Therapeutic Goods Amendment Bill 2005

No. , 2005

(Health and Ageing)

A Bill for an Act to amend the Therapeutic Goods Act 1989, and for related purposes
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A Bill for an Act to amend the *Therapeutic Goods Act 1989*, and for related purposes

The Parliament of Australia enacts:

1 **Short title**

   This Act may be cited as the *Therapeutic Goods Amendment Act 2005*.

2 **Commencement**

   (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.

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<th>Provision(s)</th>
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<tr>
<td>1. Sections 1 to 3 and anything in this Act not elsewhere covered by this table</td>
<td>The day on which this Act receives the Royal Assent.</td>
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<td>2. Schedule 1, items 1 to 117</td>
<td>The 28th day after the day on which this Act receives the Royal Assent.</td>
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<td>3. Schedule 1, item 118</td>
<td>27 November 2003.</td>
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<td>4. Schedule 1, items 119 to 157</td>
<td>The 28th day after the day on which this Act receives the Royal Assent.</td>
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<td>4. Schedule 1, item 158</td>
<td>4 October 2007.</td>
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</table>

Note: This table relates only to the provisions of this Act as originally passed by the Parliament and assented to. It will not be expanded to deal with provisions inserted in this Act after assent.

(2) Column 3 of the table contains additional information that is not part of this Act. Information in this column may be added to or edited in any published version of this Act.

3 Schedule(s)

Each Act that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.
Schedule 1—Amendments

Therapeutic Goods Act 1989

1 Subsection 3(1)
Insert:

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

2 Subsection 3(1)
Insert:
oath includes affirmation.

3 Subsection 3(1)
Insert:
penalty unit, in relation to a civil penalty provision, has the meaning given by section 42YB.

4 Subsection 3(8)
After “maximum penalty”, insert “, other than a maximum civil penalty,“.

5 At the end of section 5
Add “or to be subject to civil proceedings for a contravention of a civil penalty provision”.

6 Section 5A
Repeal the section, substitute:

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.

7 Section 14
Repeal the section, substitute:

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.

Maximum 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
   (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.

Maximum 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.

Maximum 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.

Maximum 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.

Maximum 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.

Maximum 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
   (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.

Maximum 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.

Maximum 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).

Maximum 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
   (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 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.

8 Section 15
Schedule 1  Amendments

Repeal the section, substitute:

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.

Maximum 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.

Maximum 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.

Maximum penalty: 500 penalty units.

15A Civil penalty 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 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.

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

9 Subsection 18A(7) (note)
Omit “Note”, substitute “Note 1”.

10 At the end of subsection 18A(7)
Add:

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

11 Subsection 18A(12) (paragraph (a) of the note)
Omit “and 22”, substitute “, 22 and 22AA”.

12 Subsection 18A(12) (paragraph (b) of the note)
Omit “section 30F”, substitute “sections 30F and 30FA”.

13 Subsection 18A(12) (paragraph (f) of the note)
After “sections 35,”, insert “35A,”.

14 After section 19A
Insert:

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

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

(1) A person commits an offence if:
(a) the person:
(i) imports into Australia therapeutic goods for use in humans; or
(ii) exports from Australia therapeutic goods for use in humans; or
(iii) manufactures in Australia therapeutic goods for use in humans; or
(iv) supplies in Australia therapeutic goods for use in humans; and
(b) none of the following subparagraphs applies in relation to the goods:
   (i) the goods are registered goods or listed goods in relation to the person;
   (ii) the goods are exempt goods;
   (iii) the goods are exempt under section 18A;
   (iv) the goods are the subject of an approval or authority under section 19;
   (v) the goods are the subject of an approval under section 19A; and
(c) either:
   (i) the use of the goods has resulted in, 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.

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

Maximum penalty: 2,000 penalty units.

Note: A person may commit an offence against subsection 20(2A) or (2C), or may contravene section 22A (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.

Maximum 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

(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:
      (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.

15 Subsections 20(1), (1AA), (1A), (2) and (3)

Repeal the subsections.

Note: The heading to section 20 is replaced by the heading “Criminal offences relating to
notifying the Secretary and to importing goods exempt under section 18A”.

16 After section 20

Insert:

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
17 After section 21

Insert:

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.

Maximum 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.

Maximum 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.

Maximum 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.

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

Maximum 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.

Maximum 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).

Maximum 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).

Maximum 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
(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.

Maximum 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.

Maximum 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.

18 Subsections 22(2A), (3), (3A) and (4)

Repeal the subsections.

19 Subsection 22(7AB) (penalty)

Omit “300 penalty units”, substitute “2,000 penalty units”.

20 Subsection 22(7AB) (note 1)

Repeal the note, substitute:

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.

21 Subsection 22(7A) (penalty)

Repeal the penalty, substitute:

Maximum penalty: 500 penalty units.
22 Subsection 22(8) (penalty)

Repeal the penalty, substitute:

Maximum penalty: 500 penalty units.

23 After section 22

Insert:

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.

24 Section 22A

Repeal the section, substitute:

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 used of the goods, if the goods were used, would result in harm or injury to any person.

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

Maximum 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.

Maximum 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.

### 25 Subsection 29A(1) (penalty)

Repeal the penalty, substitute:

Maximum penalty: Imprisonment for 12 months or 1,000 penalty units, or both.
Note: The heading to section 29A is replaced by the heading “Criminal offence for failing to notify adverse effects etc. of goods”.

26 After section 29A

Insert:

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.

27 Paragraph 29B(1)(a)

After “subsection 29A(2)”, insert “ or 29AA(2)”.

28 Subsection 29B(3) (penalty)

Repeal the penalty, substitute:
Maximum penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

29 Subsection 29B(4) (penalty)
Repeal the penalty, substitute:

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

30 After section 29B
Insert:

29C Civil penalties for failing to notify adverse effects etc. where application withdrawn or lapses

Civil penalty for failing to comply with requirements of a notice

(1) A person contravenes this subsection if the person does not comply with the requirements of a notice under subsection 29B(1) within 30 days after the day on which the notice is given to the person.

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

Civil penalty for giving false or misleading information in purported compliance with requirements of a notice

(2) A person contravenes this subsection if the person, in purported compliance with a notice under subsection 29B(1), gives information that is false or misleading in a material particular.

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

31 Paragraph 30(2)(ca)
After “subsection 29A(1)”, insert “or 29AA(1)”.

32 Subsection 30EA(1) (table item 5)
Omit “20(1) or 42E(1)”, substitute “19B(1), (2) or (4), 19D(1), 42E(1) or 42EA(1)”.

33 Section 30EC

Repeal the section, substitute:

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.

   Maximum 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.

   Maximum 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.

   Maximum 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.

34 After subsection 30F(4)

Insert:

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
(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.

Maximum 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.

   Maximum 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.

Note: The heading to section 30F is altered by omitting “Goods” and substituting “Criminal
offences for goods”.

35 Subsection 30F(5) (penalty)

Repeal the penalty, substitute:

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

36 After section 30F

Insert:

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.
37 Subsection 31(4) (penalty)

Repeal the penalty, substitute:

Maximum penalty: 500 penalty units.

38 After subsection 31(5)

Insert:

(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.

Maximum 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.

Maximum 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.
39 Subsection 31(6)

Repeal the penalty, substitute:

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

40 After section 31

Insert:

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.

41 At the end of section 31A

Add:

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.

42 At the end of section 31AA

Add:
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.

43 At the end of section 31B

Add:

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.

44 Section 31C

Repeal the section, substitute:

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.

Maximum 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).

45 Paragraph 31D(1)(a)

Omit “subsection 31C(1)”, substitute “the notice”.

46 Subsection 31D(1) (penalty)
Repeal the penalty, substitute:

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

47 Paragraph 31E(1)(c)
Omit “subsection 31C(1)”, substitute “a notice given under section 31A, 31AA or 31B”.

48 Subsection 31E(1) (penalty)
Repeal the penalty, substitute:

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

49 Subsection 31F(1)
Omit “section 31C”, substitute “a notice given under section 31A, 31AA or 31B”.

50 Subsection 31F(2)
Omit all the words after paragraph (c), substitute:

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.

51 Section 35
Repeal the section, substitute:

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.

Maximum 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.

Maximum 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

(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.

Maximum 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.

Maximum 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) Strict liability applies to paragraph (5)(c).
(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.

Maximum 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.

Maximum 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;
   (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.
Maximum 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.

Maximum 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.

Maximum 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, that 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.

52 After paragraph 38(1A)(b)

Insert:
(ba) an order requiring any of the following persons to pay a pecuniary penalty for the contravention of a civil penalty provision:
   (i) the applicant or person;
   (ii) another person who controls the applicant or person (whether directly, or indirectly through one or more interposed entities);
   (iii) another person whom the applicant or person controlled (whether directly, or indirectly through one or more interposed entities) at the time civil penalty provision was contravened or at the time of the order; or

53 Paragraphs 41(1)(aa), (ab) and (ac)

Repeal the paragraphs, substitute:

(aa) the holder has been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision; or

(ab) the holder controls another person (whether directly, or indirectly through one or more interposed entities) and that other person:
   (i) has been convicted of an offence against this Act or a law of a State or Territory relating to therapeutic goods; or
   (ii) has been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision; or

(ac) the holder controlled another person (whether directly, or indirectly through one or more interposed entities) when that other person:
   (i) committed an offence against this Act or a law of a State or Territory relating to therapeutic goods, being an offence for which the person was convicted; or
   (ii) contravened a civil penalty provision, being a contravention for which the person was ordered to pay a pecuniary penalty; or

(ad) the holder is controlled by another person (whether directly, or indirectly through one or more interposed entities) when that other person:
   (i) has been convicted of an offence against this Act or a law of a State or Territory relating to therapeutic goods; or
54 Subsection 41(1A)
   After “(b)”, insert “, (ba)”.

55 At the end of paragraph 41B(c)
   Add “and civil penalty provisions”.

56 Section 41BC
   After “contains offences”, insert “and civil penalty provisions”.

57 Section 41BC (note)
   After “some offences”, insert “and civil penalty provisions”.

58 Section 41C (note)
   After “offence”, insert “or may contravene a civil penalty provision”.

59 Section 41D (note 1)
   After “offence”, insert “or may contravene a civil penalty provision”.

60 Subsection 41EB(2) (note)
   Repeal the note, substitute:
   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.

61 After paragraph 41EC(4)(b)
   Insert:
   (ba) an order requiring any of the following persons to pay a pecuniary penalty for the contravention of a civil penalty provision:
   (i) the applicant or person;
   (ii) another person who controls the applicant or person (whether directly, or indirectly through one or more interposed entities);
   (iii) another person whom the applicant or person controlled (whether directly, or indirectly through one or more
interposed entities) at the time civil penalty provision was contravened or at the time of the order; or

62 Section 41EI

Repeal the section, substitute:

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.

Maximum 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.

Maximum 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.

Maximum 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.

### 63 Division 2 of Part 4-4 (note under the heading to the Division)

Repeal the note, substitute:

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)).

### 64 Subsection 41ET(1A)

After “(b)”, insert “, (ba)”.

### 65 Section 41FA (note 2)

After “offence”, insert “or may contravene a civil penalty provision”.

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66 Subsection 41FC(2) (note)

Repeal the note, substitute:

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.

67 Section 41FE

Repeal the section, substitute:

41FE Criminal offences for making a false statement

1 (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.

2 Maximum 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 (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.

Maximum 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.

Maximum 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:
68 Division 2 of Part 4-5 (note under the heading to the Division)

   Repeal the note, substitute:

   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)).

69 Paragraph 41FN(3)(d)

   After “subsection 41MP(2)”, insert “or 41MPA(2)”.

70 Section 41GI (note)

   After “offence”, insert “or may contravene a civil penalty provision”.

71 Paragraph 41GN(1)(d)

   After “subsection 41MP(1)”, insert “or 41MPA(1)”.

72 Subsection 41HA(1) (note)

   After “offences”, insert “and civil penalty provisions”.

73 Subsection 41HA(2) (note)

   Omit “subsection 41MN(3)”, substitute “subsection 41MN(9)”.

74 Subsections 41HB(2) and (7) (note)

   Omit “subsection 41MN(3)”, substitute “subsection 41MN(9)”.

75 Section 41J (note)

   Omit “sections 41MP and 41MQ”, substitute “sections 41MP, 41MPA, 41MQ and 41MR”.

76 Subsections 41JB(3) and (4)

   Repeal the subsections, substitute:

   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.

Maximum 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.

Maximum 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.
Maximum 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.

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

77 After section 41JB

Insert:

41JBA Civil penalty for giving false or misleading information in purported compliance with a notice

A person contravenes this section if:
(a) the person is given a notice under section 41JA; and
(b) the person gives information in purported compliance with the notice; and
(c) the information is false or misleading in a material particular.

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

78 Subsection 41JC(2)

Omit all the words after paragraph (c), substitute:

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.
79 At the end of section 41JD

Add:

(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.

80 At the end of section 41JE

Add:

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.

81 At the end of section 41JF

Add:

(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.

82 Section 41JG

Repeal the section, substitute:

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 41JD, 41JE or 41JF; and
   (b) the person fails to comply with the notice.

Maximum 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 41JD, 41JE and 41JF.

83 Paragraph 41JH(c)

Omit “subsection 41JG(1)”, substitute “the notice”.

84 Section 41JH (penalty)

Repeal the penalty, substitute:

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

85 Paragraph 41JI(1)(c)

Omit “subsection 41JG(1)”, substitute “a notice given under section 41JD, 41JE or 41JF”.

86 Subsection 41JI(1) (penalty)

Repeal the penalty, substitute:

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

87 Subsection 41JJ(1)

Omit “section 41JG”, substitute “a notice given under section 41JD, 41JE or 41JF”.

88 Subsection 41JJ(2)

Omit all the words after paragraph (c), substitute:

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.

89 Section 41KC

Repeal the section, substitute:
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.

   Maximum 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.

   Maximum 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 41KA.

   Maximum 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.

90 Part 4-11 (heading)
Repeal the heading, substitute:

Part 4-11—Offences and civil penalty provisions
relating to medical devices

91 Section 41M
After “contains offences”, insert “and civil penalty provisions”.

92 Section 41M (note)
After “some offences”, insert “and civil penalty provisions”.

93 Section 41MA
Repeal the section, substitute:

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
(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.

Maximum 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
   
   (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.

Maximum 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.

Maximum 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
(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.

Maximum 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 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 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.

Maximum 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.

Maximum 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
   (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.

Maximum 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
   (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.

Maximum 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.

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

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.

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.

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.

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

94 Subsection 41MB(1)
Omit “Section 41MA does”, substitute “Sections 41MA and 41MAA do”.

95 Subsection 41MB(2) (note)
Repeal the note, substitute:
   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.

96 Section 41MC
Repeal the section, substitute:

41MC Criminal offences relating to breaching a condition of a consent
(1) The consent of the Secretary under section 41MA or 41MAA may be given:
   (a) unconditionally or subject to conditions; or
   (b) in respect of particular medical devices or kinds of medical devices.
(2) A person commits an offence if:
   (a) the person does an act or omits to do an act; and
   (b) the act or omission breaches a condition of a consent; and
(c) the act or omission has resulted, or will result in, harm or injury to any person.

Maximum 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.

Maximum 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.

Maximum penalty: 500 penalty units.

41MCA Civil penalty relating to breaching a condition of a consent

(1) The consent of the Secretary under section 41MA or 41MAA may be given:
(a) unconditionally or subject to conditions; or
(b) in respect of particular medical devices or kinds of medical devices.

(2) A person 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.

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

97 Paragraph 41MD(a)
Repeal the paragraph, substitute:
(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

98 Section 41ME
Repeal the section, substitute:

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
(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.

Maximum 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
(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.

Maximum 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.

Maximum 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
   (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.

Maximum 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 manufactures a medical device; and
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(b) the person exports the device from Australia; and

c) the conformity assessment procedures have not been applied
to the device; 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.

Maximum 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.

Maximum 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.

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.

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

99 Section 41MF

Repeal the section, substitute:

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
(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.

Maximum 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 (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.
Maximum 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

(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.

Maximum 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.

Maximum 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.

**100 Subsection 41MG(1)**

After “41ME”, insert “, 41MEA”.
101 Subsection 41MG(2) (note)
Repeal the note, substitute:

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.

102 At the end of Division 2 of Part 4-11
Add:

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.

Note: The heading to section 41MH is replaced by the heading “Criminal offence for making false statements in declarations”.

103 Section 41MI
Repeal the section, substitute:

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;

(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; 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.

Maximum 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

(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;

(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; and

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

Maximum 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;
   (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.

Maximum 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;

   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 paragraphs apply in relation to the device:
   (i) the device is of a kind included in the Register in relation to the person;
   (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.

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.

104 Paragraph 41MJ(a)

   Repeal the paragraph, substitute:
      (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

105 Subsections 41ML(1) and (2)

   Repeal the subsections.

   Note: The heading to section 41ML is replaced by the heading "False advertising about medical devices".

106 After section 41ML

   Insert:
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.

107  Section 41MN

Repeal the section, substitute:

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.

Maximum 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.

Maximum 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.

Maximum 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.

Maximum 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.

   Maximum 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) 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 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).

   Maximum 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.

108 Division 4 of Part 4-11 (heading)

Repeal the heading, substitute:

Division 4—Other offences and civil penalty provisions

109 Section 41MO

Repeal the section, substitute:

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).

Maximum 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).
Maximum 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).

Maximum 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

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

Maximum 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.

Maximum 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.

Maximum penalty: 500 penalty units.

110 Subsection 41MP(1) (penalty)
Repeal the penalty, substitute:

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

Note: The heading to section 41MP is replaced by the heading “Criminal offence for failing
to notify adverse events etc.”.

111 Subparagraphs 41MP(2)(a)(i) and (ii)
Omit “a kind”, substitute “the kind”.

112 After section 41MP
Insert:

41MPA Civil penalty for failing to notify adverse events etc.

   (1) A person contravenes this section if:

________________________________________________________________________
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.

113 Paragraph 41MQ(1)(a)

After “subsection 41MP(2)”, insert “or 41MPA(2)”.

114 Subsection 41MQ(3) (penalty)

Repeal the penalty, substitute:

Maximum penalty: Imprisonment for 12 months or 1,000 penalty units, or both.
Schedule 1 Amendments

115 Subsection 41MQ(4) (penalty)

Repeal the penalty, substitute:

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

116 At the end of Division 4 of Part 4-11

Add:

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.

117 At the end of subsections 42C(1) and (2)

Add:

Note: Advertising that requires approval under Part 2 of the Therapeutic Goods Regulations 1990 must also comply with the Therapeutic Goods Advertising Code.
118 Paragraph 42C(4)(a)
Omit all the words after “in specified media”, substitute:
   a particular advertisement in specified media referred to in
   paragraph (a), (c) or (d) of the definition of specified media;
   and

119 At the end of subsections 42C(4) and (6)
Add:
   Note: Advertising that requires approval under Part 2 of the Therapeutic
   Goods Regulations 1990 must also comply with the Therapeutic

120 At the end of subsection 42E(1)
Add:
   Maximum penalty: 7 years imprisonment or 2,000 penalty units,
   or both.

121 Subsection 42E(4)
Repeal the subsection.

122 After section 42E
Insert:

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(1)(a)(i)).

123 Subsection 42T(1) (penalty)

Repeal the penalty, substitute:
Maximum penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

124 Subsection 42T(2) (penalty)
Repeal the penalty, substitute:

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

125 Subsection 42V(6)
Repeal the subsection, substitute:

(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.

Maximum 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.

Maximum penalty: 2,000 penalty units.

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

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

126 After section 42V

Insert:

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
(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.

127 Subsection 42W(1) (penalty)
Repeal the penalty, substitute:

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

128 Subsection 42W(2) (penalty)
Repeal the penalty, substitute:

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

129 After Chapter 5
Insert:
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
(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 or believes 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.

Maximum 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 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) The penalty must not exceed an amount equal to one-fifth of the maximum penalty that could have been imposed on the person for 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.

130 Section 45A (definition of evidential material)

Repeal the definition, substitute:

**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.

131 Subsection 47(1)

After “evidential material”, insert “(within the meaning of paragraph (a) of the definition of that expression)”.

132 Paragraph 47(4)(a)

After “evidential material”, insert “(within the meaning of paragraph (a) of the definition of that expression)”.

133 After section 47

Insert:

47A Searches and seizures related to contraventions of 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 (within the meaning of paragraph (b) of the definition of that expression) 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.

(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 51AA.

(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 believes on reasonable grounds to be evidential material (within the meaning of paragraph (b) of the definition of that expression); 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 in contravening, continuing to contravene, or repeating a contravention of a civil penalty provision;

the warrant is taken to authorise the authorised person to seize that other thing.
134 **Subsection 48(1)**

Omit “and 47(1)(b)”, substitute “, 47(1)(b) and 47A(1)(b)”.

135 **At the end of subsection 48(1)**

Add:

; (i) to secure a thing, until a warrant is obtained to seize it, being a thing:

(i) that the authorised person finds during the exercise of monitoring powers under section 46 or 49 on the premises; and

(ii) that the authorised person believes on reasonable grounds is evidential material (within the meaning of paragraph (b) of the definition of that expression); and

(iii) that the authorised person believes on reasonable grounds would be lost, destroyed or tampered with before the warrant can be obtained.

136 **Section 48C**

After “evidential material” (wherever occurring), insert “(within the meaning of paragraph (a) of the definition of that expression).”

137 **At the end of paragraph 48E(2)(b)**

Add “or the contravention of a civil penalty provision”.

138 **Paragraphs 48J(2)(a) and (b)**

Repeal the paragraphs, substitute:

(a) if the thing was seized in accordance with section 47:

(i) for the purposes of an investigation as to whether an offence against this Act has been committed; or

(ii) to enable evidence of an offence against this Act to be secured for the purposes of a prosecution; or

(b) if the thing was seized in accordance with section 47A:

(i) for the purposes of an investigation as to whether a civil penalty provision has been contravened; or

(ii) to enable evidence of the contravention of a civil penalty provision to be secured for the purposes of civil proceedings;

139 **At the end of subsection 50(2)**
Add “(within the meaning of paragraph (a) of the definition of that expression)”.

140 After section 51

Insert:

51AA Civil penalty contravention 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 (within the meaning of paragraph (b) of the definition of that expression).

(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) 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 47A(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.

141 After section 53

Insert:
53A Alternative verdicts for various offences

If a jury acquits a person of an offence against a provision listed in column 2 of an item in the following table, but is satisfied beyond reasonable doubt of facts that prove that the person is guilty of the offence listed in column 3 of that item, the jury may convict the person of the offence listed in column 3 of that item:

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**Schedule 1  Amendments**

### Alternative verdicts for various offences

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**142 Subsections 54(1) and (3)**

Repeal the subsections, substitute:

(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.

Note: The heading to section 54 is replaced by the heading “**Offences and forfeiture**”.

**143 Section 54AB(1) (penalty)**

Repeal the penalty, substitute:

Maximum penalty: 7 years imprisonment or 2,000 penalty units,

or both.

Note: The heading to section 54AB is replaced by the heading “**Criminal offence for
damaging etc. documents**”.

**144 After section 54AB**
Insert:

**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.

145 After section 54A

Insert:

**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
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.

146 Subsections 55(1), (2), (3) and (4)
After “this Act,”, insert “or for a contravention of a civil penalty provision,”.

147 Paragraph 56A(1)(a)

After “section 18”, insert “or 18A”.

148 Subsection 56A(3)

After “this Act”, insert “or the contravention of a civil penalty provision”.

149 Subsection 56A(4)

Repeal the subsection, substitute:

(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.

150 Subsection 56A(5)

After “this Act”, insert “or the contravention of a civil penalty provision”.

151 Subsection 60(1) (paragraph (b) of the definition of initial decision)

After “section 14”, insert “or 14A”.

152 Subsection 60(1) (paragraph (k) of the definition of initial decision)

After “section 41MA”, insert “or 41MAA”.

153 Subsection 61(3A)

After “31A,”, insert “31AA,”.
154 **After paragraph 61(4A)(b)**

Insert:

or (ba) the head of an international organisation that has a function relating to therapeutic goods, health or law enforcement;

155 **At the end of subsection 61(4A)**

Add:

; (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.

156 **After subsection 61(4A)**

Insert:

(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.

157 **After subsection 61(5)**

Insert:

(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.

**Therapeutic Goods Amendment (Medical Devices) Act 2002**

158 **Item 12 of Schedule 2**

Repeal the item, substitute:
12 Paragraph 19D(3)(a) and (4)(a)

Omit “(other than listed goods that are therapeutic devices)”. 