraph (2)(a) or (7)(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;

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

- (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* as soon as is practicable after the decision is made.

**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).

**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).

**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.



## **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).

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

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

The administrative processes under this Chapter are:

- (a) issuing conformity assessment certificates for some manufacturers of medical devices; and
- (b) including medical devices in the Register; and
- (c) suspending or cancelling entries of medical devices from the Register; and

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- (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 recovery 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).

## 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 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:

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- (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*, 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*, 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 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
  - (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.
- (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;
    - (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.
- (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.

## **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.

### **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.



## **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.

## **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*.

## **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 *Legislative Instruments Act 2003* deals with when a legislative instrument takes effect.

- (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 Pharmacopoeia-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:
  - (a) Standards Australia International Limited;
  - (b) the International Organisation for Standardization;
  - (c) the International Electrotechnical Commission;

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- (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*.

**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.

## **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.

## 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;
  - (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.

## 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 *Legislative Instruments Act 2003* deals with when a legislative instrument takes effect.

- (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 International Limited;
  - (b) the International Organisation for Standardization;
  - (c) the European Committee for Standardization;
  - (d) any other organisation declared by the Minister by notice published in the *Gazette*.



**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).

## 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 before a valid application can be made for including a kind of medical device in the Register under this Chapter: see subsection 41FC(2).

## **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.

- (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

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- (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;
    - (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 certificate; or
  - (ix) had a conformity assessment certificate 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.
- 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).

#### **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.

**41EF Duration of certificate**

- (1) The conformity assessment certificate commences on the day specified for the purpose in the certificate.
- (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 (if any) specified in the certificate; or
  - (c) until the certificate is revoked under Division 4.

**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 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 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
  - (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, or will 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 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.

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

Penalty: 2,000 penalty units.

- (3) Subsection (2) is an offence of strict liability.

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

- (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.

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

#### **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.

## **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), (6) and (8)), 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.

#### *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.

*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 or variation 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
  - (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.

### **Division 3—Suspension of conformity assessment certificates**

Note: Suspension of a conformity assessment certificate leads to suspension from the Register of the kinds of medical devices to which the certificate applied (see subsection 41GF(1)). Applications to include such devices in the Register are not effective (see paragraph 41FC(2)(c)).

#### **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.

Section 41EO

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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:
  - (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.

## **Division 4—Revocation of conformity assessment certificates**

Note: Revocation of a conformity assessment certificate leads to cancellation of the entry from the Register of the kinds of medical devices to which the certificate applied (see paragraph 41GK(b)). Applications to include such devices in the Register are not effective (see paragraph 41FC(2)(c)).

### **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**

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.

### **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
  - (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 certificate; or
  - (ix) had a conformity assessment certificate 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.

Section 41EU

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(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.

(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*, 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.

**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.

## **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 (and certain other requirements are complied with).

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

## **Division 1—Including medical devices in the Register**

### **41FA What this Division is about**

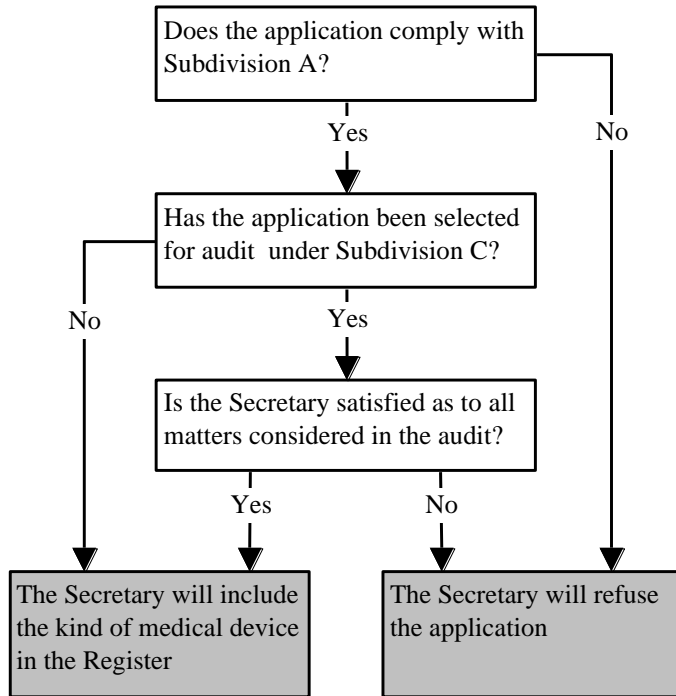
Kinds of medical devices are usually included in the Register automatically once a proper application is made, together with the required certification. However, applications may be selected for audit, which involves checking some or all aspects of the application and certification.

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

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.

**41FB How this Division works**

This diagram shows how this Division applies to an application for a kind of medical device to be included in the Register.



**Subdivision A—Applications**

**41FC Applications**

- (1) An application for a kind of medical device to be included in the Register 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.
- (2) An application is not effective if:
  - (a) the application is not made in accordance with subsection (1); or

- (b) the prescribed application fee has not been paid; or
- (c) 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 this section can be made, and no such certificate is in force; or
- (d) 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 41FE and 41FEA.

- (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.

#### **41FD Matters to be certified**

The applicant must certify that:

- (a) devices of the kind in question are medical devices; and
- (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) an appropriate conformity assessment procedure has been applied to devices of that kind; and

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- (g) the applicant:
  - (i) has available sufficient information to substantiate the application of those conformity assessment procedures; 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) devices of that kind comply with every requirement (if any) relating to advertising applicable under Part 5-1 or under the regulations; and
- (i) devices of that kind do not contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; and
- (ia) devices of that kind are not to be used exclusively for one or more of the purposes specified under section 41BEA; and
- (j) the information included in or with the application is complete and correct.

Note: See section 41BH on compliance with the essential principles and section 41BI on applying the conformity assessment procedures.

**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, or will 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 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.

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

Penalty: 2,000 penalty units.

- (3) Subsection (2) is an offence of strict liability.

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

- (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.

**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 is made in accordance with section 41FC for a kind of medical device to be included in the Register in relation to a person; and
    - (b) the requirements of section 41FD have been complied with; the Secretary must include the kind of device in the Register in relation to the person, unless the application has been selected under section 41FH for audit.
  - (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.
  - (2) As soon as practicable after the kind of device has been included in the Register, the Secretary must give 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.
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### **41FG Notification of unsuccessful applications**

The Secretary must notify the applicant in writing, within 20 working days after receiving an application under subsection 41FC(1), if an application for a kind of medical device to be included in the Register is unsuccessful.

### **Subdivision C—Auditing of applications**

#### **41FH Selecting applications for auditing**

- (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, within 20 working days after the application is made, give the applicant a written notice that:
    - (i) informs the applicant of the selection; and
    - (ii) requests the applicant to provide any further information necessary for the auditing of the application; and
  - (b) the application must be dealt with under this Subdivision and not under Subdivision B.

#### **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.
- (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.

Section 41FJ

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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.

**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
- (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 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 audit of the application; or
- (b) the applicant does not comply with a requirement by the Secretary 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.

### **Subdivision D—Miscellaneous**

#### **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.

#### **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.
- (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.

## **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), (2) and (4)), 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:
  - (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 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
    - (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 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

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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; 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 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:
  - (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 or variation 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
  - (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.

## **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 certificate 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 Register under Division 2 (other than under paragraph 41GL(a) or (d) 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*, 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
  - (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

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- (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*, 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:
- (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* 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
  - (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 under Part 4-4**

#### **41GF 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 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.

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**Part 4-6** Suspension and cancellation from the Register

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- (3) The Secretary must cause to be published in the *Gazette*, as soon as practicable after the suspension, a notice setting out particulars of the suspension.

**41GG Duration of suspension**

- (1) The suspension 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 the suspension 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.
- (2) 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* 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.

## **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
  - (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) both of the following apply:
  - (i) under the regulations, an authority constituted by or under the regulations gives a direction to, or makes a requirement of, the person in relation to an advertisement of the kind of device to ensure that advertising complies with the Therapeutic Goods Advertising Code;
  - (ii) the person does not comply with the direction or requirement; or
- (h) there is a serious breach, involving the kind of device, of the requirements 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.

**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 the kind of device should have been included in the Register; 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

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documents relating to whether medical devices of that kind are being:

- (i) supplied in Australia; or
  - (ii) imported into Australia; or
  - (iii) exported from Australia; and
- (b) either:
- (i) the information or documents given are to the effect that medical devices of that kind are not being supplied in Australia, imported into Australia or exported from Australia; or
  - (ii) the person fails to comply with the notice under section 41JA within a further 10 working days from the day specified in that notice.

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

- (1) The Secretary may, by written notice given to the person in relation to whom a kind of medical device is included in the Register, cancel the entry of the kind of device from the Register if:
- (a) medical devices that were devices of that kind when the kind of device was included in the Register have changed so those medical devices are no longer devices of that kind; or
  - (b) the person in relation to whom the kind of medical device is included in the Register refuses or fails to comply with a condition to which that inclusion is subject; or
  - (c) the Secretary gives to the person a notice under section 41JA:
    - (i) that requires the person to give to the Secretary information or documents relating to the kind of device; and
    - (ii) in respect of which section 41GM does not apply; 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.

Note: The matters that must be certified under section 41FD include compliance with the essential principles and the application of conformity assessment procedures, being able to substantiate the compliance and application, and compliance with advertising requirements.

- (2) However, before cancelling the entry of the kind of device from the Register, the Secretary must:
  - (a) inform the person in writing that the Secretary proposes the cancellation and set out the reasons for it; and
  - (b) give the person a reasonable opportunity to make submissions to the Secretary in relation to the proposed cancellation.
- (3) The Secretary is not to make a decision relating to the proposed cancellation until the Secretary has had regard to any submissions the person makes under paragraph (2)(b).

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

- (1) If the Secretary is satisfied that the ground for cancelling the entry of a kind of medical device from the Register applies only to some medical devices of that kind, the Secretary must limit the cancellation to the medical devices to which that ground or any other ground for cancellation applies.
- (2) If the cancellation of the entry of a kind of medical device from the Register is limited to some medical devices of that kind, the Secretary:
  - (a) must vary the entry in the Register accordingly; and
  - (b) must not delete the entry from the Register because of the cancellation.

#### **41GP Publication of cancellation of entry from Register**

The Secretary must cause to be published in the *Gazette*, 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.

## **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 recovery 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;
- (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
  - (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

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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).

**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, 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.

## **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 particular medical 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.

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.
- (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;
  - (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 accompanied by any information about the devices that is required by the Secretary.

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- (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;
  - (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 medical 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.
- (2) An authority may be given subject to conditions specified in the authority.

- (3) The Secretary may impose conditions (or further conditions) on a person's authority by giving the person written notice of the conditions.
- (4) An authority 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.
- (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:
  - (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

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- (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
- (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 *Legislative Instruments 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
- (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 *Legislative Instruments 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.

*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:
  - (a) the Secretary is satisfied that paragraph (1)(c), (d), (e) or (f), 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

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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) or (2) is not a legislative instrument.



## **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;
- 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.

## **Division 1—Information relating to compliance with requirements and other matters**

### **41JA Secretary may require information**

- (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 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 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;
- (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 the devices comply with every requirement (if any) 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 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.
- (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

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spent convictions and require persons aware of such convictions to disregard them).

**41JB Complying with the Secretary's requirements**

- (1) The person must give the information or documents to the Secretary:
  - (a) within such reasonable time, being not less than 10 working days from the day on which the notice is given, as is specified in the notice; and
  - (b) in such form as is specified in the notice.
- (2) The form may require or permit information to be given in accordance with specified software requirements:
  - (a) on a specified kind of data processing device; or
  - (b) by way of a specified kind of electronic transmission.

*Offence for failing to comply with a notice*

- (3) A person commits an offence if:
  - (a) the person is given a notice under section 41JA; and
  - (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).

*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, or will 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 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 (7) instead: see section 53A.

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

Penalty: 2,000 penalty units.

- (6) Subsection (5) is an offence of strict liability.

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

- (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.

#### **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.

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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.

**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), (5) or (7); 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.

## **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, 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;

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- (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.

**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.

*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.

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**41JF Secretary may require information relating to authorities under section 41HC**

- (1) The Secretary may give to a person who is granted an authority under section 41HC (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.
- (2) 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.
- (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.

**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) 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.
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- (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.

#### **41JG Criminal offences for failing to give information or documents sought under this Division**

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.

Note: The privilege against self incrimination is not a reasonable excuse for the purposes of this section. However, section 41JJ limits the use in prosecutions of information etc. obtained under sections 41JCA, 41JD, 41JE, 41JF and 41JFA.

#### **41JH False or misleading information**

A person to whom a notice is given under section 41JCA, 41JD, 41JE, 41JF or 41JFA is guilty of 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.

#### **41JI False or misleading documents**

- (1) A person is guilty of an offence if:
  - (a) the person produces a document to the Secretary; and

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- (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.

- (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.

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.
- (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 recovery of medical devices**

### **41K What this Part is about**

The Secretary can require action to recover 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 recovery 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.

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<b>Circumstances in which requirements may be imposed</b>		
<b>Item</b>	<b>Circumstance relating to a kind of medical device</b>	<b>Person subject to requirements</b>
1.	It is supplied while it is included in the Register, but 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 conformity assessment 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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<b>Circumstances in which requirements may be imposed</b>		
<b>Item</b>	<b>Circumstance relating to a kind of medical device</b>	<b>Person subject to requirements</b>
3.	<p>It is supplied while:</p> <p>(a) medical devices of that kind are exempt devices; or</p> <p>(b) there is an approval under section 41HB relating to devices of that kind; or</p> <p>(c) there is an authority under section 41HC relating to devices of that kind; or</p> <p>(d) there is an approval under subsection 41HD(1) or (2) relating to devices of that kind;</p> <p>but medical devices of that kind do not comply with the essential principles</p>	The person supplying the kind of medical device
4.	<p>It is supplied while:</p> <p>(a) medical devices of that kind are exempt devices; or</p> <p>(b) there is an approval under section 41HB relating to devices of that kind; or</p> <p>(c) there is an authority under section 41HC relating to devices of that kind; or</p> <p>(d) there is an approval under subsection 41HD(1) or (2) relating to devices of that kind;</p> <p>but the conformity assessment procedures have not been applied to medical devices of that kind</p>	The person supplying the kind of medical device

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**Circumstances in which requirements may be imposed**

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<b>Item</b>	<b>Circumstance relating to a kind of medical device</b>	<b>Person subject to requirements</b>
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) 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

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- (2) The requirements may be one or both of the following:
- (a) to take specified steps, in the specified manner and within such reasonable period as is specified, to recover 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

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paragraph (1)(a) have occurred in relation to medical devices of that kind.

- (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 recover medical devices under this section does not apply to a medical device that cannot be recovered 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*, as soon as practicable after imposing a requirement under section 41KA, a notice setting out particulars of the requirement.

**41KC Criminal offences for failing to comply with requirements relating to a kind of medical device**

- (1) A person commits an offence if:
  - (a) the person does an act or omits to do an act; and
  - (b) the act or omission breaches a requirement imposed on the person under section 41KA; and
  - (c) the act or omission has resulted in, or will 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.

- (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 requirement imposed on the person under section 41KA; and
  - (c) the act or omission is likely to result in harm or injury to any person.

Penalty: 2,000 penalty units.

- (3) Subsection (2) is an offence of strict liability.



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

- (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.

**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.

## **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;
  - (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.

**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  $\frac{3}{4}$  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

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- (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  $\frac{3}{4}$  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.

## **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 (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).

## 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, or will result in, harm or injury to any person; or
    - (ii) the use of the device, if the device were used, would result in harm or injury to any person; and
  - (e) the harm or injury has resulted, will result, or would result, because the device does not comply with the essential principles.

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.

- (2) 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) the use of the device, if the device were used, would be likely to result in harm or injury to any person; and
- (e) the harm or injury would be likely to result because the device does not comply with the essential principles.

Penalty: 2,000 penalty units.

- (3) Subsection (2) is an offence of strict liability.

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

- (4) 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: Imprisonment for 12 months or 1,000 penalty units, or both.

*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, or will result in, harm or injury to any person; or
    - (ii) the use of the device, if device were used, would result in harm or injury to any person; and
  - (e) the harm or injury has resulted, will result, or would result, because the device does not comply with the essential principles.

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 (8) instead: see section 53A.

- (6) 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) the use of the device, if the device were used, would be likely to result in harm or injury to any person; and
  - (e) the harm or injury would be likely to result because the device does not comply with the essential principles.

Penalty: 2,000 penalty units.

- (7) Subsection (6) is an offence of strict liability.

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

- (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.

*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; 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, or will result in, harm or injury to any person; or
  - (ii) the use of the device, if the device were used, would result in harm or injury to any person; and
- (e) the harm or injury has resulted, will result, or would result, because the device does not comply with the essential principles.

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 (12) instead: see section 53A.

- (10) 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; 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) the use of the device, if the device were used, would be likely to result in harm or injury to any person; and
  - (e) the harm or injury would be likely to result because the device does not comply with the essential principles.

Penalty: 2,000 penalty units.

- (11) Subsection (10) is an offence of strict liability.

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

- (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; 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: Imprisonment for 12 months or 1,000 penalty units, or both.

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*Exception*

- (13) Paragraphs (9)(b), (10)(b) and (12)(b) do not apply to the extent that the essential principles in question relate to labelling medical devices for supply in Australia.

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

**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:
- (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; 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.

- (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

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(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, or will result in, harm or injury to any person.

Penalty: 2,000 penalty units.

Note: 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.

(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 breaches a condition of a consent; and
- (c) the act or omission is likely to result in harm or injury to any person.

Penalty: 1,000 penalty units.

(4) Subsection (3) is an offence of strict liability.

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; and
- (b) the act or omission breaches a condition of a consent.

Penalty: 500 penalty units.

**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), (2), (4), (9), (10) or (12) or a contravention of subsection 41MAA(1) or (3); and
- (b) the Secretary notifies the Chief Executive Officer 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.

## 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, or will result in, harm or injury to any person; or
    - (ii) the use of the device, if the device were used, would result in harm or injury to any person; and
  - (e) the harm or injury has resulted, will result, or would 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: 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.

- (2) 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) the use of the device, if the device were used, would be likely to result in harm or injury to any person; and

- (e) the harm or injury would be likely to result because the conformity assessment procedures have not been applied to the device.

Penalty: 2,000 penalty units.

- (3) Subsection (2) is an offence of strict liability.

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

- (4) 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: Imprisonment for 12 months or 1,000 penalty units, or both.

*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, or will result in, harm or injury to any person; or
    - (ii) the use of the device, if the device were used, would result in harm or injury to any person; and
  - (e) the harm or injury has resulted, will result, or would 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: 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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- (6) 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) the use of the device, if the device were used, would be likely to result in harm or injury to any person; and
  - (e) the harm or injury would be likely to result because the conformity assessment procedures have not been applied to the device.

Penalty: 2,000 penalty units.

- (7) Subsection (6) is an offence of strict liability.

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

- (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.

**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:
  - (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, or will result in, harm or injury to any person; or
    - (ii) the use of the device, if the device were used, would result in harm or injury to any person; and
  - (d) the harm or injury has resulted, will result, or would 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.

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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 (2) instead: see section 53A.

- (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
  - (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, or will result in, harm or injury to any person; or
    - (ii) the use of the device, if the device were used, would result in harm or injury to any person; and
  - (d) the harm or injury has resulted, will result, or would 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: 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 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.

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.

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 is guilty of an offence if:

- (a) the person makes a statement in or in connection with a declaration, relating to the application of conformity assessment 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.

**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 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.

### **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) or (2) that is held by the person; and
  - (c) either:
    - (i) the use of the device has resulted in, or will result in, harm or injury to any person; or
    - (ii) the use of the device, if the device were used, would 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.

- (2) A person commits an offence if:
- (a) the person:
    - (i) imports a medical device into Australia; or

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- (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) or (2) that is held by the person; and
- (c) the use of the device, if the device were used, would be likely to result in harm or injury to any person.

Penalty: 2,000 penalty units.

- (3) Subsection (2) is an offence of strict liability.

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

- (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) or (2) that is held by the person.

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

- (5) Strict liability applies to paragraph (4)(b).

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

*Defence if person was not the sponsor of the goods*

- (6) It is a defence to a prosecution under subsection (1), (2) or (4) 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, or will not, 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 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.

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;

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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
  - (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*.

#### **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;

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- (iv) the device is the subject of an approval under subsection 41HD(1) 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:

- (a) the importation or exportation of a medical device is an offence under subsection 41MI(1), (2) or (4) or a contravention of section 41MIB; and  
(b) the Secretary notifies the Chief Executive Officer 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 is guilty of 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) 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.

#### **41ML False advertising about medical devices**

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: 60 penalty units.

#### **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) or (2).

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**41MM Claims about arranging supplies of medical devices not included in the Register**

A person is guilty of an offence if:

- (a) the person claims, by any means, that the person or another person can arrange the supply of medical devices; and
- (b) the devices are not:
  - (i) medical devices of a kind included in the Register; or
  - (ii) exempt devices.

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, or will 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.

(2) 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 is likely to result in harm or injury to any person.

Penalty: 2,000 penalty units.

- (3) Subsection (2) is an offence of strict liability.

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

- (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.

*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, or will result in, harm or injury to a person.

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

Note: A jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (8) instead: see section 53A.

- (6) 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 is likely to result in harm or injury to a person.

Penalty: 2,000 penalty units.

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(7) Subsection (6) is an offence of strict liability.

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

(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.

*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
  - (iv) a condition of an approval under subsection 41HD(1) or (2).

Penalty: 60 penalty units.

**41MNA Civil penalties for breaching conditions**

(1) A person contravenes this subsection if:

- (a) a kind of medical device is included in the Register in relation to the person; and
- (b) the person does an act or omits to do an act; and
- (c) the act or omission breaches a condition of the inclusion of the kind of device in the Register.

Maximum civil penalty:

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

- (2) A person contravenes this subsection if:
- (a) a conformity assessment certificate is issued in respect of the person; and
  - (b) the person does an act or omits to do an act; and
  - (c) the act or omission breaches a condition of the conformity assessment certificate.

Maximum civil penalty:

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

## **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.

- (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*.

- (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:

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

## **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 section 41HC 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, or will result in, harm or injury to any person; or
    - (ii) the use of the device, if the device were used, would result in harm or injury to any person; and
  - (d) the harm or injury has resulted, will result, or would 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.

- (2) A person commits an offence if:
- (a) the person has been granted an authority under section 41HC 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) the use of the device, if the device were used, would be likely to result in harm or injury to any person; and
- (d) the harm or injury 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: 2,000 penalty units.

- (3) Subsection (2) is an offence of strict liability.

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

- (4) A person commits an offence if:
- (a) the person has been granted an authority under section 41HC 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.

- (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, or will result in, harm or injury to any person; or

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- (ii) the use of the device, if the device were used, would 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.

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

Penalty: 2,000 penalty units.

- (7) Subsection (6) is an offence of strict liability.

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

- (8) 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: 500 penalty units.

**41MP Criminal offence for failing to notify adverse events etc.**

- (1) A person is guilty of 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.

- (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 recover 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 (other than one issued 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 particular device;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:
- (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 recover 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 (other than one issued 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 particular device; 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 is guilty of 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.

- (4) A person is guilty of 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.

**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.

## **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 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) Section 42DKB applies 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 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

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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.

**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**

The Minister may, by legislative instrument, make a code relating to advertisements about therapeutic goods.

## **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 is guilty of 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 is guilty of 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.

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 is guilty of 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 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*).

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- (6) A person is guilty of 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.



## **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 about therapeutic goods.

Note: Under subsection 42DL(1) it is an offence for a person to publish or broadcast an advertisement about therapeutic goods that contains a restricted representation, about those goods, the use of which has not been approved under subsection 42DF(1) or permitted under subsection 42DK(1).

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**42DE Applications for approval of use of restricted representation**

An application for approval of the use of a restricted representation must be:

- (a) made to the Secretary in writing, in a form approved by the Secretary; and
- (b) signed by or on behalf of the applicant.

**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.

**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:
    - (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

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- (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.
- (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.

**42DK Use of restricted or prohibited representations**

- (1) The Secretary may, by notice in writing published in the *Gazette* or on the Department's website, permit, in relation to therapeutic goods, the use of a restricted representation (including its use on the label of the goods or in information included in the package in which the goods are contained).
- (2) The Secretary may, by notice in writing published in the *Gazette* or on the Department's website, permit a prohibited representation to be included on the label of therapeutic goods, or in information included in the package in which therapeutic goods are contained, if the representation is necessary for the appropriate use of the goods.

## **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 published or broadcast**

- (1) If a representation in an advertisement about therapeutic goods is false or misleading, the Secretary may, by notice given to the person apparently responsible for publishing or broadcasting the advertisement, prevent that person from publishing or broadcasting, or causing to be published or broadcast, an advertisement containing that representation (whether express or implied) about those goods.
- (2) A notice under subsection (1) is not a legislative instrument.

### **42DL Advertising offences**

- (1) A person must not publish or broadcast an advertisement about therapeutic goods:
  - (a) that contains a prohibited representation (whether in express terms or by necessary implication) about those goods; or
  - (b) that does not contain a required representation about those goods; or
  - (c) that contains a restricted representation, about those goods, the use of which has not been approved under subsection 42DF(1) or permitted under subsection 42DK(1); or
  - (d) that is in contravention of a notice referred to in section 42DKB that was given to the person; or
  - (e) that contains:
    - (i) a reference to the Act other than in a statement of the registration number, listing number or device number of the goods; or

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- (ii) a statement 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 statement of their availability as a pharmaceutical benefit or a statement authorised or required by a government or government authority (including a foreign government or foreign government authority); or
- (f) that contains a statement referring to goods, or substances or preparations containing goods, included in Schedule 3, 4 or 8 to the current Poisons Standard, other than a statement authorised or required by a government or government authority (including a foreign government or foreign government authority); or
- (g) that are not entered in the Register; or
- (h) if the goods are therapeutic goods, or come within a class of therapeutic goods, that:
  - (i) are exempt goods or exempt devices prescribed in the regulations for the purposes of this provision; or
  - (ii) have been approved under subsection 19(1) or section 41HB of this Act for importation into, exportation from, or supply within, Australia.

Penalty: 60 penalty units.

- (2) For the purposes of an offence against subsection (1), strict liability applies to the following physical elements:
  - (a) that the use of a restricted representation, as referred to in paragraph (1)(c), has not been approved under subsection 42DF(1) or permitted under subsection 42DK(1);
  - (b) that the notice referred to in paragraph (1)(d) is a notice referred to in section 42DKB;
  - (c) that goods, substances or preparations referred to in paragraph (1)(f) are included in Schedule 3, 4 or 8 to the current Poisons Standard;
  - (d) that the therapeutic goods, or class of therapeutic goods, referred to in paragraph (1)(h):
    - (i) are exempt goods or exempt devices prescribed in the regulations made for the purposes of subparagraph (1)(h)(i); or

- (ii) have been approved under subsection 19(1) or section 41HB of the Act for importation into, exportation from or supply within, Australia.
- (3) It is a defence to a prosecution under subsection (1) if:
- (a) in relation to an advertisement mentioned in paragraph (1)(a) or (f)—the advertisement is made by, or on behalf of, the Commonwealth; and
  - (b) in relation to an advertisement mentioned in paragraph (1)(f)—the goods, substances or preparations are mentioned in Appendix H of the current Poisons Standard; and
  - (c) in relation to goods mentioned in paragraph (1)(g)—the goods are exempt goods or exempt devices other than goods of a kind mentioned in paragraph (1)(h).

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

#### **42DM Compliance with Code**

- (1) A person is guilty of an offence if:
- (a) the person publishes or broadcasts an advertisement about therapeutic goods; and
  - (b) the advertisement does not comply with the Therapeutic Goods Advertising Code.

Penalty: 60 penalty units.

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

## **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 principles of the Therapeutic Goods Advertising Code specified in regulations made for the purposes of this section as if those principles applied to generic information in the same way as they apply to advertisements.

### **42DP Offences—publication of generic information**

- (1) A person is guilty of an offence if:
  - (a) the person publishes or broadcasts generic information about therapeutic goods; and
  - (b) the publication or broadcasting of that generic information does not comply with principles contained in the part of the Therapeutic Goods Advertising Code that are specified in Regulations.

Penalty: 60 penalty units.

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



## Part 5-2—Counterfeit therapeutic goods

### 42E Offence of dealing with counterfeit therapeutic goods

- (1) A person is guilty of 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.

- (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);
  - (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.

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- (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;
- 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 Chief Executive Officer 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.

*Exported counterfeit therapeutic goods*

- (2) If the Secretary notifies the Chief Executive Officer 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.

## **Part 5-3—Product tampering**

### **42T Notifying of actual or potential tampering**

- (1) A person is guilty of 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 or the National Manager of the Therapeutic Goods Administration.

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

- (2) A person is guilty of 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
    - (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 or the National Manager of the Therapeutic Goods Administration of the information or demand within 24 hours after receiving it.

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

- (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
- (d) proposing to cause the therapeutic goods to be tampered with.

#### **42V Recovery of therapeutic goods because of actual or potential tampering**

- (1) The Secretary may, in writing, impose requirements under this section on a person if:

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- (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 recover 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 recovered 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*, as soon as practicable after imposing such requirements, a notice setting out particulars of the requirements.
- (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, or will result in, harm or injury to any person; or

- (ii) the use of the goods, if the goods were used, would result in harm or injury to any person; and
- (c) the harm or injury has resulted, will result, or would result, because the person failed to comply with the requirement.

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 (6C) instead: see section 53A.

- (6A) 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) the use of the goods, if the goods were used, would be likely to result in harm or injury to any person; and
  - (c) the harm or injury would be likely to result because the person failed to comply with the requirement.

Penalty: 2,000 penalty units.

- (6B) Subsection (6A) is an offence of strict liability.

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

- (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.

- (7) This section does not prevent the Secretary from taking action under section 30 or Division 1 or 2 of Part 4-6.

#### **42VA Civil penalty relating to the recovery 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

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

**42VB Relief from liability for contraventions relating to the recovery 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.
- (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 recovery requirements**

- (1) A person is guilty of 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 recover 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.

(2) A person is guilty of 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 that person or another person, to recover 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.

(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.

## 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.

*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).

**42YB Meaning of penalty unit**

In this Act, ***penalty unit***, in relation to a civil penalty provision, has the same meaning as given by section 4AA of the *Crimes Act 1914*.

**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.

**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

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- (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.
- (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.

## **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:

- (a) the individual previously gave the evidence or produced the documents in proceedings for a pecuniary penalty order

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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.

## **Part 5A-2—Infringement notices**

### **42YJ Infringement notices in respect of offences**

- (1) The regulations may make provision enabling a person who is alleged to have committed an offence against this Act to pay to the Commonwealth, as an alternative to prosecution, a specified penalty.

Note: An offence against this Act includes an offence against the regulations: see subsection 3(7).

- (2) If an individual is alleged to have committed an offence against this Act, the penalty must not exceed an amount equal to one-fifth of the maximum penalty that could have been imposed on the individual for that offence.
- (3) If a body corporate is alleged to have committed an offence against this Act, the penalty must not exceed an amount equal to 5 times the amount specified under subsection (2) in relation to that offence.

### **42YK Infringement notices in respect of civil penalty provisions**

- (1) The regulations may make provision enabling a person who is alleged to have contravened a civil penalty provision to pay to the Commonwealth, as an alternative to civil penalty proceedings against the person, a specified penalty.
- (2) The penalty must not exceed an amount equal to one-tenth of the maximum penalty prescribed for contravening that provision.

## 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.



## **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.

#### **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).

*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

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- (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) or (2) 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:
- (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

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- (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.

*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 or an annual

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licensing 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.

**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 *Financial Management and Accountability Act 1997*.

- (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 and annual licensing 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 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

- (b) to enable the Commonwealth to participate in the international harmonisation of regulatory controls on therapeutic goods and other related activities.

## 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.

#### **46 Searches to monitor compliance with Act**

- (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).
- (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;
  - (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.
- (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.

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- (3) An authorised person is not entitled to exercise any powers under subsection (1) in relation to premises if:
- (a) the occupier of the premises has required the authorised person to produce his or her identity card for inspection by the occupier; and
  - (b) the authorised person fails to comply with the requirement.
- (4) 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 section 19; or
    - (ii) who has been granted an approval under section 19A; 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 section 41HB or 41HC; or
    - (iib) who has been granted an approval under subsection 41HD(1) or (2); or
    - (iii) in relation to whom therapeutic goods are registered, listed or included in the Register;  
being premises connected with the importation, export, manufacture or supply of therapeutic goods, or the keeping of records relating to the importation, export, manufacture or supply of therapeutic goods; 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.



#### **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:
  - (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) and subsection 48(1); and
  - (c) if the authorised person finds the thing on the premises—seize it.

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- (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:
  - (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;
  - (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;
  - (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.

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- (3) The copy of the warrant referred to in subsection (1) need not include the signature of the magistrate who issued the warrant.

**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.

**48C Use of electronic equipment at premises**

- (1) The 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 if he or she believes on reasonable grounds that the operation of the equipment can be carried out without damage to the equipment.
- (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) if the material can, by using facilities at the premises, be put in documentary form—operate the facilities to put the material in that form and seize the documents so produced; or
  - (c) if the material can be transferred to a disk, tape or other storage device that:
    - (i) is brought to the premises; or

- (ii) is at the premises and the use of which for the purpose has been agreed to in writing by the occupier of the premises;  
operate the equipment or other facilities to copy the material to the storage device and take the storage device from the premises.
- (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 copy 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) If the authorised person believes on reasonable grounds that the expert assistance will not be available within 24 hours, he or she may apply to the magistrate for an extension of 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.

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**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 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 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:
    - (a) the thing that has been seized was seized under paragraph 48C(2)(b) or (c); or
    - (b) possession by the occupier of the document, film, computer file, thing or information could constitute an offence or the contravention of a civil penalty provision.
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**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.

**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.

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- (3) The thing may be returned under subsection (2) either unconditionally or on such terms and conditions as the Secretary sees fit.

**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 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) 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 orally or by affidavit, such further information (if any) as the

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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
    - (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
  - (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
  - (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

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- (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 Searches at request of manufacturer**

- (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:
  - (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*.

## 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
- (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 *Legislative Instruments 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;
  - (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.
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**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.
- (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 *Legislative Instruments Act 2003* does not apply to the instrument.
- (4B) Despite subsection 14(2) of the *Legislative Instruments 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:

  - (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;

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- (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:
- (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.

**52EA Poisons Standard—validation etc.**

*Scope*

- (1) This section applies to the following instruments:
  - (a) the first Poisons Standard;
  - (b) an instrument made under paragraph 52D(2)(a) or (b) before the commencement of this section;whether or not the instrument is in force as at the commencement of this section.

*Disallowance*

- (2) Section 42 (disallowance) of the *Legislative Instruments Act 2003* does not apply, and is taken never to have applied, to the instrument.

*Deemed registration etc.*

- (3) If:
  - (a) the instrument was required to be registered under Division 2 of Part 4 of the *Legislative Instruments Act 2003*; and

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- (b) the instrument was not registered;  
that Act has effect, and is taken always to have had effect, as if:
  - (c) the instrument had been lodged for registration immediately after the instrument was made; and
  - (d) the instrument had been registered immediately after it was lodged for registration; and
  - (e) any other requirement imposed by that Act in relation to the instrument had been met.
- (4) If:
  - (a) the instrument was required to be registered under Division 3 of Part 4 of the *Legislative Instruments Act 2003*; and
  - (b) the instrument was not lodged for registration on or before the last day for lodging the instrument for registration (the *last lodgment day*) worked out under section 29 of that Act;  
that Act has effect, and is taken always to have had effect, as if:
    - (c) the instrument had been lodged for registration on the last lodgment day; and
    - (d) the instrument had been registered immediately after it was lodged for registration; and
    - (e) any other requirement imposed by that Act in relation to the instrument had been met.

*Definition*

- (5) In this section:

*register* has the same meaning as in the *Legislative Instruments Act 2003*.

**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;
- (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.

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- (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.

## Chapter 7—Miscellaneous

### 53 Retention of material on withdrawal of application

Where a person withdraws an application for:

- (a) registration; or
- (b) listing; 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:

<b>Alternative verdicts for various offences</b>		
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<b>Item</b>	<b>If a prosecution is for an offence against...</b>	<b>the jury may instead convict the person of an offence against...</b>
1	subsection 14(1)	subsection 14(4)
2	subsection 14(6)	subsection 14(9)
3	subsection 14(10)	subsection 14(13)
4	subsection 15(2)	subsection 15(5)
5	subsection 19B(1)	subsection 19B(4)
6	subsection 21A(1)	subsection 21A(4)
7	subsection 21A(5)	subsection 21A(8)
8	subsection 21A(9)	subsection 22(7A)
9	subsection 21A(12)	subsection 22(8)
10	subsection 22A(1)	subsection 22A(4)

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<b>Alternative verdicts for various offences</b>		
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<b>Item</b>	<b>If a prosecution is for an offence against...</b>	<b>the jury may instead convict the person of an offence against...</b>
11	subsection 30EC(1)	subsection 30EC(4)
12	subsection 30F(4B)	subsection 30F(5)
13	subsection 31(5A)	subsection 31(6)
14	subsection 35(1)	subsection 35(4)
15	subsection 35(5)	subsection 35(9)
16	subsection 35B(1)	subsection 35B(4)
17	subsection 41EI(1)	subsection 41EI(4)
18	subsection 41FE(1)	subsection 41FE(4)
19	subsection 41JB(4)	subsection 41JB(7)
20	subsection 41KC(1)	subsection 41KC(4)
21	subsection 41MA(1)	subsection 41MA(4)
22	subsection 41MA(5)	subsection 41MA(8)
23	subsection 41MA(9)	subsection 41MA(12)
24	subsection 41MC(2)	subsection 41MC(5)
25	subsection 41ME(1)	subsection 41ME(4)
26	subsection 41ME(5)	subsection 41ME(8)
27	subsection 41MF(1)	subsection 41MF(2)
28	subsection 41MF(3)	subsection 41MF(4)
29	subsection 41MI(1)	subsection 41MI(4)
30	subsection 41MN(1)	subsection 41MN(4)
31	subsection 41MN(5)	subsection 41MN(8)
32	subsection 41MO(1)	subsection 41MO(4)
33	subsection 41MO(5)	subsection 41MO(8)
34	subsection 42V(6)	subsection 42V(6C)

**54 Offences and forfeiture**

- (3) If a court:
- (a) convicts a person of an offence against this Act; or
  - (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*.
- (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 is guilty of an offence punishable on conviction by a fine of no more than the number of penalty units specified in whichever of subsection (2) or (3) applies.

- (1A) In subsection (1):

*engage in conduct* means:

- (a) do an act; or
  - (b) omit to perform an act.
- (2) If:
    - (a) the condition or requirement relates to the possession, custody, transport, use or disposal of the goods; or
    - (b) the regulation providing for the condition or requirement states that the purpose of the condition or requirement is to protect the safety of the public;the number of penalty units for the contravention is 240 penalty units.
  - (3) If subsection (2) does not apply, the number of penalty units for the contravention is 50 penalty units.

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**54AB Criminal offence for damaging etc. documents**

- (1) A person is guilty of 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.

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

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

**54AC Civil penalty for damaging etc. documents**

A person contravenes this section if:

- (a) the person damages, destroys, alters, conceals or falsifies a document; and
- (b) the document is created, retained or issued for the purposes of this Act, or for purposes that include the purposes of this Act; and
- (c) the damage, destruction, alteration, concealment or falsification is likely to interfere with the proper administration of this Act or the regulations.

Maximum civil penalty:

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

**54A Time for bringing prosecutions**

A prosecution for an offence against this Act may be commenced at any time within 3 years after the commission of the offence.

**54B Application of this Act to an executive officer of a body corporate**

- (1) An executive officer of a body corporate commits an offence if:
- (a) the body corporate commits an offence against this Act; 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 the maximum penalty that a Court could impose in respect of an individual for the offence committed by the body corporate.
- (3) An executive officer of a body corporate contravenes this subsection if:
  - (a) the body corporate contravenes a civil penalty provision; and
  - (b) the officer knew that the contravention would occur; and
  - (c) the officer was in a position to influence the conduct of the body in relation to the contravention; and
  - (d) the officer failed to take all reasonable steps to prevent the contravention.
- (4) The maximum civil penalty for a contravention of subsection (3) is the maximum civil penalty that a Court could impose in respect of an individual for the civil penalty provision contravened by the body corporate.
- (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.

**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

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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, servants 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, servant or agent of the body corporate within the scope of his or her actual or apparent authority; and
  - (b) that the director, servant or agent had the state of mind.
- (2) Any conduct engaged in on behalf of a body corporate by a director, servant or agent of the body corporate 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 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 a servant or agent of the person within the scope of his or her actual or apparent authority; and
  - (b) the servant 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 a servant 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.
- (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 and the United States Pharmacopoeia-National Formulary.

**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
  - (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 or authority under section 19 granted to a particular person in relation to particular therapeutic goods; or
  - (ba) there was no approval or authority in effect under section 41HB or 41HC granted to a particular person in relation to particular medical devices;
  - (bb) there was no approval under subsection 41HD(1) 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
  - (d) particular therapeutic goods were or were not included in the Register as registered goods; or
  - (e) particular therapeutic goods were or were not included in the Register as listed goods; 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
  - (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
  - (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).
- (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.

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- (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:
    - (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) 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) 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) or 41HB(1)(d);
  - (c) the conditions to which any approvals granted by delegates are to be subject;
  - (d) requiring information to be given by delegates to the Secretary.
- (6) The powers of the Secretary under subsection 19(5) 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) or 41HC(1).
- (8) The powers of the Secretary under section 19A may be delegated only to either or both of the following persons:
  - (a) the National Manager of the Therapeutic Goods Administration;
  - (b) a person who holds, occupies or performs the duties of a position in the Therapeutic Goods Administration prescribed by the regulations for the purposes of this paragraph.
- (9) The powers of the Secretary under section 41HD may be delegated only to either or both of the following persons:
  - (a) the National Manager of the Therapeutic Goods Administration;
  - (b) a person who holds, occupies or performs the duties of a position in the Therapeutic Goods Administration prescribed by the regulations for the purposes of this paragraph.

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- (10) The power of the Minister under subsection 18A(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.
- (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.
- (3) No licence or inspection fees are to apply to non-profit hospital supply units.

**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:

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- (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 or 9D; or
  - (b) refusing to grant a consent under section 14 or 14A; or
  - (c) under Part 3-2 (registration and listing of therapeutic goods); or
  - (d) under Part 3-3 (manufacturing of therapeutic goods); or
  - (e) under Part 4-4 (conformity assessment certificates); or
  - (f) under Part 4-5 (including medical devices in the Register), other than:
    - (i) a decision under section 41FH (selecting applications for auditing); or
    - (ii) a decision about which aspects of the matters referred to in paragraphs 41FI(1)(a) and (b) to consider in auditing an application under Subdivision C of Division 1 of Part 4-5; or
  - (g) under Part 4-6 (suspension and cancellation from the Register); or
  - (h) under Part 4-7 (exempting medical devices from inclusion in the Register); or
  - (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.

**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:
    - (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;
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- (d) a proposal to cancel the entry of a kind of medical device on the Register under section 41GN.
- (2) A person whose interests are affected by an initial decision may, by notice in writing given to the Minister:
  - (a) in the case of a decision particulars of which are required to be notified in the *Gazette*—within 90 days after those particulars are so notified; or
  - (b) in any other case—within 90 days after the decision first comes 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.
- (3) Subject to paragraph 60A(2)(b), the Minister must, as soon as practicable after receiving a request under subsection (2), reconsider the initial decision and, as a result of that reconsideration, may:
  - (a) confirm the initial decision; or
  - (b) revoke the initial decision, or revoke that decision and make a decision in substitution for the initial decision.
- (3A) Subject to subsection 60A(2), in reconsidering the initial decision:
  - (a) the Minister must take into account any information referred to in subsection (2A); and
  - (b) the Minister must not take into account any other information provided by, or on behalf of, the person after the making of the request, other than:
    - (i) information provided in response to a request from the Minister; or
    - (ii) information that indicates that the quality, safety or efficacy of therapeutic goods is unacceptable.
- (3B) Paragraph (3A)(a) does not limit the information the Minister may take into account in reconsidering the initial decision.
- (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.
- (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 or 41EC in relation to therapeutic goods.
- (2) If a person (the *appellant*) whose interests are affected by the decision requests the Minister to reconsider the decision, and lodges initial new information in support of that request, the Minister must either:
  - (a) take that information into account when he or she reconsiders the decision; or
  - (b) remit the matter to an authorised delegate for a fresh decision.

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(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
  - (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.

(6A) If:

- (a) the matter relates to a decision under section 41EC; and
- (b) the Minister or the Tribunal remits the matter; and
- (c) the appellant has paid, as a further conformity assessment fee, the conformity assessment fee that the appellant would have to pay under section 41LA on making a new application for a conformity assessment certificate;

the authorised delegate must make a decision under section 41EC, taking into account the initial new information or later new information (or both), as the case may be, as if a fresh application for a conformity assessment certificate had been made.

- (7) To remove any doubt, the authorised delegate's fresh decision is to be treated, for the purposes of subsequent applications of section 60 and this section, as a decision under Part 3-2 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
- (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).

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*later new information* means information that:

- (a) was in existence at the time the decision on reconsideration was made; and
- (b) was not made available to the Minister or delegate of the Minister for the purpose of making that decision; and
- (c) is relevant to that decision;

and includes any opinions that are wholly or substantially based on such information (whether the opinions were formed before or after that decision was made).

## 61 Release of information

- (1) In this section:

*therapeutic goods information* means information in relation to therapeutic goods that is held by the Department and relates to the performance of the Department's functions (including functions relating to the EC Mutual Recognition Agreement 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.



- (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, 41JCA, 41JD, 41JE or 41JF to:
- (a) an authority of the Commonwealth, a State or a Territory that has functions relating to therapeutic goods; and
  - (b) the body in a State or Territory responsible for the registration of medical practitioners in that State or Territory; and
  - (c) the body in a State or Territory responsible for the registration of pharmacists in that State or Territory.
- (4) The Secretary may release to a national regulatory authority of another country, being an authority that has national responsibility relating to therapeutic goods, therapeutic goods information relating to:
- (a) recommendations of advisory committees on therapeutic goods supplied in or proposed for supply in Australia, and any conditions that are or will be applicable to that supply; or
  - (b) decisions on the registration or listing, or the suspension or cancellation of the registration or listing, of therapeutic goods; or

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- (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 recovery of therapeutic goods);
- (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 1(d) of Information Privacy Principle 11 in section 14 of the *Privacy Act 1988*, to be authorised by law.
- (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 co-operative arrangements relating to the assessment or regulation of therapeutic goods, therapeutic goods information the release of which is consistent with those arrangements.
- (5AA) The Secretary may release to a person, body or authority that is specified, or is of a kind specified, under subsection (5AB) therapeutic goods information of a kind specified under that subsection for a purpose specified under that subsection.
- (5AB) For the purpose of subsection (5AA), the Minister may, by legislative instrument, specify one or more of the following:
  - (a) a person, body or authority;
  - (b) kinds of persons, bodies or authorities;
  - (c) kinds of therapeutic goods information;
  - (d) purposes.
- (5A) The Secretary may release to the public therapeutic goods information relating to any decision or action taken under this Act or the regulations.
- (5B) The release of therapeutic goods information under subsection (5A) is not taken, for the purposes of paragraph 1(d) of Information Privacy Principle 11 in section 14 of the *Privacy Act 1988*, to be authorised by law.
- (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).

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- (6) The Secretary may release to a person, on application by that person, therapeutic goods information of a kind identified in the regulations relating to:
  - (a) therapeutic goods included in the Register; or
  - (b) therapeutic goods in relation to which an application for registration, listing or inclusion in the Register has been made.
- (6A) Regulations made for the purposes of subsection (6) may:
  - (a) relate to therapeutic goods generally or to a class of such goods; and
  - (b) authorise the release of therapeutic goods information to persons generally or to a class of persons.
- (7) The Secretary may release therapeutic goods information:
  - (a) the release of which is necessary to ensure the safe use of particular therapeutic goods; or
  - (b) relating to the reasons for the withdrawal of therapeutic goods from supply in Australia.
- (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.
- (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.
- (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) 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;

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- (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;
- (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.

## 62 Consequential amendments

The Acts specified in the Schedule are amended as set out in the Schedule.

## 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
  - (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
  - (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 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

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- (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
  - (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.



## **Chapter 8—Repeal and transitional provisions**

### **64 Interpretation**

In this Part, *former Act* means the *Therapeutic Goods Act 1966*.

### **65 Repeal**

The former Act is repealed.

### **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

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- (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 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
  - (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.
- (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

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- (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 former Act, and any requirements that were in force at that time under section 15 of the former Act, continue in force as if they were standards made under Part 3-1 of this Act.

## **Schedule—Consequential Amendments**

Section 62

**Note:**

The amendments made by this Schedule are incorporated in the compilations on ComLaw.

*Agricultural and Veterinary Chemicals Act 1988*

[repealed by Act No. 36, 1964, s. 24]

*Commonwealth Serum Laboratories Act 1961*

*Sea Installations Act 1987*

For access to the wording of the amendments made by this Schedule, *see* Act No. 21, 1990.



**Table of Acts****Notes to the *Therapeutic Goods Act 1989*****Note 1**

The *Therapeutic Goods Act 1989* as shown in this compilation comprises Act No. 21, 1990 amended as indicated in the Tables below.

All relevant information pertaining to application, saving or transitional provisions prior to 30 May 2000 is not included in this compilation. For subsequent information *see* Table A.

**Table of Acts**

Act	Number and year	Date of Assent	Date of commencement	Application, saving or transitional provisions
<i>Therapeutic Goods Act 1989</i>	21, 1990	17 Jan 1990	15 Feb 1991	
<i>Community Services and Health Legislation Amendment Act (No. 2) 1990</i>	141, 1990	28 Dec 1990	Part 8 (ss. 78–81): (a)	—
<i>Community Services and Health Legislation Amendment Act 1991</i>	84, 1991	26 June 1991	S. 14: 1 Aug 1991 (see s. 2(2) and <i>Gazette</i> 1991, No. S207) Remainder: Royal Assent	Ss. 33–36
<i>Therapeutic Goods Amendment Act 1991</i>	204, 1991	24 Dec 1991	24 Dec 1991	Ss. 4(2), 10(2) and 13(2)
<i>Health, Housing and Community Services Legislation Amendment Act 1992</i>	88, 1992	30 June 1992	Ss. 82–88: Royal Assent (b)	S. 83(2)
<i>Health and Community Services Legislation Amendment Act (No. 2) 1993</i>	76, 1993	25 Nov 1993	Ss. 29(h) and 30–32: 14 Feb 1994 (see <i>Gazette</i> 1994, No. GN5) Ss. 29(i), 37(b), 38(b), 47 and 50(1)(d): 2 May 1994 (see <i>Gazette</i> 1994, No. S149) Remainder: Royal Assent	Ss. 33(2), 36(2), 41(2), 49(2), 50(2) and 51(2)
<i>Customs, Excise and Bounty Legislation Amendment Act 1995</i>	85, 1995	1 July 1995	S. 12 (items 5, 6): 1 July 1995 (c) S. 18: Royal Assent (c)	S. 18

**Table of Acts**

Act	Number and year	Date of Assent	Date of commencement	Application, saving or transitional provisions
<i>Therapeutic Goods Amendment Act 1996</i>	6, 1996	11 June 1996	11 June 1996	S. 84
<i>Therapeutic Goods Amendment Act 1997</i>	116, 1997	7 July 1997	Schedule 1 (Part 2 [items 2–14]): 1 Jan 1999 (see <i>Gazette</i> 1998, No. S609) Remainder: Royal Assent	—
<b>as amended by</b>				
<i>Therapeutic Goods Legislation Amendment Act 1999</i>	3, 1999	29 Mar 1999	(see 3, 1999 below)	—
<i>Audit (Transitional and Miscellaneous) Amendment Act 1997</i>	152, 1997	24 Oct 1997	Schedule 2 (item 1249): 1 Jan 1998 (see <i>Gazette</i> 1997, No. GN49) (d)	—
<i>Therapeutic Goods Legislation Amendment Act 1998</i>	34, 1998	17 Apr 1998	17 Apr 1998	—
<i>Therapeutic Goods Legislation Amendment Act 1999</i>	3, 1999	29 Mar 1999	Schedule 2: (e) Remainder: 1 Apr 1999 (see <i>Gazette</i> 1999, No. S143)	—
<i>Public Employment (Consequential and Transitional) Amendment Act 1999</i>	146, 1999	11 Nov 1999	Schedule 1 (items 936–938): 5 Dec 1999 (see <i>Gazette</i> 1999, No. S584) (f)	—
<i>Therapeutic Goods Amendment Act 2000</i>	12, 2000	31 Mar 2000	31 Mar 2000	—
<i>Therapeutic Goods Amendment Act (No. 2) 2000</i>	56, 2000	30 May 2000	30 May 2000	Sch. 1 (item 5) [see Table A]
<i>Therapeutic Goods Amendment Act (No. 3) 2000</i>	120, 2000	12 Sept 2000	Schedule 1: 10 Oct 2000 Remainder: Royal Assent	Sch. 1 (items 4, 6, 8, 10, 17) [see Table A]
<i>Gene Technology (Consequential Amendments) Act 2000</i>	170, 2000	21 Dec 2000	22 June 2001 (see s. 2)	—
<i>Therapeutic Goods Amendment Act 2001</i>	14, 2001	22 Mar 2001	22 Sept 2001	Sch. 1 (item 36) [see Table A]



**Table of Acts**

Act	Number and year	Date of Assent	Date of commencement	Application, saving or transitional provisions
<i>Australia New Zealand Food Authority Amendment Act 2001</i>	81, 2001	10 July 2001	S. 2(6): Royal Assent (g) Schedule 3 (item 8): 1 July 2002 (see <i>Gazette</i> 2002, No. GN30) (g)	S. 2(6) [see Table A]
<i>Health and Aged Care Legislation Amendment (Application of Criminal Code) Act 2001</i>	111, 2001	17 Sept 2001	17 Sept 2001	S. 4 [see Table A]
<i>Therapeutic Goods Amendment Act (No. 1) 2002</i>	23, 2002	4 Apr 2002	4 Apr 2002	—
<i>Therapeutic Goods Amendment (Medical Devices) Act 2002</i>	24, 2002	4 Apr 2002	Schedule 1: 4 Oct 2002 Schedule 2: (h) Remainder: Royal Assent	Sch. 1 (items 38, 46, 55) [see Table A] S. 2(1) (item 3) (rep. by 140, 2007, Sch. 1 [item 7])
<b>as amended by</b>				
<i>Therapeutic Goods and Other Legislation Amendment Act 2002</i>	56, 2002	3 July 2002	Schedule 3 (item 22): (see 56, 2002 below)	—
<i>Therapeutic Goods Amendment Act (No. 1) 2006</i>	39, 2006	3 May 2006	Schedule 1 (item 158): (h)	—
<i>Therapeutic Goods Amendment Act 2007</i>	140, 2007	14 Sept 2007	Schedule 1 (items 7, 8): 3 Oct 2007	—
<i>Therapeutic Goods and Other Legislation Amendment Act 2002</i>	56, 2002	3 July 2002	Schedule 1 (items 6, 7), Schedule 3 (items 4, 22) and Schedule 4 (item 1): (i) Remainder: Royal Assent	Sch. 3 (items 20, 21) [see Table A]
<i>Therapeutic Goods Amendment Act (No. 1) 2003</i>	39, 2003	27 May 2003	Schedule 1 (items 1–19) and Schedule 2: 27 Nov 2003 Schedule 1 (item 79): (j) Remainder: Royal Assent	Sch. 1 (items 41, 55, 60) [see Table A]
<i>US Free Trade Agreement Implementation Act 2004</i>	120, 2004	16 Aug 2004	Schedule 7: 1 Jan 2005	Sch. 7 (item 7) [see Table A]

**Table of Acts**

Act	Number and year	Date of Assent	Date of commencement	Application, saving or transitional provisions
<i>Financial Framework Legislation Amendment Act 2005</i>	8, 2005	22 Feb 2005	S. 4 and Schedule 1 (items 493, 496): Royal Assent	S. 4 and Sch. 1 (item 496) [see Table A]
<i>Therapeutic Goods Amendment Act (No. 2) 2006</i>	2, 2006	1 Mar 2006	Schedule 1: 3 Apr 2006 (see F2006L00889) Remainder: Royal Assent	Sch. 1 (item 15) [see Table A]
<i>Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Act 2006</i>	5, 2006	3 Mar 2006	3 Mar 2006	S. 3 [see Table A]
<i>Therapeutic Goods Amendment Act (No. 1) 2006</i>	39, 2006	3 May 2006	Schedule 1 (items 1–117, 119–157): 31 May 2006 Schedule 1 (item 118): 27 Nov 2003 Remainder: Royal Assent	S. 2(1) (item 5) (rep. by 140, 2007, Sch. 1 [item 4])
<b>as amended by</b>				
<i>Therapeutic Goods Amendment Act 2007</i>	140, 2007	14 Sept 2007	Schedule 1 (items 4–6): 3 Oct 2007	—
<i>National Health and Medical Research Council Amendment Act 2006</i>	50, 2006	9 June 2006	Schedule 1: 1 July 2006 Remainder: Royal Assent	—
<i>Therapeutic Goods Amendment Act (No. 3) 2006</i>	96, 2006	5 Sept 2006	5 Sept 2006	—
<i>Therapeutic Goods Amendment Act 2007</i>	140, 2007	14 Sept 2007	3 Oct 2007	—
<i>Therapeutic Goods Amendment (Poisons Standard) Act 2008</i>	9, 2008	20 Mar 2008	20 Mar 2008	—
<i>Statute Law Revision Act 2008</i>	73, 2008	3 July 2008	Schedule 1 (item 47): (k)	—
<i>Therapeutic Goods Legislation Amendment (Annual Charges) Act 2008</i>	96, 2008	3 Oct 2008	Schedule 1 (items 1–3): 1 Jan 2009 (see F2008L04263)	Sch. 1 (item 3) [see Table A]

**Table of Acts**

Act	Number and year	Date of Assent	Date of commencement	Application, saving or transitional provisions
<i>Therapeutic Goods Amendment (Medical Devices and Other Measures) Act 2009</i>	38, 2009	17 June 2009	Schedules 1, 2 and 5–7: 18 June 2009 Schedule 3: 1 Dec 2009 (see F2009L03387) Schedule 4: 1 July 2009 Remainder: Royal Assent	Sch. 2 (item 4), Sch. 3 (item 23), Sch. 4 (item 20), Sch. 5 (item 3) and Sch. 6 (item 12) [see Table A]
<i>Therapeutic Goods Amendment (2009 Measures No. 1) Act 2009</i>	76, 2009	27 Aug 2009	Schedules 1, 3, 6 and Schedule 7 (items 1–28): 28 Aug 2009 Schedule 2: 25 Feb 2010 (see F2009L03994) Schedule 4: [see Note 2] Schedule 5: 8 Feb 2010 (see F2009L03994) Schedule 7 (items 29–58): 25 Jan 2010 (see F2009L03994) Remainder: Royal Assent	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) [see Table A]
<i>Therapeutic Goods Amendment (2009 Measures No. 2) Act 2009</i>	96, 2009	29 Sept 2009	Schedule 1: 1 July 2010 Schedule 2 and Schedule 3 (items 1–7): 30 Sept 2009 Schedule 3 (items 8–10): 29 Mar 2010 Remainder: Royal Assent	Sch. 1 (item 13), Sch. 2 (item 4) and Sch. 3 (items 7, 10) [see Table A]
<i>Statute Law Revision Act 2010</i>	8, 2010	1 Mar 2010	Schedule 5 (item 124): Royal Assent Schedule 5 (item 137(a)): (I)	—

**Table of Acts**

Act	Number and year	Date of Assent	Date of commencement	Application, saving or transitional provisions
<i>Therapeutic Goods Amendment (2009 Measures No. 3) Act 2010</i>	54, 2010	31 May 2010	Schedule 1: [see Note 3 and Table A] Schedules 2–6: 1 June 2010 Remainder: Royal Assent	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) [see Table A]
<i>Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010</i>	141, 2010	15 Dec 2010	Schedule 1 and Schedule 2 (items 7A–21): 16 Dec 2010 Schedule 1A and Schedule 2 (items 1A–7): 12 Jan 2011 Schedule 2 (items 22, 23): [see (m) and Note 4] Remainder: Royal Assent	Sch. 1A (item 10) and Sch. 2 (items 7, 21) [see Table A]

**Act Notes**

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- (a) The *Therapeutic Goods Act 1989* was amended by Part 8 (sections 78–81) only of the *Community Services and Health Legislation Amendment Act (No. 2) 1990*, subsection 2(6) of which provides as follows:
- (6) Part 8 commences immediately after the commencement of the *Therapeutic Goods Act 1989*.
- The *Therapeutic Goods Act 1989* came into operation on 15 February 1991.
- (b) The *Therapeutic Goods Act 1989* was amended by sections 82–88 only of the *Health, Housing and Community Services Legislation Amendment Act 1992*, subsection 2(1) of which provides as follows:
- (1) Subject to this section, this Act commences on the day on which it receives the Royal Assent.
- (c) The *Therapeutic Goods Act 1989* was amended by the *Customs, Excise and Bounty Legislation Amendment Act 1995*, subsections 2(1) and (5) of which provide as follows:
- (1) Subject to subsections (2), (3), (4), (5) and (6), this Act commences on the day on which it receives the Royal Assent.
- (5) Schedules 2 and 3, items 1, 26 to 45, 49 to 53 and 56 and 67 of Schedule 4, Schedule 6, items 6 to 11 of Schedule 7 and Schedules 8 and 10 commence on 1 July 1995.
- (d) The *Therapeutic Goods Act 1989* was amended by Schedule 2 (item 1249) only of the *Audit (Transitional and Miscellaneous) Amendment Act 1997*, subsection 2(2) of which provides as follows:
- (2) Schedules 1, 2 and 4 commence on the same day as the *Financial Management and Accountability Act 1997*.
- (e) Subsection 2(3) of the *Therapeutic Goods Legislation Amendment Act 1999* provides as follows:
- (3) Schedule 2 is taken to have commenced immediately after the commencement of Part 2 of Schedule 1 to the *Therapeutic Goods Amendment Act 1997*.
- Part 2 of Schedule 1 commenced on 1 January 1999 (see *Gazette* 1998, No. S609).
- (f) The *Therapeutic Goods Act 1989* was amended by Schedule 1 (items 936–938) only of the *Public Employment (Consequential and Transitional) Amendment Act 1999*, subsections 2(1) and (2) of which provide as follows:
- (1) In this Act, **commencing time** means the time when the *Public Service Act 1999* commences.
- (2) Subject to this section, this Act commences at the commencing time.
- (g) The *Therapeutic Goods Act 1989* was amended by Schedule 3 (item 8) only of the *Australia New Zealand Food Authority Amendment Act 2001*, subsections 2(1)(a), (2) and (5) of which provide as follows:
- (1) The following provisions commence on the day on which this Act receives the Royal Assent:
- (a) sections 1, 2 and 3;
- (2) Part 1 of Schedule 1 (other than item 120A), and Schedule 3, commence on the first day after the commencement of this section on which an amendment of the Australia New Zealand Joint Food Standards Agreement comes into force in accordance with Article 10 of that Agreement.
- (5) As soon as practicable after the commencement of the following provisions:
- (a) Part 1 of Schedule 1 (other than item 120A);
- (b) Schedule 3;
- the Minister must cause to be published in the *Gazette* a notice specifying the day on which those provisions commenced.
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**Act Notes**

- (h) The proposed amendments made by Schedule 2 (items 1–11 and 13–23) of the *Therapeutic Goods Amendment (Medical Devices) Act 2002* and Schedule 2 (item 12) of the *Therapeutic Goods Amendment (Medical Devices) Act 2002* as amended by Schedule 1 (item 158) of the *Therapeutic Goods Amendment Act (No. 1) 2006* were repealed by Schedule 1 (item 8) of the *Therapeutic Goods Amendment Act 2007* before they commenced.
- (i) Subsection 2(1) (items 2(b), 4, 6 and 7) of the *Therapeutic Goods and Other Legislation Amendment Act 2002* provides as follows:
- (1) Each provision of this Act specified in column 1 of the table commences, or is taken to have commenced, on the day or at the time specified in column 2 of the table.

**Commencement information**

Column 1	Column 2	Column 3
Provision(s)	Commencement	Date/Details
2. Schedule 1, items 6 and 7	The later of: (b) immediately after Schedule 1 to the <i>Therapeutic Goods Amendment (Medical Devices) Act 2002</i> commences	4 October 2002
4. Schedule 3, item 4	Immediately after item 22 of Schedule 3 commences, subject to subsection (3)	4 October 2002
6. Schedule 3, item 22	Immediately after Schedule 1 to the <i>Therapeutic Goods Amendment (Medical Devices) Act 2002</i> commences, subject to subsection (3)	4 October 2002
7. Schedule 4, item 1	Immediately after Schedule 1 to the <i>Therapeutic Goods Amendment (Medical Devices) Act 2002</i> commences	4 October 2002

- (j) Subsection 2(1) (item 4) of the *Therapeutic Goods Amendment Act (No. 1) 2003* provides as follows:
- (1) Each provision of this Act specified in column 1 of the table commences, or is taken to have commenced, on the day or at the time specified in column 2 of the table.

Provision(s)	Commencement	Date/Details
4. Schedule 1, item 79	Immediately after the commencement of the <i>Health and Aged Care Legislation Amendment (Application of Criminal Code) Act 2001</i>	17 September 2001

- (k) Subsection 2(1) (item 31) of the *Statute Law Revision Act 2008* provides as follows:
- (1) Each provision of this Act specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Provision(s)	Commencement	Date/Details
31. Schedule 1, item 47	Immediately after the commencement of item 79 of Schedule 1 to the <i>Therapeutic Goods Amendment Act (No. 1) 2003</i> .	17 September 2001

**Act Notes**

(l) Subsection 2(1) (items 31 and 38) of the *Statute Law Revision Act 2010* provides as follows:

- (1) Each provision of this Act specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

<b>Provision(s)</b>	<b>Commencement</b>	<b>Date/Details</b>
31. Schedule 5, items 1 to 51	The day this Act receives the Royal Assent.	1 March 2010
38. Schedule 5, Parts 2 and 3	Immediately after the provision(s) covered by table item 31.	1 March 2010

(m) Subsection 2(1) (item 5) of the *Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010* provides as follows:

- (1) Each provision of this Act specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

<b>Provision(s)</b>	<b>Commencement</b>	<b>Date/Details</b>
5. Schedule 2, Part 3	The later of: (a) immediately after the commencement of the provision(s) covered by table item 2; and (b) immediately after the commencement of Schedule 1 to the <i>Therapeutic Goods Amendment (2009 Measures No. 3) Act 2010</i> .	[see Note 4] (paragraph (b) applies)





**Table of Amendments****Table of Amendments**

ad. = added or inserted   am. = amended   rep. = repealed   rs. = repealed and substituted

Provision affected	How affected
<b>Chapter 1</b>	
Heading to Part 1 .....	rep. No. 24, 2002
Heading to Chapt. 1 .....	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; Nos. 14, 81 and 111, 2001; No. 24, 2002 (as am. by No. 56, 2002); No. 56, 2002; No. 39, 2003; Nos. 5, 39 and 50, 2006; No. 9, 2008; Nos. 38, 76 and 96, 2009; Nos. 54 and 141, 2010
S. 3A.....	ad. No. 116, 1997 am. No. 12, 2000
S. 3B.....	ad. No. 56, 2002
S. 3C.....	ad. No. 38, 2009
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
S. 6 .....	am. No. 76, 1993
S. 6AA .....	ad. No. 6, 1996 am. No. 111, 2001 rep. No. 5, 2006
S. 6AB .....	ad. No. 6, 1996 rep. No. 5, 2006
S. 6A.....	ad. No. 76, 1993 am. No. 146, 1999 rep. No. 56, 2002
Ss. 6AAA–6AAD .....	ad. No. 56, 2002
S. 6AAE .....	ad. No. 56, 2002 am. No. 56, 2002
Ss. 6B, 6C.....	ad. No. 76, 1993
S. 7 .....	am. No. 76, 1993; No. 24, 2002; No. 141, 2010
S. 7A.....	ad. No. 76, 1993
S. 7B.....	ad. No. 76, 1993 am. No. 24, 2002
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
<b>Chapter 2</b>	
Chapt. 2 .....	ad. No. 24, 2002
S. 9A.....	ad. No. 24, 2002 am. No. 56, 2002

**Table of Amendments**

ad. = added or inserted   am. = amended   rep. = repealed   rs. = repealed and substituted

Provision affected	How affected
S. 9B.....	ad. No. 24, 2002 am. No. 140, 2007
S. 9C.....	ad. No. 24, 2002 am. No. 38, 2009
S. 9D.....	ad. No. 24, 2002 am. No. 141, 2010
S. 9E.....	ad. No. 24, 2002
<b>Chapter 3</b>	
Heading to Part 2.....	rep. No. 24, 2002
Heading to Chapt. 3.....	ad. No. 24, 2002
Note to Chapt. 3.....	ad. No. 24, 2002 rs. No. 140, 2007
<b>Part 3-1</b>	
Heading to Part 3-1.....	ad. No. 24, 2002
S. 10.....	am. No. 24, 2002; Nos. 38 and 76, 2009
Note to s. 10(1).....	ad. No. 76, 2009
S. 10A.....	ad. No. 24, 2002
Ss. 11, 12.....	rep. No. 76, 2009
S. 13.....	rs. No. 38, 2009
S. 14.....	am. No. 85, 1995; No. 6, 1996; No. 39, 2003 rs. No. 39, 2006 am. No. 38, 2009
Ss. 14A, 14B.....	ad. No. 39, 2006
S. 15.....	am. No. 6, 1996; No. 111, 2001 rs. No. 39, 2006 am. No. 38, 2009
S. 15AA.....	ad. No. 39, 2006
<b>Part 3-2</b>	
Heading to Part 3.....	rep. No. 24, 2002
Heading to Part 3-2.....	ad. No. 24, 2002
<b>Division 1</b>	
S. 15A.....	ad. No. 24, 2002
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. 38, 2009; No. 54, 2010
Note to s. 18A(7) Renumbered Note 1.....	No. 39, 2006
Note 2 to s. 18A(7).....	ad. No. 39, 2006
Note to s. 18A(12).....	am. No. 39, 2006
S. 19.....	am. No. 204, 1991; No. 6, 1996; No. 120, 2000; No. 54, 2010

**Table of Amendments**

ad. = added or inserted   am. = amended   rep. = repealed   rs. = repealed and substituted

Provision affected	How affected
S. 19A.....	ad. No. 6, 1996 am. No. 76, 2009
S. 19B.....	ad. No. 39, 2006 am. No. 38, 2009
Ss. 19C, 19D .....	ad. No. 39, 2006
Heading to s. 20.....	rs. No. 6, 1996; No. 39, 2006
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
Note to s. 20(1) .....	ad. No. 23, 2002 rep. No. 39, 2006
Note to s. 20(1A).....	ad. No. 111, 2001 rep. No. 39, 2006
S. 20A.....	ad. No. 39, 2006
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
S. 21B.....	ad. No. 39, 2006
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; Nos. 38 and 96, 2009
Note 1 to s. 22(7AB).....	rs. No. 39, 2006
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
S. 22B.....	ad. No. 39, 2006
<b>Division 2</b>	
S. 23AA .....	ad. No. 6, 1996 rep. No. 5, 2006
S. 23 .....	am. No. 84, 1991; No. 76, 1993; No. 141, 2010
S. 24 .....	am. Nos. 84 and 204, 1991
S. 24A.....	ad. No. 84, 1991 am. No. 204, 1991
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
S. 24E.....	ad. No. 88, 1992
Heading to s. 25.....	rs. No. 6, 1996
S. 25 .....	am. Nos. 84 and 204, 1991; No. 76, 1993; No. 116, 1997; No. 12, 2000; Nos. 24 and 56, 2002; No. 39, 2003; No. 120, 2004; No. 2, 2006; Nos. 54 and 141, 2010

**Table of Amendments**


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ad. = added or inserted   am. = amended   rep. = repealed   rs. = repealed and substituted

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Provision affected	How affected
Note to s. 25(1) .....	ad. No. 34, 1998
S. 25AA .....	ad. No. 141, 2010
S. 25A.....	ad. No. 34, 1998 am. No. 54, 2010
Heading to s. 25B .....	am. No. 56, 2002
S. 25B.....	ad. No. 116, 1997 am. No. 56, 2002
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
Heading to s. 26AA .....	am. No. 56, 2002
S. 26AA .....	ad. No. 116, 1997 am. No. 56, 2002
Heading to s. 26A .....	rs. No. 14, 2001
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
S. 26B.....	ad. No. 120, 2004 am. No. 2, 2006; No. 38, 2009
S. 26BA .....	ad. No. 2, 2006
S. 26BB .....	ad. No. 76, 2009 rs. No. 141, 2010
Heading to s. 26BC.....	am. No. 141, 2010
S. 26BC .....	ad. No. 76, 2009
Heading to s. 26BD.....	am. No. 141, 2010
S. 26BD .....	ad. No. 76, 2009 am. No. 141, 2010
S. 26BE .....	ad. No. 76, 2009 rep. No. 141, 2010
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
S. 28A.....	ad. No. 76, 2009
Note to s. 29 .....	ad. No. 76, 2009
Heading to s. 29A .....	rs. No. 39, 2006
S. 29A.....	ad. No. 88, 1992 am. No. 6, 1996; No. 39, 2003; No. 39, 2006; No. 38, 2009
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
S. 29C.....	ad. No. 39, 2006

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**Table of Amendments**

ad. = added or inserted   am. = amended   rep. = repealed   rs. = repealed and substituted

Provision affected	How affected
Ss. 29D–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
S. 30A.....	ad. No. 6, 1996 am. No. 111, 2001; No. 23, 2002 rep. No. 39, 2003 ad. No. 76, 2009
S. 30B.....	ad. No. 116, 1997 rep. No. 39, 2003
S. 30C.....	ad. No. 170, 2000 am. No. 96, 2009
Heading to s. 30D .....	am. No. 96, 2009
S. 30D.....	ad. No. 170, 2000 am. No. 96, 2009
S. 30E.....	ad. No. 170, 2000
<b>Division 2A</b>	
Div. 2A of Part 3-2.....	ad. No. 39, 2003
S. 30EA .....	ad. No. 39, 2003 am. No. 39, 2006; No. 76, 2009; No. 54, 2010
S. 30EB .....	ad. No. 39, 2003
S. 30EC .....	ad. No. 39, 2003 rs. No. 39, 2006 am. No. 38, 2009
S. 30ECA.....	ad. No. 39, 2006
Heading to s. 30ED.....	am. No. 76, 2009
S. 30ED .....	ad. No. 39, 2003 am. No. 76, 2009
<b>Division 3</b>	
Heading to s. 30F.....	am. No. 39, 2006
S. 30F .....	ad. No. 23, 2002 am. No. 39, 2006; No. 38, 2009
S. 30FA.....	ad. No. 39, 2006
S. 30G .....	ad. No. 23, 2002
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; Nos. 14 and 111, 2001; No. 39, 2003; No. 39, 2006; No. 38, 2009; Nos. 54 and 141, 2010
S. 31AAA .....	ad. No. 39, 2006
Heading to s. 31A .....	rs. No. 23, 2002
S. 31A.....	ad. No. 120, 2000 am. No. 39, 2006
S. 31AA .....	ad. No. 23, 2002 am. No. 39, 2006

**Table of Amendments**

ad. = added or inserted   am. = amended   rep. = repealed   rs. = repealed and substituted

Provision affected	How affected
S. 31B.....	ad. No. 120, 2000 am. No. 39, 2006
Heading to s. 31C .....	am. No. 23, 2002 rs. No. 39, 2006
S. 31C.....	ad. No. 120, 2000 am. No. 23, 2002 rs. No. 39, 2006 am. No. 38, 2009
S. 31D.....	ad. No. 120, 2000 am. No. 23, 2002; No. 39, 2006; No. 38, 2009
S. 31E.....	ad. No. 120, 2000 am. No. 39, 2006; No. 38, 2009
S. 31F .....	ad. No. 120, 2000 am. No. 39, 2006
S. 32 .....	am. Nos. 84 and 204, 1991; No. 76, 1993; No. 6, 1996 rep. No. 24, 2002
S. 33 .....	rep. No. 24, 2002
<b>Part 3-3</b>	
Heading to Part 4 .....	rep. No. 24, 2002
Heading to Part 3-3.....	ad. No. 24, 2002
S. 33A.....	ad. No. 24, 2002
S. 35 .....	am. No. 6, 1996; No. 111, 2001; No. 23, 2002; No. 39, 2003 rs. No. 39, 2006 am. No. 38, 2009
S. 35A.....	ad. No. 39, 2006
S. 35B.....	ad. No. 39, 2006 am. No. 38, 2009
S. 35C.....	ad. No. 39, 2006
S. 36 .....	am. No. 76, 2009
Subheads. to s. 37(2), (3).....	ad. No. 76, 2009
S. 37 .....	am. No. 76, 1993; No. 56, 2002; No. 96, 2006; No. 76, 2009
Subhead. to s. 38(1A) .....	ad. No. 76, 2009
Subhead. to s. 38(2).....	ad. No. 76, 2009
Subheads. to s. 38(3), (4).....	ad. No. 76, 2009
S. 38 .....	am. No. 76, 1993; No. 34, 1998; No. 39, 2003; No. 39, 2006; Nos. 38 and 76, 2009
Ss. 38A, 38B.....	ad. No. 76, 2009
S. 39 .....	am. No. 23, 2002
S. 40 .....	am. No. 76, 1993; No. 56, 2002; No. 39, 2003; Nos. 38 and 76, 2009
Ss. 40A, 40B.....	ad. No. 76, 2009
S. 41 .....	am. No. 34, 1998; No. 23, 2002; No. 39, 2003; No. 39, 2006; Nos. 38 and 76, 2009
S. 41AA .....	ad. No. 38, 2009
S. 41AAA.....	ad. No. 76, 2009

**Table of Amendments**

ad. = added or inserted   am. = amended   rep. = repealed   rs. = repealed and substituted

Provision affected	How affected
S. 42.....	am. No. 76, 1993
Renumbered s. 41A .....	No. 24, 2002
S. 41A.....	am. No. 76, 2009
<b>Chapter 4</b>	
Chapt. 4 .....	ad. No. 24, 2002
Note to Chapt. 4.....	rs. No. 140, 2007
<b>Part 4-1</b>	
<b>Division 1</b>	
S. 41B.....	ad. No. 24, 2002 am. No. 39, 2006
S. 41BA .....	ad. No. 24, 2002
S. 41BB .....	ad. No. 24, 2002 am. No. 38, 2009
S. 41BC .....	ad. No. 24, 2002 am. No. 39, 2006
Note to s. 41BC.....	am. No. 39, 2006
<b>Division 2</b>	
Ss. 41BD, 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
Ss. 41BH, 41BI .....	ad. No. 24, 2002
<b>Division 3</b>	
Ss. 41BJ, 41BK.....	ad. No. 24, 2002
<b>Part 4-2</b>	
S. 41C.....	ad. No. 24, 2002
Note to s. 41C.....	am. No. 39, 2006
<b>Division 1</b>	
S. 41CA .....	ad. No. 24, 2002
<b>Division 2</b>	
S. 41CB .....	ad. No. 24, 2002 am. No. 76, 2009
Note to s. 41CB(1) .....	ad. No. 76, 2009
S. 41CC .....	ad. No. 24, 2002 am. No. 38, 2009
S. 41CD .....	ad. No. 24, 2002
<b>Part 4-3</b>	
S. 41D.....	ad. No. 24, 2002
Note 1 to s. 41D.....	am. No. 39, 2006
<b>Division 1</b>	
Ss. 41DA, 41DB.....	ad. No. 24, 2002

**Table of Amendments**

ad. = added or inserted   am. = amended   rep. = repealed   rs. = repealed and substituted

Provision affected	How affected
<b>Division 2</b>	
S. 41DC .....	ad. No. 24, 2002 am. No. 76, 2009
Note to s. 41DC(1) .....	ad. No. 76, 2009
Ss. 41DD, 41DE .....	ad. No. 24, 2002
<b>Part 4-4</b>	
S. 41E .....	ad. No. 24, 2002
<b>Division 1</b>	
Ss. 41EA, 41EB .....	ad. No. 24, 2002
Note to s. 41EB(2) .....	rs. No. 39, 2006
S. 41EC .....	ad. No. 24, 2002 am. No. 39, 2003; No. 39, 2006; No. 38, 2009
S. 41ED .....	ad. No. 24, 2002 am. No. 54, 2010
Ss. 41EE, 41EF .....	ad. No. 24, 2002
S. 41EG .....	ad. No. 24, 2002 am. No. 38, 2009; No. 141, 2010
S. 41EH .....	ad. No. 24, 2002
S. 41EI .....	ad. No. 24, 2002 rs. No. 39, 2006 am. No. 38, 2009
S. 41EIA .....	ad. No. 39, 2006
<b>Division 2</b>	
Note to heading of Div. 2 .....	rs. No. 39, 2006
S. 41EJ .....	ad. No. 24, 2002 am. Nos. 38 and 76, 2009
Ss. 41EK, 41EL .....	ad. No. 24, 2002
<b>Division 3</b>	
Ss. 41EM–41EQ .....	ad. No. 24, 2002
<b>Division 4</b>	
Ss. 41ER, 41ES .....	ad. No. 24, 2002
S. 41ET .....	ad. No. 24, 2002 am. No. 39, 2003; No. 39, 2006; No. 38, 2009
Ss. 41EU–41EW .....	ad. No. 24, 2002
<b>Part 4-5</b>	
S. 41F .....	ad. No. 24, 2002
<b>Division 1</b>	
S. 41FA .....	ad. No. 24, 2002
Note 2 to s. 41FA .....	am. No. 39, 2006
S. 41FB .....	ad. No. 24, 2002
<b>Subdivision A</b>	
S. 41FC .....	ad. No. 24, 2002
Note to s. 41FC(2) .....	rs. No. 39, 2006



**Table of Amendments**

ad. = added or inserted   am. = amended   rep. = repealed   rs. = repealed and substituted

Provision affected	How affected
S. 41FD .....	ad. No. 24, 2002 am. No. 39, 2003; No. 96, 2009
S. 41FE.....	ad. No. 24, 2002 am. No. 39, 2003 rs. No. 39, 2006 am. No. 38, 2009
S. 41FEA .....	ad. No. 39, 2006
<b>Subdivision B</b>	
S. 41FF.....	ad. No. 24, 2002 am. No. 96, 2009
S. 41FG .....	ad. No. 24, 2002
<b>Subdivision C</b>	
Ss. 41FH–41FJ.....	ad. No. 24, 2002
S. 41FK.....	ad. No. 24, 2002 am. No. 141, 2010
<b>Subdivision D</b>	
Ss. 41FL, 41FM .....	ad. No. 24, 2002
<b>Division 2</b>	
Note to heading of Div. 2.....	rs. No. 39, 2006
S. 41FN .....	ad. No. 24, 2002 am. No. 39, 2006; No. 76, 2009
Ss. 41FO, 41FP .....	ad. No. 24, 2002
<b>Part 4-6</b>	
<b>Division 1</b>	
<b>Subdivision A</b>	
S. 41G .....	ad. No. 24, 2002
Ss. 41GA–41GE .....	ad. No. 24, 2002
<b>Subdivision B</b>	
Ss. 41GF–41GH .....	ad. No. 24, 2002
<b>Subdivision C</b>	
S. 41GI .....	ad. No. 24, 2002
Note to s. 41GI.....	am. No. 39, 2006
S. 41GJ.....	ad. No. 24, 2002
<b>Division 2</b>	
S. 41GK.....	ad. No. 24, 2002
S. 41GL .....	ad. No. 24, 2002 am. No. 39, 2003
S. 41GM .....	ad. No. 24, 2002
S. 41GN.....	ad. No. 24, 2002 am. No. 39, 2006
Ss. 41GO–41GQ.....	ad. No. 24, 2002
<b>Part 4-6A</b>	
Part 4-6A .....	ad. No. 38, 2009
Ss. 41GR–41GW .....	ad. No. 38, 2009

**Table of Amendments**

ad. = added or inserted   am. = amended   rep. = repealed   rs. = repealed and substituted

Provision affected	How affected
S. 41GX .....	ad. No. 38, 2009 rep. No. 54, 2010
S. 41GY .....	ad. No. 38, 2009
<b>Part 4-7</b>	
Heading to Part 4-7 .....	rs. No. 38, 2009
S. 41H .....	ad. No. 24, 2002 am. No. 38, 2009; No. 141, 2010
S. 41HA .....	ad. No. 24, 2002
Notes to s. 41HA(1), (2) .....	am. No. 39, 2006
S. 41HB .....	ad. No. 24, 2002
Note to s. 41HB(2) .....	am. No. 39, 2006
Note to s. 41HB(7) .....	am. No. 39, 2006
S. 41HC .....	ad. No. 24, 2002 am. No. 54, 2010
S. 41HD .....	ad. No. 141, 2010
<b>Part 4-8</b>	
S. 41J .....	ad. No. 24, 2002 am. No. 38, 2009
Note to s. 41J .....	am. No. 39, 2006
<b>Division 1</b>	
S. 41JA .....	ad. No. 24, 2002 am. No. 39, 2003; Nos. 38 and 76, 2009
S. 41JB .....	ad. No. 24, 2002 am. No. 39, 2006; No. 38, 2009
S. 41JBA .....	ad. No. 39, 2006
S. 41JC .....	ad. No. 24, 2002 am. No. 39, 2006
<b>Division 2</b>	
S. 41JCA .....	ad. No. 38, 2009
Ss. 41JD–41JF .....	ad. No. 24, 2002 am. No. 39, 2006
S. 41JFA .....	ad. No. 141, 2010
S. 41JG .....	ad. No. 24, 2002 rs. No. 39, 2006 am. No. 38, 2009; No. 141, 2010
Note to s. 41JG .....	am. No. 38, 2009; No. 141, 2010
Ss. 41JH–41JJ .....	ad. No. 24, 2002 am. No. 39, 2006; No. 38, 2009; No. 141, 2010
<b>Part 4-9</b>	
S. 41K .....	ad. No. 24, 2002
S. 41KA .....	ad. No. 24, 2002 am. No. 38, 2009; Nos. 54, and 141, 2010
S. 41KB .....	ad. No. 24, 2002

**Table of Amendments**

ad. = added or inserted   am. = amended   rep. = repealed   rs. = repealed and substituted

Provision affected	How affected
S. 41KC .....	ad. No. 24, 2002 rs. No. 39, 2006 am. No. 38, 2009
S. 41KCA.....	ad. No. 39, 2006
S. 41KD .....	ad. No. 24, 2002
<b>Part 4-10</b>	
S. 41L.....	ad. No. 24, 2002
Ss. 41LA–41LE .....	ad. No. 24, 2002
<b>Part 4-11</b>	
Heading to Part 4-11 .....	rs. No. 39, 2006
S. 41M.....	ad. No. 24, 2002 am. No. 39, 2006; No. 38, 2009
Note to s. 41M .....	am. No. 39, 2006
<b>Division 1</b>	
S. 41MA.....	ad. No. 24, 2002 am. No. 39, 2003 rs. No. 39, 2006 am. No. 38, 2009
S. 41MAA.....	ad. No. 39, 2006 am. No. 38, 2009
S. 41MB.....	ad. No. 24, 2002 am. No. 39, 2006
Note to s. 41MB(2) .....	rep. No. 39, 2006
Notes 1, 2 to s. 41MB(2) .....	ad. No. 39, 2006
S. 41MC.....	ad. No. 24, 2002 rs. No. 39, 2006 am. No. 38, 2009
S. 41MCA .....	ad. No. 39, 2006
S. 41MD.....	ad. No. 24, 2002 am. No. 39, 2006
<b>Division 2</b>	
S. 41ME.....	ad. No. 24, 2002 am. No. 39, 2003 rs. No. 39, 2006 am. No. 38, 2009
S. 41MEA.....	ad. No. 39, 2006 am. No. 38, 2009
S. 41MF .....	ad. No. 24, 2002 am. No. 39, 2003 rs. No. 39, 2006 am. No. 38, 2009
S. 41MG .....	ad. No. 24, 2002 am. No. 39, 2006
Note to s. 41MG(2) .....	rep. No. 39, 2006
Notes 1, 2 to s. 41MG(2) .....	ad. No. 39, 2006

**Table of Amendments**

ad. = added or inserted   am. = amended   rep. = repealed   rs. = repealed and substituted

Provision affected	How affected
Heading to s. 41MH .....	rs. No. 39, 2006
S. 41MH.....	ad. No. 24, 2002 am. No. 39, 2003; No. 38, 2009
S. 41MHA .....	ad. No. 39, 2006
<b>Division 3</b>	
S. 41MI .....	ad. No. 24, 2002 am. No. 39, 2003 rs. No. 39, 2006 am. No. 38, 2009; No. 141, 2010
S. 41MIA.....	ad. No. 39, 2006
S. 41MIB.....	ad. No. 39, 2006 am. No. 38, 2009; No. 141, 2010
S. 41MJ .....	ad. No. 24, 2002 am. No. 39, 2006
S. 41MK.....	ad. No. 24, 2002 am. No. 38, 2009; No. 141, 2010
Heading to s. 41ML.....	rs. No. 39, 2006; No. 96, 2009
S. 41ML .....	ad. No. 24, 2002 am. No. 39, 2006; No. 38, 2009 rs. No. 96, 2009
S. 41MLA.....	ad. No. 39, 2006 am. No. 141, 2010
S. 41MM .....	ad. No. 24, 2002 am. No. 38, 2009
S. 41MN.....	ad. No. 24, 2002 rs. No. 39, 2006 am. No. 38, 2009; No. 141, 2010
S. 41MNA .....	ad. No. 39, 2006
<b>Division 3A</b>	
Div. 3A of Part 4-11.....	ad. No. 38, 2009
Ss. 41MNB–41MND.....	ad. No. 38, 2009
<b>Division 4</b>	
Heading to Div. 4 of ..... Part 4-11	rs. No. 39, 2006
S. 41MO .....	ad. No. 24, 2002 rs. No. 39, 2006 am. No. 38, 2009
Heading to s. 41MP .....	rs. No. 39, 2006
S. 41MP.....	ad. No. 24, 2002 am. No. 39, 2006; No. 38, 2009
Ss. 41MPA, 41MPB .....	ad. No. 39, 2006
S. 41MQ .....	ad. No. 24, 2002 am. No. 39, 2006; No. 38, 2009
S. 41MR.....	ad. No. 39, 2006

**Table of Amendments**

ad. = added or inserted   am. = amended   rep. = repealed   rs. = repealed and substituted

Provision affected	How affected
<b>Chapter 5</b>	
Heading to Part 4A.....	rep. No. 24, 2002
Heading to Chapt. 5.....	ad. No. 24, 2002
Part 4A.....	ad. No. 3, 1999
<b>Part 5-1</b>	
Heading to Part 5-1.....	ad. No. 24, 2002 rs. No. 39, 2003
<b>Division 1</b>	
Heading to Div. 1 of ..... Part 5-1	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
S. 42A.....	ad. No. 3, 1999 rep. No. 39, 2003
S. 42B.....	ad. No. 3, 1999 am. No. 39, 2003; No. 38, 2009
S. 42BAA.....	ad. No. 76, 2009
<b>Division 2</b>	
Heading to Div. 2 of ..... Part 5-1	ad. No. 39, 2003
S. 42BA.....	ad. No. 39, 2003
S. 42C.....	ad. No. 3, 1999 rs. No. 39, 2003 am. No. 39, 2006
Notes to s. 42C(1), (2).....	ad. No. 39, 2006
Note to s. 42C(4).....	ad. No. 39, 2006
Note to s. 42C(6).....	ad. No. 39, 2006
S. 42D.....	ad. No. 3, 1999 rep. No. 39, 2003
<b>Division 3</b>	
Div. 3 of Part 5-1.....	ad. No. 39, 2003
S. 42DA.....	ad. No. 39, 2003 rs. No. 38, 2009
S. 42DB.....	ad. No. 39, 2003
S. 42DC.....	ad. No. 39, 2003 rep. No. 38, 2009
S. 42DD.....	ad. No. 39, 2003 am. Nos. 38 and 76, 2009
Note to s. 42DD(1).....	ad. No. 38, 2009
S. 42DE.....	ad. No. 39, 2003
S. 42DF.....	ad. No. 39, 2003 am. No. 76, 2009

**Table of Amendments**

ad. = added or inserted   am. = amended   rep. = repealed   rs. = repealed and substituted

Provision affected	How affected
Ss. 42DG–42DJ.....	ad. No. 39, 2003
S. 42DK.....	ad. No. 39, 2003 am. No. 8, 2010
<b>Division 3A</b>	
Heading to Div. 3A of Part 5-1.....	ad. No. 38, 2009
Ss. 42DKA, 42DKB.....	ad. No. 38, 2009
S. 42DL.....	ad. No. 39, 2003 am. No. 38, 2009; No. 54, 2010
S. 42DM.....	ad. No. 39, 2003
<b>Division 4</b>	
Div. 4 of Part 5-1.....	ad. No. 39, 2003
Ss. 42DN–42DP.....	ad. No. 39, 2003
<b>Part 5-2</b>	
Heading to Part 4B.....	rep. No. 24, 2002
Heading to Part 5-2.....	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
Ss. 42EA, 42EB.....	ad. No. 39, 2006
S. 42F.....	ad. No. 56, 2000
<b>Part 5-3</b>	
Heading to Part 4C.....	rep. No. 24, 2002
Heading to Part 5-3.....	ad. No. 24, 2002
Part 4C.....	ad. No. 120, 2000
S. 42T.....	ad. No. 120, 2000 am. No. 39, 2006; No. 38, 2009
S. 42U.....	ad. No. 120, 2000
S. 42V.....	ad. No. 120, 2000 am. No. 24, 2002; No. 39, 2006; No. 38, 2009
Ss. 42VA, 42VB.....	ad. No. 39, 2006
S. 42W.....	ad. No. 120, 2000 am. No. 39, 2006; No. 38, 2009
S. 42X.....	ad. No. 120, 2000
<b>Chapter 5A</b>	
Chapt. 5A.....	ad. No. 39, 2006
<b>Part 5A-1</b>	
<b>Division 1</b>	
S. 42Y.....	ad. No. 39, 2006
Ss. 42YA–42YD.....	ad. No. 39, 2006
S. 42YE.....	ad. No. 39, 2006 am. No. 38, 2009
<b>Division 2</b>	
Ss. 42YF–42YI.....	ad. No. 39, 2006

**Table of Amendments**

ad. = added or inserted   am. = amended   rep. = repealed   rs. = repealed and substituted

Provision affected	How affected
<b>Part 5A-2</b>	
Ss. 42YJ, 42YK.....	ad. No. 39, 2006
<b>Part 5A-3</b>	
S. 42YL.....	ad. No. 39, 2006 am. No. 8, 2010
<b>Chapter 6</b>	
Heading to Part 5.....	rep. No. 24, 2002
Heading to Chapt. 6.....	ad. No. 24, 2002
<b>Part 6-1</b>	
Heading to Part 6-1.....	ad. No. 24, 2002
S. 43.....	am. No. 24, 2002
S. 44.....	am. No. 84, 1991; No. 24, 2002 rs. No. 96, 2008
S. 44A.....	ad. No. 96, 2008
S. 44B.....	ad. No. 54, 2010
S. 45.....	rs. No. 152, 1997 am. No. 24, 2002 rs. No. 8, 2005
<b>Part 6-2</b>	
Heading to Part 6.....	rep. No. 6, 1996
Heading to Part 5A.....	ad. No. 6, 1996 rep. No. 24, 2002
Heading to Part 6-2.....	ad. No. 24, 2002
S. 45A.....	ad. No. 6, 1996 am. No. 39, 2006
S. 46.....	rs. No. 6, 1996
S. 46A.....	ad. No. 6, 1996 am. Nos. 23 and 24, 2002; Nos. 38 and 76, 2009; No. 141, 2010
S. 46B.....	ad. No. 6, 1996
Heading to s. 47.....	am. No. 39, 2006
S. 47.....	am. No. 76, 1993 rs. No. 6, 1996 am. No. 39, 2006
S. 48.....	am. No. 6, 1996; No. 111, 2001; Nos. 38 and 76, 2009
Ss. 48A, 48B.....	ad. No. 6, 1996
S. 48C.....	ad. No. 6, 1996 am. No. 39, 2006
S. 48D.....	ad. No. 6, 1996
S. 48E.....	ad. No. 6, 1996 am. No. 39, 2006
Ss. 48F–48H.....	ad. No. 6, 1996
S. 48J.....	ad. No. 6, 1996 am. No. 39, 2006
S. 49.....	am. No. 6, 1996

**Table of Amendments**

ad. = added or inserted   am. = amended   rep. = repealed   rs. = repealed and substituted

Provision affected	How affected
Heading to s. 50.....	am. No. 39, 2006
S. 50.....	am. No. 6, 1996; No. 39, 2006
Heading to s. 51.....	am. No. 39, 2006
S. 51.....	am. No. 6, 1996
S. 51A.....	ad. No. 76, 1993
S. 51B.....	ad. No. 6, 1996 am. No. 38, 2009
S. 52.....	am. No. 6, 1996; No. 111, 2001; No. 38, 2009
<b>Part 6-3</b>	
Heading to Part 5B.....	rep. No. 24, 2002
Heading to Part 6-3.....	ad. No. 24, 2002 rs. No. 96, 2009
Part 5B.....	ad. No. 3, 1999
S. 52AA.....	ad. No. 96, 2009
S. 52A.....	ad. No. 3, 1999 am. No. 96, 2009
Ss. 52B, 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
S. 52E.....	ad. No. 3, 1999 rs. No. 96, 2009
S. 52EAA.....	ad. No. 96, 2009
Ss. 52EA, 52EB.....	ad. No. 9, 2008
S. 52EC.....	ad. No. 96, 2009
Heading to Part 5C.....	rep. No. 24, 2002
Heading to Part 6-4.....	ad. No. 24, 2002 rep. No. 76, 2009
Part 5C.....	ad. No. 3, 1999
Part 6-4.....	rep. No. 76, 2009
Ss. 52F, 52G.....	ad. No. 3, 1999 rep. No. 76, 2009
<b>Chapter 7</b>	
Heading to Part 6.....	ad. No. 6, 1996 rep. No. 24, 2002
Heading to Chapt. 7.....	ad. No. 24, 2002
S. 53.....	rs. No. 24, 2002
S. 53A.....	ad. No. 39, 2006
Heading to s. 54.....	rs. No. 6, 1996; No. 39, 2006
S. 54.....	am. No. 204, 1991; No. 76, 1993; No. 6, 1996; No. 24, 2002; No. 39, 2006
S. 54AA.....	ad. No. 3, 1999 am. No. 111, 2001; No. 39, 2003; No. 73, 2008



**Table of Amendments**

ad. = added or inserted   am. = amended   rep. = repealed   rs. = repealed and substituted

Provision affected	How affected
Heading to s. 54AB .....	rs. No. 39, 2006
S. 54AB .....	ad. No. 39, 2003 am. No. 39, 2006; No. 38, 2009
S. 54AC .....	ad. No. 39, 2006
S. 54A .....	ad. No. 6, 1996
Ss. 54B, 54C .....	ad. No. 39, 2006
S. 55 .....	am. No. 6, 1996; No. 39, 2006
S. 56 .....	am. No. 24, 2002; No. 38, 2009
S. 56A .....	ad. No. 6, 1996 am. No. 24, 2002; No. 39, 2006; Nos. 38 and 76, 2009; No. 141, 2010
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
S. 58 .....	am. No. 76, 1993; No. 76, 2009
S. 60 .....	am. No. 6, 1996; No. 24, 2002; No. 39, 2003; No. 39, 2006; No. 76, 2009; No. 141, 2010
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
S. 61A .....	ad. No. 54, 2010
S. 63 .....	am. No. 204, 1991; No. 76, 1993; No. 6, 1996; No. 34, 1998; No. 24, 2002
<b>Chapter 8</b>	
Heading to Part 7 .....	rep. No. 24, 2002
Heading to Chapt. 8 .....	ad. No. 24, 2002
S. 66 .....	am. No. 76, 1993
Heading to s. 68 .....	am. No. 24, 2002
S. 69 .....	am. No. 24, 2002
<b>Schedule</b>	
Schedule .....	am. No. 141, 1990

## Note 2

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### Note 2

*Therapeutic Goods Amendment (2009 Measures No. 1) Act 2009*  
(No. 76, 2009)

The following amendments commence on 1 July 2011:

### Schedule 4

#### 1 Subsection 3(1)

Insert:

*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.

#### 2 Subsection 3(1)

Insert:

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

#### 3 Subsection 3(1)

Insert:

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

#### 4 Subsection 3(1)

Insert:

*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.

**5 Subsection 3(1)**

Insert:

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

**6 Subsection 3(1)**

Insert:

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

**7 Subsection 3(1)**

Insert:

*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).

**8 Subsection 3(1) (at the end of the definition of *standard*)  
(before the note)**

Add:

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

**9 After section 3**

Insert:

## Note 2

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### 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.

#### *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 *Legislative Instruments 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
  - (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.

## Note 2

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### *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 *Legislative Instruments 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).

## 10 Subsection 10(1)

Omit “or the United States Pharmacopeia-National Formulary”, substitute “, the United States Pharmacopeia-National Formulary, a homoeopathic pharmacopoeia or an anthroposophic pharmacopoeia”.

## 11 Subparagraph 10(2)(a)(iv)

Omit “or the United States Pharmacopeia-National Formulary”, substitute “, the United States Pharmacopeia-National Formulary, a homoeopathic pharmacopoeia or an anthroposophic pharmacopoeia”.

## 12 After section 13

Insert:

## 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.
- (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

**Note 3**

(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.

Note: The heading to section 13 is altered by omitting “**standards**” and substituting “**Ministerial standards and default standards**”.

**13 Section 56**

Omit “and the United States Pharmacopeia-National Formulary”, substitute “, the United States Pharmacopeia-National Formulary, a homoeopathic pharmacopoeia and an anthroposophic pharmacopoeia”.

As at 12 January 2011 the amendments are not incorporated in this compilation.

**Note 3**

*Therapeutic Goods Amendment (2009 Measures No. 3) Act 2010*  
(No. 54, 2010)

The following amendments commence on 31 May 2011 unless proclaimed earlier:

**Schedule 1****1 Subsection 3(1)**

Insert:

*biological* has the meaning given by section 32A.

**2 Subsection 3(1)**

Insert:

*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.

**3 Subsection 3(1)**

Insert:

### Note 3

---

**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.

#### 4 Subsection 3(1) (definition of *included in the Register*)

Repeal the definition, substitute:

***included in the Register***:

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

#### 5 Subsection 3(1) (paragraph (a) of the definition of *medicine*)

After “goods”, insert “(other than biologicals)”.

#### 6 Subsection 3(1) (definition of *therapeutic device*)

After “means therapeutic goods”, insert “(other than biologicals)”.

#### 7 Subsection 3(1) (definition of *therapeutic goods*)

After “and includes”, insert “biologicals,”.

#### 8 After paragraph 6AAE(6)(b)

Insert:

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

#### 9 Paragraph 7B(1)(b)

Omit “or are exempt goods in relation to Part 3-2”, substitute “, are exempt goods in relation to Part 3-2, are included in the Register under Part 3-2A or are exempt under subsection 32CA(2) or section 32CB”.

#### 10 After paragraph 9(1)(a)

Insert:



**Note 3**

---

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

**11 Subsection 9A(3)**

Omit “3 parts”, substitute “4 parts”.

**12 After paragraph 9A(3)(b)**

Insert:

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

**13 Paragraph 9A(4)(b)**

Repeal the paragraph, substitute:

- (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

**14 After paragraph 9A(4)(c)**

Insert:

- (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

**15 After subsection 9D(3)**

Insert:

(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
- (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:

### Note 3

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- (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.

### 16 Subsection 9D(4)

Omit “the part for goods to be known as registered goods or to the part for goods to be known as listed goods (whichever is applicable)”, substitute “whichever other part of the Register is applicable”.

### 17 After subsection 14(5)

Insert:

- (5A) Subsection (1), (2) or (4) 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*.

Note: The heading to subsection 14(5) is replaced by the heading “*Exceptions*”.

### 18 After subsection 14(9)

Insert:

#### *Exception*

- (9A) Subsection (6), (7) or (9) 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*.

### 19 After subsection 14(13)

Insert:

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*Exception*

- (13A) Subsection (10), (11) or (13) 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.

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

**20 After subsection 14A(1)**

Insert:

*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.

**21 After subsection 14A(2)**

Insert:

*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.

**22 After subsection 14A(3)**

Insert:

*Exception*

- (3A) Subsection (3) does not apply if:
- (a) the therapeutic goods are a biological; and

### **Note 3**

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

### **23 At the end of Part 3-1**

Add:

#### **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.

### **24 After section 15A**

Insert:

#### **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;
  - (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.

**25 After Part 3-2**

Insert:

**Note 3**

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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 recovery 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
  - (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

**Note 3**

- (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 *Legislative Instruments 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 *Legislative Instruments 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 32DD.

**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).

**Note 3**

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**Division 2—Main criminal offences and civil penalties**

**32B What this Division is about**

<p>This Division contains criminal offences and civil penalties relating to the import, export, manufacture, supply and use of biologicals.</p>
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**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) or (2) that is held by the person; and
  - (c) either:
    - (i) the use of the biological has resulted in, or will result in, harm or injury to any person; or
    - (ii) the use of the biological, if the biological were used, would 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.

- (2) A person commits an offence if:



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- (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) or (2) that is held by the person; and
- (c) the use of the biological, if the biological were used, would be likely to result in harm or injury to any person.

Penalty: 2,000 penalty units.

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

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

- (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) or (2) that is held by the person.

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

#### *Defences*

- (5) Subsection (1), (2) or (4) 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, or will not, 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 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*.

### **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

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approval covering the exportation from Australia of the biological; and

(c) either:

- (i) the use of the biological has resulted in, or will result in, harm or injury to any person; or
- (ii) the use of the biological, if the biological were used, would 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.

(2) 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) the use of the biological, if the biological were used, would be likely to result in harm or injury to any person.

Penalty: 2,000 penalty units.

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

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

(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.

#### *Defences*

- (5) Subsection (1), (2) or (4) 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*.

- (6) Subsection (1) does not apply if:
- (a) harm or injury did not, or will not, 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 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*.

### **32BC Criminal offences for manufacturing a biological**

- (1) 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:

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- (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, or will result in, harm or injury to any person; or
  - (ii) the use of the biological, if the biological were used, would 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.

- (2) 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; and
  - (c) the use of the biological, if the biological were used, would be likely to result in harm or injury to any person.

Penalty: 2,000 penalty units.

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

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

- (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;

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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.

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

#### *Defences*

- (5) Subsection (1), (2) or (4) 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, or will not, 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 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*.

### **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);

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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) that is held by the person;
  - (vi) the biological is the subject of an approval under subsection 32CO(1) 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, or will result in, harm or injury to any person; or
  - (ii) the use of the biological, if the biological were used, would 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.

- (2) 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) that is held by the person;
    - (vi) the biological is the subject of an approval under subsection 32CO(1) or (2) that is held by the person,

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being an approval covering the supply in Australia of the biological; and

- (c) the use of the biological, if the biological were used, would be likely to result in harm or injury to any person.

Penalty: 2,000 penalty units.

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

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

- (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) that is held by the person;
  - (vi) the biological is the subject of an approval under subsection 32CO(1) 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.

#### *Defences*

- (5) Subsection (1), (2) or (4) 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*.



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- (6) Subsection (1) does not apply if:
- (a) harm or injury did not, or will not, 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 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*.

**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

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- 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
  - (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:
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***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*.

**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) 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;
    - (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 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
  - (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

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approval covering the supply in Australia of the biological;

- (v) the biological is the subject of an authority under subsection 32CM(1) that is held by the person;
- (vi) the biological is the subject of an approval under subsection 32CO(1) 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
  - (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.

### **32BG Criminal offence and civil penalty relating to a failure to notify the Secretary about manufacturing**

*Criminal offence*

- (1) A person commits an offence if:

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

#### *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:
    - (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) that is held by the person;

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- (vi) the biological is the subject of an approval under subsection 32CO(1) 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.

### **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) 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); 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, or will 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, or will result in, harm or injury to any of those humans.



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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.

- (2) 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) 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); and
  - (d) either:
    - (i) if the person used the biological in the treatment of another person—the use of the biological 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 is likely to result in harm or injury to any of those humans.

Penalty: 2,000 penalty units.

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

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

- (4) A person commits an offence if:
- (a) the person uses a biological; and

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- (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) 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).

Penalty for contravention of this subsection: 500 penalty units.

### 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.

*Advertising biological for an indication*

- (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: 60 penalty units.

*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 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) that is held by the person;
    - (vi) the biological is the subject of an approval under subsection 32CO(1) or (2) that is held by the 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

### **Note 3**

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(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 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);
- (f) representations that a biological is the subject of an approval under subsection 32CO(1) or (2).

## **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 *Legislative Instruments 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 *Legislative Instruments Act 2003*.

- (3) An exemption under this section may be subject to conditions that are prescribed in the regulations.

- (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 46(3) 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.

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- (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:
- (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

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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.

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 46(3) 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:

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- (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).

### 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
  - (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.

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Penalty: Imprisonment for 5 years or 2,000 penalty units, or both.

- (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*.

### **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 recover the biologicals included in that batch (except any of those biologicals that cannot be recovered 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 recover 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.
- (4) The Secretary must, as soon as practicable after giving the notice, cause particulars of it to be published in the *Gazette*.

*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

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(d) either:

- (i) the use of any of the biologicals has resulted in, or will 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 harm or injury to any person; and
- (e) the harm or injury has resulted, will result, or would result, because the person failed to comply with that requirement.

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

(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; and
- (d) the use of any of the biologicals, if any of the biologicals were used, would be likely to result in harm or injury to any person; and
- (e) the harm or injury would be likely to result because the person failed to comply with that requirement.

Penalty: 2,000 penalty units.

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

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

(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: 60 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.

**Subdivision D—Exempting biologicals for special and experimental 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.
- (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
  - (b) be accompanied by such information relating to the biological the subject of the application as is required by the Secretary.

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- (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
  - (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.

*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 medical 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.

Note: Section 32CN contains criminal offences relating to the giving an authority to a medical practitioner.

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- (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.
- (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 medical 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;



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- (iii) the supply is not in accordance with regulations made for the purpose of subsection 32CM(6); and
- (d) either:
  - (i) the use of the biological has resulted in, or will result in, harm or injury to any person; or
  - (ii) the use of the biological, if the biological were used, would result in harm or injury to any person; and
- (e) the harm or injury has resulted, will result, or would 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.

- (2) 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) the use of the biological, if the biological were used, would be likely to result in harm or injury to any person; and
  - (e) the harm or injury 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: 2,000 penalty units.

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

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

- (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 for contravention of this subsection: 500 penalty units.

### **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) either:
    - (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); or
    - (ii) an application that complies with section 32DA or 32DD has been made for inclusion of the biological in the Register; 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.
- (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) an application that complies with section 32DA or 32DD has been made for inclusion of the biological in the Register; 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.

*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.

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#### *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) or (2).

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), 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) or (2) is not a legislative instrument.

**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
  - (c) the biological conforms to every standard (if any) applicable to it; and
  - (d) the biological complies with every requirement (if any) relating to advertising applicable under Part 5-1 or under the regulations; and

### Note 3

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- (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.
- (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**

- (1) A person may make an application to the Secretary to include a biological, other than a Class 1 biological, in the Register.
- (2) An application is not effective unless:
  - (a) the application is made in accordance with a form that is approved, in writing, by the Secretary and that relates to that biological; and
  - (b) the application is accompanied by any documents that the form requires; and
  - (c) the application is delivered to an office of the Department specified in the form; and
  - (d) if the Secretary so requires—the applicant has delivered to that office a reasonable number of samples of the biological; and
  - (e) the application is accompanied by the prescribed application fee.

Note: An evaluation fee is also payable: see sections 32DI to 32DM.

- (3) The Secretary may approve different forms for different classes of biologicals that are prescribed by the regulations for the purposes of section 32AA.
- (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.

### **Note 3**

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#### **32DE Evaluation of biologicals**

- (1) If an application is made in accordance with section 32DD for a biological to be included in the Register in relation to a person, 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
  - (c) whether the biological conforms to any standard applicable to it; and
  - (d) whether the biological complies with every requirement (if any) relating to advertising applicable under Part 5-1 or under the regulations; 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).

#### **32DF Inclusion of biological in the Register**

- (1) If:
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**Note 3**

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- (a) an application is made in accordance with section 32DD for a biological to be included in the Register in relation to a person; 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.

*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:

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### Note 3

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- (a) an application is made under subsection 32DD(1) to include a 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.

#### **32DH Lapsing of application**

- (1) An application under subsection 32DD(1) 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 in accordance with section 32DD for a biological to be included in the Register, 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.

**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.

**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  $\frac{3}{4}$  of the evaluation fee before the completion of the

### Note 3

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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  $\frac{3}{4}$  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.

## **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:

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- (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:
  - (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.

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- (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.
- (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:
    - (i) the use of the biological has resulted in, or will result in, harm or injury to any person; or
    - (ii) the use of the biological, if the biological were used, would 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.

- (2) 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) the use of the biological, if the biological were used, would be likely to result in harm or injury to any person.

Penalty: 2,000 penalty units.

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

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

- (4) A person commits an offence if:

### **Note 3**

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- (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 for contravention of this subsection: Imprisonment for 12 months or 1,000 penalty units, or both.

#### **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.

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.

##### *Civil penalty*

- (2) A person contravenes this subsection if:



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- (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:

- (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

### Note 3

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- (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 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.

- (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.

#### *Civil penalties*

- (5) A person contravenes this subsection if:
  - (a) the Secretary gives a notice to the person under subsection (1); and

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- (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.
- (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.

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#### **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
- (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; 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
  - (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.
- (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.

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#### *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:
- (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.

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**Note 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.

*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).

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#### **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:
  - (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
  - (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.



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- (3) The imposition or variation or removal of a condition under subsection (1) 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 a later day specified in the notice, being a day not earlier than 28 days after 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, or will 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.

- (2) 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 is likely to result in harm or injury to any person.

Penalty: 2,000 penalty units.

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

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

- (4) A person commits an offence if:

### **Note 3**

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- (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 for contravention of this subsection: Imprisonment for 12 months or 1,000 penalty units, or both.

### **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.

## **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

**Note 3**

- (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) or (d)).

*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:
  - (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 in Gazette*

- (5) As soon as practicable after giving a notice under subsection (1), the Secretary must cause to be published in the *Gazette* a notice setting out particulars of the suspension.

### **Note 3**

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*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.
- (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 in Gazette*

- (4) As soon as practicable after giving a notice under subsection (3), the Secretary must cause to be published in the *Gazette* 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

**Note 3**

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
  - (b) on the Secretary's own initiative.

*Publication in Gazette*

- (3) As soon as practicable after giving a notice under subsection (1), the Secretary must cause to be published in the *Gazette* 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.

**Note 3**

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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
  - (h) the person has failed to comply with a condition mentioned in subsection 32EA(1) or (3); or
  - (i) both of the following apply:
    - (i) under the regulations, an authority constituted by or under the regulations gives a direction to, or makes a

requirement of, the person in relation to an advertisement of the biological to ensure that advertising complies with the Therapeutic Goods Advertising Code;

- (ii) the person does not comply with the direction or requirement; or
- (j) there is a breach, involving the biological, of the requirements relating to advertising applicable under Part 5-1 or under the regulations.

(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 the biological should have been included in the Register; and
  - (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:

### Note 3

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- (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 unacceptable; 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.
- (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
  - (g) the biological does not comply with a requirement relating to advertising applicable to it under Part 5-1 or under the regulations.



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- (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 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.

**32GE Publication of cancellation of entry from Register**

The Secretary must cause to be published in the *Gazette*, 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

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cancellation is given to the person in relation to whom the biological was included in the Register.

**Division 8—Public notification and recovery of biologicals**

**32H What this Division is about**

The Secretary may require a person to recover 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 recovery 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.

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**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 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 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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**Note 3**


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<b>Circumstances in which requirements may be imposed</b>		
<b>Item</b>	<b>Circumstance relating to biological</b>	<b>Person subject to requirements</b>
3	<p>It is supplied while:</p> <p>(a) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2); or</p> <p>(b) it is exempt under section 32CB; or</p> <p>(c) it is the subject of an approval under subsection 32CK(1); or</p> <p>(d) it is the subject of an authority under subsection 32CM(1); or</p> <p>(e) it is the subject of an approval under subsection 32CO(1) or (2);</p> <p>but it does not conform with a standard applicable to it</p>	The person supplying it
4	<p>It is a biological, other than a Class 1 biological, and it is supplied while:</p> <p>(a) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2); or</p> <p>(b) it is exempt under section 32CB; or</p> <p>(c) it is the subject of an approval under subsection 32CK(1); or</p> <p>(d) it is the subject of an authority under subsection 32CM(1); or</p> <p>(e) it is the subject of an approval under subsection 32CO(1) or (2);</p> <p>but the manufacturing principles have not been observed in its manufacture</p>	The person supplying it

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**Note 3**

<b>Circumstances in which requirements may be imposed</b>		
<b>Item</b>	<b>Circumstance relating to biological</b>	<b>Person subject to requirements</b>
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); and (f) it is not the subject of an approval under subsection 32CO(1) 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 supplied in contravention of subsection 42E(1) or section 42EA	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 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 unacceptable	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

(2) The requirements may be one or more of the following:

**Note 3**

- (a) to take specified steps, in the specified manner and within such reasonable period as is specified, to recover 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;
  - (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.
- (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 recover a biological under this section does not apply to a biological that cannot be recovered 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*, as soon as practicable after imposing a 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, or will 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.

- (2) A person commits an offence if:

### Note 3

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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; and
- (c) the act or omission is likely to result in harm or injury to any person.

Penalty: 2,000 penalty units.

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

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

- (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 for contravention of this subsection: Imprisonment for 12 months or 1,000 penalty units, or both.

### 32HD 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 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.

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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;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;

**Note 3**

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- (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 the biological complies with every requirement (if any) 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.
- (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
  - (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).

- (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, or will result in, harm or injury to any person; or
    - (ii) the use of the biological, if the biological were used, would 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 (5) instead: see section 53A.

- (3) 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

### Note 3

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- (d) the use of the biological, if the biological were used, would be likely to result in harm or injury to any person.

Penalty: 2,000 penalty units.

- (4) An offence against subsection (3) is an offence of strict liability.

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

- (5) 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 for contravention of this subsection: Imprisonment for 12 months or 1,000 penalty units, or both.

### **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 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

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**Note 3**

- (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), (2), (3) or (5); 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 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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#### *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:
- (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 3**

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;
  - (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;

### Note 3

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- (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.

#### *Compliance*

- (4) A person given a notice under subsection (1), (2) or (3) 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) or (2) in relation to a biological a

**Note 3**

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.

- (2) A person commits an offence if:
  - (a) the person is given a notice under section 32JE, 32JF, 32JG or 32JH; and

### **Note 3**

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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 for contravention of this subsection: Imprisonment for 12 months or 1,000 penalty units, or both.

### **32JJ 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 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) or (2); 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.

### **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.

## **26 After section 33A**

Insert:

## **33B Application of this Part to biologicals**

This Part does not apply to a Class 1 biological.

## **27 Paragraphs 35(1)(a), (2)(a) and (4)(a)**

After “section 18A”, insert “or 32CB”.

## **28 Paragraphs 35(5)(c), (7)(c) and (9)(c)**

After “section 18A”, insert “or 32CB”.

## **29 Paragraphs 35A(1)(c) and (2)(c)**

After “section 18A”, insert “or 32CB”.

### **Note 3**

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#### **30 At the end of section 39**

Add:

(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;

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).

#### **31 Paragraph 40(4)(a)**

Repeal the paragraph, substitute:

(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:

- (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

#### **32 After paragraph 41(1)(g)**

Insert:

- (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

#### **33 After section 41BJ**

Insert:

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**41BJA Application of this Chapter to a biological**

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

*Biologicals currently included in the Register*

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

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

*Pending applications*

- (3) If:
- (a) before the commencement of this section, an application was made under this Chapter for the inclusion in the Register of therapeutic goods that are a biological; and
  - (b) immediately before that commencement, the application was not finally determined; and
  - (c) the application had not been withdrawn before that commencement;
- this Chapter continues to apply to the biological on and after that commencement until the earliest of the following:
- (d) the time the biological is included in the Register under Part 3-2A;
  - (e) if the application is unsuccessful when it is finally determined—the time the application is finally determined;
  - (f) the time the application is withdrawn;
  - (g) the time the application lapses.

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

- (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.

### **Note 3**

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#### *Transitional*

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

#### **34 After paragraph 42DL(1)(f)**

Insert:

- (fa) that contains a statement referring to a biological, other than a statement authorised or required by a government or government authority (including a foreign government or foreign government authority); or

#### **35 Subsection 42V(7)**

Omit “section 30”, substitute “section 29D or 30, Division 6 or 7 of Part 3-2A”.

#### **36 After subparagraph 46A(4)(a)(ii)**

Insert:

- (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) or (2); or

#### **37 After paragraph 53(b)**

Insert:

- (ba) inclusion of a biological in the Register; or

#### **38 Section 53A (after table item 13)**

Insert:

**Note 3**


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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)
13F	subsection 32CN(1)	subsection 32CN(4)
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)

**39 After paragraph 56A(1)(a)**

Insert:

- (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

**40 After paragraph 56A(1)(b)**

Insert:

- (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

**41 After paragraph 56A(1)(c)**

Insert:

- (ca) there was no approval under subsection 32CO(1) or (2) granted to a particular person in relation to a particular biological; or

**42 After paragraph 56A(1)(e)**

Insert:

- (eaa) a particular biological was or was not included in the Register; or

### **Note 3**

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#### **43 Subsections 57(2) and (3)**

After “paragraph 19(1)(a)”, insert “, 32CK(1)(d)”.

#### **44 Paragraph 57(5)(b)**

After “paragraph 19(1)(a)”, insert “, 32CK(1)(d)”.

#### **45 Subsections 57(6) and (7)**

After “subsection 19(5)”, insert “, 32CM(1)”.

#### **46 Subsection 57(8)**

After “section 19A”, insert “or 32CO”.

#### **47 After subsection 57(10)**

Insert:

(10A) The power of the Minister under subsection 32CB(1) may be delegated only to the Secretary.

#### **48 Subsection 59(3)**

Repeal the subsection.

#### **49 Subsection 60(1) (after paragraph (c) of the definition of *initial decision*)**

Insert:

(ca) under Part 3-2A (Biologicals); or

#### **50 Subsection 60A(1)**

After “section 25”, insert “, 32DF, 32DG”.

#### **51 After subsection 60A(6)**

Insert:

(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.

**52 Subsection 60A(7)**

After “Part 3-2”, insert “, 3-2A”.

**53 Subsection 60A(8) (after paragraph (a) of the definition of *authorised delegate*)**

Insert:

(aa) exercising a power to decide whether to include a biological in the Register; or

**54 Subsection 61(3A)**

After “31B,”, insert “32JE, 32JF, 32JG, 32JH,”.

**55 After paragraph 61(4)(b)**

Insert:

(baa) decisions on the inclusion of biologicals in the Register, or the suspension or cancellation of the inclusion of biologicals in the Register; or

**56 Subsection 61(10)**

After “subsection 25(2E)”, insert “(including as that subsection applies because of subsection 32DE(2) or 32EB(3))”.

**57 After paragraph 63(2)(da)**

Insert:

(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

As at 12 January 2011 the amendments are not incorporated in this compilation.

## **Note 4**

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### **Note 4**

*Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010*  
(No. 141, 2010)

The following amendments commence immediately after the commencement of Schedule 1 to the *Therapeutic Goods Amendment (2009 Measures No. 3) Act 2010*:

### **Schedule 2**

#### **22 Before subsection 9D(3A)**

Insert:

(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.

#### **23 After paragraph 9D(3A)(a)**

Insert:

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

As at 12 January 2011 the amendments are not incorporated in this compilation.



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**Table A**

**Table A**

**Application, saving or transitional provisions**

*Therapeutic Goods Amendment Act (No. 2) 2000* (No. 56, 2000)

**Schedule 1**

**5 Application**

The amendment of section 30 of the *Therapeutic Goods Act 1989* by this Schedule applies to directions given, and requirements made, of persons after the commencement of the amendment.

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*Therapeutic Goods Amendment Act (No. 3) 2000* (No. 120, 2000)

**Schedule 1**

**4 Saving**

- (1) Regulations in force for the purposes of subsection 18(1) of the *Therapeutic Goods Act 1989* immediately before the commencement of the amendment of that subsection made by this Schedule have effect, after that commencement, as if they had been made for the purposes of that subsection after that commencement.
- (2) Subitem (1) does not prevent the amendment or repeal of the regulations.

**6 Application**

Conditions specified in regulations made for the purposes of subsection 19(1A) of the *Therapeutic Goods Act 1989* apply to an approval for the purpose mentioned in paragraph 19(1)(b) of that Act granted before or after the commencement of subsection 19(1A).

**8 Application**

Conditions specified in regulations made for the purposes of subsection 19(4A) of the *Therapeutic Goods Act 1989* apply to an approval for the purpose mentioned in paragraph 19(1)(b) of that Act granted before or after the commencement of subsection 19(4A).

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**Table A**

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**10 Application**

Subsection 19(5B) of the *Therapeutic Goods Act 1989* applies to an authority given under subsection 19(5) of that Act before or after the commencement of subsection 19(5B).

**17 Application**

- (1) Subsections 31B(1) and (2) of the *Therapeutic Goods Act 1989* apply to an approval granted under subsection 19(1) of that Act before or after the commencement of section 31B of that Act.
- (2) Subsection 31B(3) of the *Therapeutic Goods Act 1989* applies to an authority given under subsection 19(5) of that Act before or after the commencement of section 31B of that Act.

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*Therapeutic Goods Amendment Act 2001* (No. 14, 2001)

**Schedule 1**

**36 Application of amendments**

- (1) The amendments made by this Schedule do not apply, and the *Therapeutic Goods Act 1989* as in force immediately before the commencement of this Schedule continues to apply, in relation to any application made under that Act, before that commencement, for listing of therapeutic goods.
  - (2) However, the amendment made by item 5 of this Schedule applies, after that commencement, to therapeutic goods that were listed before that commencement.
  - (3) The amendment made by item 31 of this Schedule applies, after that commencement, to medicines listed under section 26A before that commencement.
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**Table A**

*Australia New Zealand Food Authority Amendment Act 2001* (No. 81, 2001)

2(6) In this section:

*Australia New Zealand Joint Food Standards Agreement* means the Agreement between the Government of Australia and the Government of New Zealand Establishing a System for the Development of Joint Food Standards, signed at Wellington on 5 December 1995.

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*Health and Aged Care Legislation Amendment (Application of Criminal Code) Act 2001* (No. 111, 2001)

#### **4 Application of amendments**

- (1) Each amendment made by this Act applies to acts and omissions that take place after the amendment commences.
- (2) For the purposes of this section, if an act or omission is alleged to have taken place between 2 dates, one before and one on or after the day on which a particular amendment commences, the act or omission is alleged to have taken place before the amendment commences.

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*Therapeutic Goods Amendment (Medical Devices) Act 2002* (No. 24, 2002)

#### **Schedule 1**

#### **38 Transitional for publication of list of goods on Register**

The first list published under section 9E of the *Therapeutic Goods Act 1989* after the commencement of this Schedule must be published within 12 months after the last list published under section 33 of the *Therapeutic Goods Act 1989*.

**Table A**

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**46 Saving of existing registrations and listings**

- (1) Despite the repeal of section 17 of the *Therapeutic Goods Act 1989* by item 45, any therapeutic goods that, immediately before the commencement of this Schedule, were included in the Register are taken to be included in the Register after that commencement.
- (2) Despite the repeal of subsection 17(5) of the *Therapeutic Goods Act 1989*, any notices that were in force immediately before the commencement of this Schedule, are taken to have been made under section 9A after that commencement.

**55 Saving of existing requests for inspection or variation of the Register**

- (1) A request for a copy of an entry in the Register under section 32 of the *Therapeutic Goods Act 1989*:
  - (a) that was made before the commencement of this Schedule; and
  - (b) that was not dealt with before that commencement;is taken, after that commencement, to be a request made under section 9C of the *Therapeutic Goods Act 1989* as in force after that commencement.
- (2) A request for a variation of an entry in the Register under section 32 of the *Therapeutic Goods Act 1989*:
  - (a) that was made before the commencement of this Schedule; and
  - (b) that was not dealt with before that commencement;is taken, after that commencement, to be a request made under section 9D of the *Therapeutic Goods Act 1989* as in force after that commencement.

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*Therapeutic Goods and Other Legislation Amendment Act 2002* (No. 56, 2002)

**Schedule 3**

**20 Application**

- (1) The amendment made by item 12 applies in relation to applications made on or after the commencement of that item.
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**Table A**

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- (2) The amendment made by item 18 applies in relation to applications for licences made on or after the commencement of that item.
  - (3) Paragraph 40(4)(a) of the *Therapeutic Goods Act 1989* as amended by this Schedule applies in relation to a request made under that paragraph on or after the commencement of this item, even if the licence to which the request relates was granted before that commencement.

**21 Transitional**

- (1) An approval of a body as an approved conformity assessment body that was in force under the *Therapeutic Goods Act 1989* immediately before the commencement time has effect after the commencement time as if it were an approval of the body by the Secretary in writing for the purposes of the definition of *EC/EFTA attestation of conformity* in subsection 3(1) of the *Therapeutic Goods Act 1989* as in force after the commencement time.
- (2) In subitem (1):  
*commencement time* means the time at which this item commences.

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*Therapeutic Goods Amendment Act (No. 1) 2003* (No. 39, 2003)

**Schedule 1****41 Saving provisions**

- (1) The repeal of subsections 30(6) and (7) of the *Therapeutic Goods Act 1989* does not affect the application, after the commencement of this item, of paragraph 30(6)(b) and subsection 30(7) of that Act in relation to a requirement imposed under paragraph 30(6)(a) of that Act before that commencement.
  - (2) The repeal of section 30A of the *Therapeutic Goods Act 1989* does not affect the application, after the commencement of this item, of subsections 30A(3) and (4) of that Act in relation to a requirement imposed under subsection 30A(2) of that Act before that commencement.
  - (3) The repeal of section 30B of the *Therapeutic Goods Act 1989* does not affect the application, after the commencement of this item, of subsections 30B(3), (4) and (5) of that Act in relation to a requirement
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**Table A**

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imposed under subsection 30B(2) of that Act before that commencement.

**55 Saving provision**

The repeal and substitution of subsection 40(1) of the *Therapeutic Goods Act 1989* does not affect the application, after the commencement of this item, of any condition that:

- (a) was imposed on a licence under that subsection; and
- (b) was in force immediately before that commencement.

**60 Application provision**

Subsection 40(4) of the *Therapeutic Goods Act 1989* as amended by this Act, and subsection 40(5) of that Act, apply to any licence in force after the commencement of this item, whether or not the licence was granted after that commencement.

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*US Free Trade Agreement Implementation Act 2004* (No. 120, 2004)

**Schedule 7**

**7 Application of amendments**

- (1) The amendments made by this Schedule apply to applications for registration or listing under section 23 of the *Therapeutic Goods Act 1989* made on or after the day on which this Schedule commences.
- (2) The amendments made by item 6 apply to legal proceedings commenced on or after the day on which this Schedule commences.

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*Financial Framework Legislation Amendment Act 2005* (No. 8, 2005)

**4 Saving of matters in Part 2 of Schedule 1**

- (1) If:
  - (a) a decision or action is taken or another thing is made, given or done; and
  - (b) the thing is taken, made, given or done under a provision of a Part 2 Act that had effect immediately before the commencement of this Act;

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**Table A**

then the thing has the corresponding effect, for the purposes of the Part 2 Act as amended by this Act, as if it had been taken, made, given or done under the Part 2 Act as so amended.

(2) In this section:

**Part 2 Act** means an Act that is amended by an item in Part 2 of Schedule 1.

**Schedule 1**

**496 Saving provision—Finance Minister’s determinations**

If a determination under subsection 20(1) of the *Financial Management and Accountability Act 1997* is in force immediately before the commencement of this item, the determination continues in force as if it were made under subsection 20(1) of that Act as amended by this Act.

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*Therapeutic Goods Amendment Act (No. 2) 2006* (No. 2, 2006)

**Schedule 1**

**15 Application**

The amendments made by this Schedule apply to applications for registration or listing of therapeutic goods that are made on or after the day on which this Schedule commences.

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*Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Act 2006* (No. 5, 2006)

**3 Purpose**

The purpose of this Act is to remove the responsibility for approval of RU486 from the Minister and to provide responsibility for approval of RU486 to the Therapeutic Goods Administration.

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**Table A**

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*Therapeutic Goods Legislation Amendment (Annual Charges) Act 2008*  
(No. 96, 2008)

**Schedule 1**

**3 Application**

- (1) The amendment made by item 1 applies in relation to the financial year beginning on 1 July 2009 and all later financial years (regardless of whether the registration, listing or inclusion in the Register of the therapeutic goods, or whether the licence, commenced before, on or after 1 July 2009).
- (2) The amendment made by item 2 applies for the purposes of working out whether a person is exempt from liability to pay annual registration charge, annual listing charge or annual charge for inclusion in the Register for the financial year beginning on 1 July 2009 and all later financial years.

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*Therapeutic Goods Amendment (Medical Devices and Other Measures) Act 2009* (No. 38, 2009)

**Schedule 2**

**4 Application**

- (1) The amendment made by item 1 applies in relation to an exemption made on or after the commencement of that item.
- (2) The amendment made by item 2 applies in relation to a revocation or variation made on or after the commencement of that item (whether the exemption was made before, on or after that commencement).

**Schedule 3**

**23 Application and transitional**

- (1) The amendments of section 38 of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to applications for licences made on or after the commencement of this item.



**Table A**

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- (2) The amendments of sections 40 and 41 of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to licences granted before, on or after the commencement of this item.
  - (3) The amendments of section 41EC of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to applications for conformity assessment certificates made on or after the commencement of this item.
  - (4) The amendment of section 41EG of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to notices given on or after the commencement of this item.
  - (5) The amendment of section 41EJ of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to conformity assessment certificates issued before, on or after the commencement of this item.
  - (6) The amendments of section 41ET of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to conformity assessment certificates issued before, on or after the commencement of this item.
  - (7) Paragraph 41ET(1)(c) of the *Therapeutic Goods Act 1989*, as in force immediately before the commencement of this item, continues to apply on and after that commencement in relation to a notice given before that commencement.
  - (8) Subsection 41JA(1A) of the *Therapeutic Goods Act 1989* applies in relation to applications for conformity assessment certificates made on or after the commencement of this item.
  - (9) Subsection 41JA(1C) of the *Therapeutic Goods Act 1989* applies in relation to conformity assessment certificates issued before, on or after the commencement of this item.

## **Schedule 4**

### **20 Application and transitional**

- (1) If:
  - (a) immediately before the commencement of this item, therapeutic goods were registered goods or listed goods; and
  - (b) at a particular time within the period of 12 months beginning on the day on which this item commences:

**Table A**

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- (i) a standard referred to in paragraph (c) or (d) of the definition of *standard* in subsection 3(1) of the *Therapeutic Goods Act 1989* (as amended by this Act) would, apart from this subitem, apply to the goods; and
  - (ii) the goods do not conform with that standard;then that standard is taken not to apply to the goods at that time.
- (2) To avoid doubt, paragraph (a) of the definition of *standard* in subsection 3(1) of the *Therapeutic Goods Act 1989* (as amended by this Act) applies in relation to orders made under section 10 of the *Therapeutic Goods Act 1989* before, on or after the commencement of this item.
- (3) An order in force under paragraph 13(7)(c) of the *Therapeutic Goods Act 1989* immediately before the commencement of this item has effect, on and after that commencement, as if it were an order in force under subsection 13(5) of that Act.

**Schedule 5**

**3 Application**

The amendment made by item 2 applies in relation to information held by the Department on or after the commencement of this item (regardless of whether the information came into existence before, on or after that commencement).

**Schedule 6**

**12 Saving and transitional**

- (1) A notice in force under section 42DC of the *Therapeutic Goods Act 1989* immediately before the commencement of this item has effect, on and after that commencement, as if it were a notice given and in force under section 42DKB of that Act.
- (2) Regulations in force for the purposes of subsection 42DD(1) of the *Therapeutic Goods Act 1989* immediately before the commencement of this item continue in force on and after that commencement as if they were regulations in force for the purposes of section 42DD of that Act.

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**Table A***Therapeutic Goods Amendment (2009 Measures No. 1) Act 2009*  
(No. 76, 2009)**Schedule 1****7 Application**

The amendment made by item 2 applies in relation to therapeutic goods included in the Register before, on or after the commencement of that item.

**Schedule 2****25 Application and transitional—amendments made by this Schedule**

- (1) The amendments made by items 4 to 7 apply in relation to applications for licences made on or after the commencement of those items.
- (2) The amendments made by items 8 to 11 apply in relation to applications for licences:
  - (a) made on or after the commencement of those items; and
  - (b) made before the commencement of those items that have not been decided by the Secretary before that commencement.
- (3) In relation to an application covered by paragraph (2)(b) of this item, paragraph 38(1)(a) of the *Therapeutic Goods Act 1989* applies on and after the commencement of this item as if the application was in respect of the one or more manufacturing sites constituted by the manufacturing premises the subject of the application.
- (4) The amendments made by items 13 to 22 apply in relation to licences granted before, on or after the commencement of those items.

**26 Transitional—existing licences**

- (1) This item applies to a licence that:
  - (a) was in force under Part 3-3 of the *Therapeutic Goods Act 1989* immediately before the commencement of this item; or
  - (b) was suspended under that Part immediately before that commencement.

**Table A**

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- (2) The *Therapeutic Goods Act 1989* applies in relation to the licence on and after that commencement as if the licence covered the one or more manufacturing sites constituted by the manufacturing premises to which the licence related immediately before that commencement.
- (3) Subitem (2) is subject to section 38B of the *Therapeutic Goods Act 1989* (about splitting multi-site licences).
- (4) If section 38B of the *Therapeutic Goods Act 1989* does not apply in relation to the licence, that Act applies in relation to the licence on and after the commencement of this item as if:
  - (a) the licence authorised the holder of the licence, at the manufacturing site constituted by the manufacturing premises to which the licence related immediately before that commencement, to carry out the steps in the manufacture of therapeutic goods that the licence allowed the holder to carry out immediately before that commencement; and
  - (b) that authorisation were an authorisation referred to in subsection 38(2B) of that Act.
- (5) Subitem (4) does not prevent the variation of that authorisation under section 40A or 40B of the *Therapeutic Goods Act 1989*.

Note: A contravention of that authorisation may lead to the licence being revoked or suspended: see paragraph 41(1)(ea) of the *Therapeutic Goods Act 1989*.

**Schedule 3**

**16 Application**

- (1) The amendments made by items 1 to 9 apply in relation to the registration or listing of therapeutic goods before, on or after the commencement of those items.
- (2) The amendments made by items 10 and 11 apply in relation to conformity assessment certificates issued before, on or after the commencement of those items.
- (3) The amendments made by items 12 and 13 apply in relation to the inclusion of a kind of medical device in the Register before, on or after the commencement of those items.

**Schedule 5****5 Application**

The amendments made by items 1 and 2 apply in relation to applications for listings made on or after the commencement of those items.

**Schedule 6****14 Saving and transitional***Standards*

- (1) The amendment made by item 1 does not affect the validity of an order made under section 10 of the *Therapeutic Goods Act 1989* before the commencement of this item.
- (2) The repeal of section 11 of the *Therapeutic Goods Act 1989* by this Schedule does not apply to an order made under section 10 of that Act before the commencement of this item.

*Medical device standards*

- (3) The amendment made by item 8 does not affect the validity of an order made under section 41CB of the *Therapeutic Goods Act 1989* before the commencement of this item.
- (4) Subsection 41CB(2) of the *Therapeutic Goods Act 1989*, as in force immediately before the commencement of this item, continues to apply on and after that commencement in relation to an order made under section 41CB of that Act before that commencement.

*Conformity assessment standards*

- (5) The amendment made by item 11 does not affect the validity of an order made under section 41DC of the *Therapeutic Goods Act 1989* before the commencement of this item.
- (6) Subsection 41DC(3) of the *Therapeutic Goods Act 1989*, as in force immediately before the commencement of this item, continues to apply on and after that commencement in relation to an order made under section 41DC of that Act before that commencement.

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**Table A**

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**Schedule 7**

**26 Application—listings of medicines**

The amendments made by items 5 to 10 apply in relation to applications for listings of medicines made on or after the commencement of those items.

**27 Application—revocation of cancellation of registration or listing upon request**

The amendment made by item 14 applies in relation to cancellations occurring before, on or after the commencement of that item.

**28 Saving—device nomenclature codes**

Despite the amendment made by item 22, regulations in force for the purposes of subsection 41BE(3) of the *Therapeutic Goods Act 1989* immediately before the commencement of this item continue in force, after that commencement, until the first determination made under that subsection (as inserted by this Act) takes effect.

**56 Saving—Therapeutic Goods Advertising Code**

- (1) Despite the amendment made by item 29, the Therapeutic Goods Advertising Code as in force immediately before the commencement of this item continues in force, after that commencement, until the first instrument made under section 42BAA of the *Therapeutic Goods Act 1989*, as inserted by this Act, takes effect.
- (2) Despite the amendment made by item 52, regulations in force for the purposes of section 42DD of the *Therapeutic Goods Act 1989* immediately before the commencement of this item continue in force, after that commencement, until the first instrument made under section 42BAA of the *Therapeutic Goods Act 1989*, as inserted by this Act, takes effect.
- (3) Despite the amendment made by item 54, regulations in force for the purposes of paragraph 42DF(4)(c) of the *Therapeutic Goods Act 1989* immediately before the commencement of this item continue in force, after that commencement, until the first instrument made under section 42BAA of the *Therapeutic Goods Act 1989*, as inserted by this Act, takes effect.

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**Table A****57 Application and transitional—registration or listing conditions**

- (1) Subsection 28(1) of the *Therapeutic Goods Act 1989*, as inserted by this Act, applies in relation to the registration or listing of therapeutic goods occurring before, on or after the commencement of this item.
- (2) Subsection 28(2B) of the *Therapeutic Goods Act 1989*, as inserted by this Act, applies in relation to the registration or listing of therapeutic goods occurring on or after the commencement of this item.
- (3) Conditions in force under subsection 28(1) of the *Therapeutic Goods Act 1989* immediately before the commencement of this item continue in force, on and after that commencement, as if they had been imposed, on that commencement, under subsection 28(2B) of the *Therapeutic Goods Act 1989*.
- (4) Subitem (3) does not prevent the variation or removal of the conditions under subsection 28(3) of the *Therapeutic Goods Act 1989* on or after the commencement of this item.
- (5) The amendment made by item 31 applies in relation to:
  - (a) conditions imposed under subsection 28(2B) of the *Therapeutic Goods Act 1989* on or after the commencement of that item (including because of subitem (3)); and
  - (b) conditions imposed under subsection 28(3) of the *Therapeutic Goods Act 1989* before, on or after the commencement of that item.
- (6) The amendment made by item 34 applies in relation to the registration or listing of therapeutic goods occurring before, on or after the commencement of that item.
- (7) The amendment made by item 36 applies in relation to the listing of medicine occurring before, on or after the commencement of that item.
- (8) This item does not affect the conditions to which the registration or listing of therapeutic goods is subject before the commencement of this item.

**58 Application—information gathering**

- (1) The amendments made by items 38 and 40 apply in relation to periods beginning before, on or after the commencement of those items.

**Table A**

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- (2) The amendment made by item 41 applies in relation to things occurring before, on or after the commencement of that item.
- (3) Regulations in force for the purposes of subsection 41JA(2) of the *Therapeutic Goods Act 1989* immediately before the commencement of this item continue in force for the purposes of that subsection on and after that commencement.

**59 Application—advertisements**

The amendments made by items 44 to 50 apply in relation to advertisements published or broadcast on or after the commencement of those items.

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*Therapeutic Goods Amendment (2009 Measures No. 2) Act 2009*  
(No. 96, 2009)

**Schedule 1**

**13 Saving and transitional**

- (1) The amendment made by item 10 does not affect the validity of an instrument made under paragraph 52D(2)(a) or (b) of the *Therapeutic Goods Act 1989* before the commencement of that item.
- (2) If:
  - (a) on or after 1 January 2010 and before the commencement of this item, the Committee referred to in section 52B of the *Therapeutic Goods Act 1989* had proposed an amendment of the current Poisons Standard; and
  - (b) before that commencement, that Committee had not amended the current Poisons Standard as a result of that proposal;then the Secretary must have regard to that proposal in relation to making the first instrument under subsection 52D(2) of that Act on or after that commencement.
- (3) If:
  - (a) on or after 1 January 2010 and before the commencement of this item, an application was made to the Committee referred to in section 52B of the *Therapeutic Goods Act 1989* for an amendment of the current Poisons Standard; and



**Table A**

- (b) the application had not been refused by that Committee before that commencement; and
- (c) before that commencement, that Committee had not proposed an amendment of the current Poisons Standard as a result of the application;

then the application has effect on and after that commencement as if it were an application made to the Secretary in accordance with section 52EAA of that Act.

**Schedule 2****4 Application**

The amendments made by items 2 and 3 apply in relation to applications made after the day on which the first instrument made under section 41BEA of the *Therapeutic Goods Act 1989* takes effect.

Note: Section 12 of the *Legislative Instruments Act 2003* deals with when a legislative instrument takes effect.

**Schedule 3****7 Application and saving**

- (1) The amendments made by items 2 and 5 apply in relation to advertisements occurring on or after the commencement of those items.
- (2) The amendment made by item 3 applies in relation to applications made on or after the commencement of that item.
- (3) The amendment made by item 4 does not affect the validity of a request made under subsection 30D(1) of the *Therapeutic Goods Act 1989* before the commencement of that item.

**10 Application**

The amendment made by item 8 applies in relation to applications for the registration or listing of medicine made on or after the commencement of this Part.

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**Table A**

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*Therapeutic Goods Amendment (2009 Measures No. 3) Act 2010*  
(No. 54, 2010)

**Schedule 2**

**15 Application**

The amendment made by item 14 applies in relation to anything done or omitted to be done on or after the commencement of that item.

**16 Saving**

Despite the repeal of provisions of the *Therapeutic Goods Act 1989* made by items 1, 2, 4 to 8 and 10 to 13, those provisions (as in force immediately before the commencement of those items) continue to apply on and after that commencement in relation to anything done or omitted to be done before that commencement.

**Schedule 3**

**3 Application**

The amendments made by items 1 and 2 apply in relation to therapeutic goods, and kinds of medical devices, included in the Register before, on or after the commencement of those items.

**Schedule 4**

**6 Application**

- (1) The amendments made by items 1 to 5 apply in relation to notices given on or after the commencement of those items.
- (2) Paragraphs 31(1)(ac) and (2)(ac) of the *Therapeutic Goods Act 1989*, as inserted by this Act, apply in relation to the registration or listing of therapeutic goods occurring before, on or after the commencement of this item.

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**Table A****Schedule 5****2 Application**

The amendment made by item 1 applies in relation to an annual registration charge, an annual listing charge, an annual charge for inclusion in the Register or an annual licensing charge that becomes payable on or after the day on which that item commences.

**Schedule 6****20 Application**

- (1) The amendment made by item 3 applies in relation to requests made on or after the commencement of that item.
- (2) The amendments made by items 4 and 5 apply in relation to advertisements published or broadcast on or after the commencement of those items.
- (3) The amendments made by items 8 to 15 and 17 to 19 apply in relation to requests made to the Minister to reconsider decisions, where the requests are made on or after the commencement of those items (regardless of whether the decisions were made before, on or after that commencement).

The following provisions commence on 31 May 2011 unless proclaimed earlier:

**Schedule 1****58 Application—licences**

The amendment made by item 31 applies in relation to licences granted before, on or after the commencement of that item.

**59 Transitional—exempt biologicals**

- (1) This item applies in relation to a class of biologicals that, immediately before the commencement of this item, was covered by an exemption of the kind referred to in paragraph 18(1)(c) of the *Therapeutic Goods Act 1989*.
- (2) At the commencement of this item, there is taken to be an exemption (the *transitional exemption*) in force under subsection 32CA(2) of that Act covering that class of biologicals.

**Table A**

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- (3) Subject to this item, the transitional exemption ceases to be in force at the end of the period (the *transitional period*) of 3 years beginning on the day this item commences.
- (4) If:
- (a) before the end of the period of 18 months beginning on the day this item commences, a person makes an application in accordance with section 32DA or 32DD of that Act to include in the Register a biological included in that class; and
  - (b) before the end of the transitional period, the person has not been notified of the Secretary's decision on the application;
- the transitional exemption, in relation to that biological, continues in force past the end of the transitional period until the person is notified of the Secretary's decision on the application.
- (5) If:
- (a) before the end of the transitional period, a person makes an application in accordance with section 32DA or 32DD of that Act to include in the Register a biological included in that class; and
  - (b) before the end of that period, the person is notified of the Secretary's decision on the application;
- the transitional exemption, in relation to that biological, ceases to be in force immediately after that notification.

**60 Transitional regulations**

The Governor-General may make regulations prescribing matters of a transitional nature (including prescribing any saving or application provisions) relating to the amendments made by this Schedule.

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*Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010*  
(No. 141, 2010)

**Schedule 1A**

**10 Application**

- (1) Paragraph 23(2)(ba) and subparagraph 25(1)(da)(i) of the *Therapeutic Goods Act 1989*, as inserted by this Act, apply in relation to applications for registration of medicine that are made after the day on
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**Table A**

which the first instrument made under subsection 3(2A) or (2B) of that Act takes effect.

- (2) Subparagraph 25(1)(da)(ii) of the *Therapeutic Goods Act 1989*, as inserted by this Act, applies in relation to applications for registration of medicine that are made on or after the day on which the first instrument made under subsection 3(2A) or (2B) of that Act takes effect.
- (3) Subparagraph 25(4)(d)(ia) of the *Therapeutic Goods Act 1989*, as inserted by this Act, applies on and after the day on which the first instrument made under subsection 3(2A) or (2B) of that Act takes effect (whether the application for registration was made before, on or after that day).
- (4) Subsection 25AA(1) of the *Therapeutic Goods Act 1989*, as inserted by this Act, applies in relation to medicine included in the Register on or after the day on which the first instrument made under subsection 3(2A) or (2B) of that Act takes effect (where the notification (in relation to the medicine) referred to in subparagraph 25(4)(d)(ia) of that Act also occurred on or after that day).

Note: Section 12 of the *Legislative Instruments Act 2003* deals with when a legislative instrument takes effect.

**Schedule 2****7 Application**

- (1) The amendments made by items 1A to 1D apply in relation to requests made on or after the commencement of those items.
- (2) The amendment made by item 1E applies in relation to applications for registration made on or after the commencement of that item.
- (3) The amendments made by items 1 and 2 apply in relation to applications for listings made on or after the commencement of those items.
- (4) The amendment made by item 6A applies in relation to a notice given on or after the commencement of that item (whether the application or request was made before, on or after that commencement).

**Table A**

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**21 Application**

- (1) The amendments made by items 8 and 9 apply in relation to applications for listings made on or after the commencement of those items.
- (2) The amendments made by items 10 to 15 apply in relation to notices given on or after the commencement of those items.
- (2A) The amendment made by item 15A applies in relation to notices given on or after the commencement of that item.
- (3) The amendments made by items 16 and 17 apply in relation to applications made on or after the commencement of those items.
- (4) The amendments made by items 18 and 19 apply in relation to initial decisions made on or after the commencement of those items.