

2004-2005

The Parliament of the
Commonwealth of Australia

HOUSE OF REPRESENTATIVES

Presented and read a first time

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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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OPC drafter to complete	
1. Does this Bill need a message? (See H of R Practice, fourth ed, pp403-408, and OGC advice.) If yes: <ul style="list-style-type: none"> • List relevant clauses/items— • Prepare message advice (see DD 5/2000, Attachment D) • Give a copy of the message advice to the Legislation area. 	No
2. Does this Bill need a notice? (See H of R Standing Order 291.) If no list relevant clauses/items—	Yes
3. Is there any reason why this Bill should not be introduced in the Senate? (See Constitution sections 53 and 55 and Drafting Direction 9/1994.)	No

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

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The Parliament of Australia enacts:

12

1 Short title

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

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2 Commencement

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(1) Each provision of this Act specified in column 1 of the table commences, or is taken to have commenced, in accordance with

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column 2 of the table. Any other statement in column 2 has effect according to its terms.

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

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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.

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3 Schedule(s)

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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.

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Schedule 1—Amendments

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Therapeutic Goods Act 1989

5

1 Subsection 3(1)

6 Insert:

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

8

2 Subsection 3(1)

9 Insert:

10 *oath* includes affirmation.

11

3 Subsection 3(1)

12 Insert:

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

15

4 Subsection 3(8)

16 After “maximum penalty”, insert “, other than a maximum civil
17 penalty,”.

18

5 At the end of section 5

19 Add “or to be subject to civil proceedings for a contravention of a civil
20 penalty provision”.

21

6 Section 5A

22 Repeal the section, substitute:

23

5A Application of the *Criminal Code*—extended geographical 24 jurisdiction

25 Section 15.2 of the *Criminal Code* (extended geographical
26 jurisdiction—category B) applies to offences against subsections
27 21A(1), (2) and (4) and sections 22A, 41FE, 42E and 42T.

28

7 Section 14

1 Repeal the section, substitute:

2 **14 Criminal offences for importing, supplying or exporting goods**
3 **that do not comply with standards**

4 *Offences relating to importing goods into Australia*

- 5 (1) A person commits an offence if:
6 (a) the person imports therapeutic goods into Australia; and
7 (b) the goods are imported without the consent in writing of the
8 Secretary; and
9 (c) the goods do not conform with a standard applicable to the
10 goods; and
11 (d) either:
12 (i) the use of the goods has resulted in, or will result in,
13 harm or injury to any person; or
14 (ii) the use of the goods, if the goods were used, would
15 result in harm or injury to any person; and
16 (e) the harm or injury has resulted, will result, or would result,
17 because the goods do not conform with the standard.

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

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

- 23 (2) A person commits an offence if:
24 (a) the person imports therapeutic goods into Australia; and
25 (b) the goods are imported without the consent in writing of the
26 Secretary; and
27 (c) the goods do not conform with a standard applicable to the
28 goods; and
29 (d) the use of the goods, if the goods were used, would be likely
30 to result in harm or injury to any person; and
31 (e) the harm or injury would be likely to result because the
32 goods do not conform with the standard.

33 Maximum penalty: 2,000 penalty units.

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

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

- 2 (4) A person commits an offence if:
3 (a) the person imports therapeutic goods into Australia; and
4 (b) the goods are imported without the consent in writing of the
5 Secretary; and
6 (c) the goods do not conform with a standard applicable to the
7 goods.

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

10 *Exception*

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

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

16 *Offences relating to supplying goods for use in Australia*

- 17 (6) A person commits an offence if:
18 (a) the person supplies therapeutic goods for use in Australia;
19 and
20 (b) the goods are supplied without the consent in writing of the
21 Secretary; and
22 (c) the goods do not conform with a standard applicable to the
23 goods; and
24 (d) either:
25 (i) the use of the goods has resulted in, or will result in,
26 harm or injury to any person; or
27 (ii) the use of the goods, if the goods were used, would
28 result in harm or injury to any person; and
29 (e) the harm or injury has resulted, will result, or would result,
30 because the goods do not conform with the standard.

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

33 Note: A jury may acquit a person of an offence against this subsection and
34 may convict the person of an offence against subsection (9) instead:
35 see section 53A.

- 1 (7) A person commits an offence if:
2 (a) the person supplies therapeutic goods for use in Australia;
3 and
4 (b) the goods are supplied without the consent in writing of the
5 Secretary; and
6 (c) the goods do not conform with a standard applicable to the
7 goods; and
8 (d) the use of the goods, if the goods were used, would be likely
9 to result in harm or injury to any person; and
10 (e) the harm or injury would be likely to result because the
11 goods do not conform with the standard.

12 Maximum penalty: 2,000 penalty units.

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

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

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

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

24 *Offences relating to exporting goods from Australia*

- 25 (10) A person commits an offence if:
26 (a) the person exports therapeutic goods from Australia; and
27 (b) the goods are exported without the consent in writing of the
28 Secretary; and
29 (c) the goods do not conform with a standard applicable to the
30 goods (other than a standard relating to the labelling of the
31 goods for supply in Australia); and
32 (d) either:
33 (i) the use of the goods has resulted in, or will result in,
34 harm or injury to any person; or

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

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

7 Note: A jury may acquit a person of an offence against this subsection and
8 may convict the person of an offence against subsection (13) instead:
9 see section 53A.

- 10 (11) A person commits an offence if:
11 (a) the person exports therapeutic goods from Australia; and
12 (b) the goods are exported without the consent in writing of the
13 Secretary; and
14 (c) the goods do not conform with a standard applicable to the
15 goods (other than a standard relating to the labelling of the
16 goods for supply in Australia); and
17 (d) the use of the goods, if the goods were used, would be likely
18 to result in harm or injury to any person; and
19 (e) the harm or injury would be likely to result because the
20 goods do not conform with the standard.

21 Maximum penalty: 2,000 penalty units.

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

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

- 24 (13) A person commits an offence if:
25 (a) the person exports therapeutic goods from Australia; and
26 (b) the goods are exported without the consent in writing of the
27 Secretary; and
28 (c) the goods do not conform with a standard applicable to the
29 goods (other than a standard relating to the labelling of the
30 goods for supply in Australia).

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

Civil penalty relating to exporting goods from Australia

- 1
- 2 (3) A person contravenes this subsection if:
- 3 (a) the person exports therapeutic goods from Australia; and
- 4 (b) the person does not have the consent in writing of the
- 5 Secretary; and
- 6 (c) the goods do not conform with a standard applicable to the
- 7 goods (other than a standard relating to the labelling of the
- 8 goods for supply in Australia).

9 **Maximum civil penalty:**

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

12 *Decisions on whether to give consent*

- 13 (4) The Secretary must, as soon as practicable after making a decision
- 14 to give a consent, cause particulars of the decision to be published
- 15 in the *Gazette*.
- 16 (5) The Secretary must, within 28 days after making a decision to
- 17 refuse to give a consent, notify the applicant in writing of the
- 18 decision and of the reasons for the decision.

19 **14B Application of *Customs Act 1901***

20 **Where:**

- 21 (a) the importation or exportation of goods is an offence under
- 22 subsection 14(1), (2), (4), (10), (11) or (13) or a
- 23 contravention of subsection 14A(1) or (3); and
- 24 (b) the Secretary notifies the Chief Executive Officer of Customs
- 25 in writing that the Secretary wishes the *Customs Act 1901* to
- 26 apply to that importation or exportation;
- 27 the *Customs Act 1901* has effect as if the goods included in that
- 28 importation or exportation were goods described as forfeited to the
- 29 Crown under section 229 of that Act because they were:
- 30 (c) prohibited imports within the meaning of that Act; or
- 31 (d) prohibited exports within the meaning of that Act;
- 32 as the case requires.

33 **8 Section 15**

1 Repeal the section, substitute:

2 **15 Criminal offences relating to breaching a condition of a consent**

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

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

7 (2) A person commits an offence if:

- 8 (a) the person does an act or omits to do an act; and
9 (b) the act or omission breaches a condition of a consent; and
10 (c) the act or omission has resulted in, or will result in, harm or
11 injury to any person.

12 Maximum penalty: 2,000 penalty units.

13 Note: A jury may acquit a person of an offence against this subsection and
14 may convict the person of an offence against subsection (5) instead:
15 see section 53A.

16 (3) A person commits an offence if:

- 17 (a) the person does an act or omits to do an act; and
18 (b) the act or omission breaches a condition of a consent; and
19 (c) the act or omission is likely to result in harm or injury to any
20 person.

21 Maximum penalty: 1,000 penalty units.

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

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

24 (5) A person commits an offence if:

- 25 (a) the person does an act or omits to do an act; and
26 (b) the act or omission breaches a condition of a consent.

27 Maximum penalty: 500 penalty units.

28 **15A Civil penalty relating to breaching a condition of a consent**

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

- 31 (a) unconditionally or subject to conditions; or
-

- 1 (b) in respect of particular goods or classes of goods.
- 2 (2) A person contravenes this section if:
- 3 (a) the person does an act or omits to do an act; and
- 4 (b) the act or omission breaches a condition of a consent.
- 5 Maximum civil penalty:
- 6 (a) for an individual—3,000 penalty units; and
- 7 (b) for a body corporate—30,000 penalty units.

8 **9 Subsection 18A(7) (note)**

9 Omit “Note”, substitute “Note 1”.

10 **10 At the end of subsection 18A(7)**

11 Add:

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

14 **11 Subsection 18A(12) (paragraph (a) of the note)**

15 Omit “and 22”, substitute “, 22 and 22AA”.

16 **12 Subsection 18A(12) (paragraph (b) of the note)**

17 Omit “section 30F”, substitute “sections 30F and 30FA”.

18 **13 Subsection 18A(12) (paragraph (f) of the note)**

19 After “sections 35,”, insert “35A,”.

20 **14 After section 19A**

21 Insert:

22 **19B Criminal offences relating to registration or listing etc. of**
23 **imported, exported, manufactured and supplied**
24 **therapeutic goods**

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

27 (1) A person commits an offence if:

28 (a) the person:

- 1 (i) imports into Australia therapeutic goods for use in
2 humans; or
3 (ii) exports from Australia therapeutic goods for use in
4 humans; or
5 (iii) manufactures in Australia therapeutic goods for use in
6 humans; or
7 (iv) supplies in Australia therapeutic goods for use in
8 humans; and
9 (b) none of the following subparagraphs applies in relation to the
10 goods:
11 (i) the goods are registered goods or listed goods in relation
12 to the person;
13 (ii) the goods are exempt goods;
14 (iii) the goods are exempt under section 18A;
15 (iv) the goods are the subject of an approval or authority
16 under section 19;
17 (v) the goods are the subject of an approval under
18 section 19A; and
19 (c) either:
20 (i) the use of the goods has resulted in, or will result in,
21 harm or injury to any person; or
22 (ii) the use of the goods, if the goods were used, would
23 result in harm or injury to any person.

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

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

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

33 (2) A person commits an offence if:

- 34 (a) the person:
35 (i) imports into Australia therapeutic goods for use in
36 humans; or
37 (ii) exports from Australia therapeutic goods for use in
38 humans; or

-
- 1 (iii) manufactures in Australia therapeutic goods for use in
2 humans; or
3 (iv) supplies in Australia therapeutic goods for use in
4 humans; and
5 (b) none of the following subparagraphs applies in relation to the
6 goods:
7 (i) the goods are registered goods or listed goods in relation
8 to the person;
9 (ii) the goods are exempt goods;
10 (iii) the goods are exempt under section 18A;
11 (iv) the goods are the subject of an approval or authority
12 under section 19;
13 (v) the goods are the subject of an approval under
14 section 19A; and
15 (c) the use of the goods, if the goods were used, would be likely
16 to result in harm or injury to any person.

17 Maximum penalty: 2,000 penalty units.

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

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

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

24 (4) A person commits an offence if:

- 25 (a) the person:
26 (i) imports into Australia therapeutic goods for use in
27 humans; or
28 (ii) exports from Australia therapeutic goods for use in
29 humans; or
30 (iii) manufactures in Australia therapeutic goods for use in
31 humans; or
32 (iv) supplies in Australia therapeutic goods for use in
33 humans; and
34 (b) none of the following subparagraphs applies in relation to the
35 goods:
36 (i) the goods are registered goods or listed goods in relation
37 to the person;
-

- 1 (ii) the goods are exempt goods;
- 2 (iii) the goods are exempt under section 18A;
- 3 (iv) the goods are the subject of an approval or authority
- 4 under section 19;
- 5 (v) the goods are the subject of an approval under
- 6 section 19A.

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

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

- 10 (5) It is a defence to a prosecution under subsection (1), (2) or (4) if
11 the defendant proves that the defendant was not the sponsor of the
12 goods at the time of the importation, exportation, manufacture or
13 supply, as the case may be.

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

16 *Exception*

- 17 (6) Subsection (1) does not apply if:
- 18 (a) harm or injury did not, or will not, directly result from:
 - 19 (i) the quality, safety or efficacy of the goods; or
 - 20 (ii) a matter relating to the labelling or packaging of the
 - 21 goods; or
 - 22 (iii) the improper use of the goods; or
 - 23 (b) harm or injury would not directly result from:
 - 24 (i) the quality, safety or efficacy of the goods; or
 - 25 (ii) a matter relating to the labelling or packaging of the
 - 26 goods; or
 - 27 (iii) the improper use of the goods.

28 Note: A defendant bears an evidential burden in relation to the matters in
29 subsection (6): see subsection 13.3(3) of the *Criminal Code*.

30 *Application of Customs Act 1901*

- 31 (7) Where:
- 32 (a) the importation or exportation of goods is an offence under
 - 33 subsection (1), (2) or (4); and

- 1 (b) the Secretary notifies the Chief Executive Officer of Customs
2 in writing that the Secretary wishes the *Customs Act 1901* to
3 apply to that importation or exportation;
4 the *Customs Act 1901* has effect as if the goods included in that
5 importation or exportation were goods described as forfeited to the
6 Crown under section 229 of that Act because they were:
7 (c) prohibited imports within the meaning of that Act; or
8 (d) prohibited exports within the meaning of that Act;
9 as the case requires.

10 **19C Notice required to adduce evidence in support of exception**
11 **under subsection 19B(6)**

- 12 (1) If:
13 (a) a defendant is committed for trial for an offence against
14 subsection 19B(1); or
15 (b) an offence against subsection 19B(1) is to be heard and
16 determined by a court of summary jurisdiction;
17 the committing magistrate or the court must:
18 (c) inform the defendant of the requirements of this section; and
19 (d) cause a copy of this section to be given to the defendant.
- 20 (2) A defendant must not, without leave of the court, adduce evidence
21 in support of the exception under subsection 19B(6) unless:
22 (a) if paragraph (1)(a) applies—more than 21 days before the
23 trial begins; or
24 (b) if paragraph (1)(b) applies—more than 21 days before the
25 hearing of the offence begins;
26 he or she gives notice of particulars of the exception.
- 27 (3) A defendant must not, without leave of the court, call any other
28 person to give evidence in support of the exception unless:
29 (a) the notice under subsection (2) includes the name and
30 address of the person or, if the name and address is not
31 known to the defendant at the time he or she gives the notice,
32 any information in his or her possession that might be of
33 material assistance in finding the person; and
34 (b) if the name or the address is not included in the notice—the
35 court is satisfied that the defendant before giving the notice

1 **19D Civil penalties relating to registration or listing etc. of imported,**
 2 **exported, manufactured and supplied therapeutic goods**

3 *Civil penalty relating to importing, exporting, manufacturing or*
 4 *supplying goods for use in humans*

- 5 (1) A person contravenes this subsection if:
- 6 (a) the person does any of the following:
- 7 (i) imports into Australia therapeutic goods for use in
 8 humans;
- 9 (ii) exports from Australia therapeutic goods for use in
 10 humans;
- 11 (iii) manufactures in Australia therapeutic goods for use in
 12 humans;
- 13 (iv) supplies in Australia therapeutic goods for use in
 14 humans; and
- 15 (b) none of the following subparagraphs applies in relation to the
 16 goods:
- 17 (i) the goods are registered goods or listed goods in relation
 18 to the person;
- 19 (ii) the goods are exempt goods;
- 20 (iii) the goods are exempt under section 18A;
- 21 (iv) the goods are the subject of an approval or authority
 22 under section 19;
- 23 (v) the goods are the subject of an approval under
 24 section 19A.

25 **Maximum civil penalty:**

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

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

32 *Exception if person was not the sponsor of the goods*

- 33 (2) Subsection (1) does not apply if the person proves that he or she
 34 was not the sponsor of the goods at the time of the importation,
 35 exportation, manufacture or supply, as the case may be.

1 *Civil penalty relating to the importing of registered or listed goods*

- 2 (3) A person contravenes this subsection if:
- 3 (a) therapeutic goods are registered or listed in relation to the
 - 4 person (other than listed goods that are therapeutic devices);
 - 5 and
 - 6 (b) the person imports the goods into Australia; and
 - 7 (c) the registration number or listing number of the goods is not
 - 8 set out on the label of the goods in the prescribed manner
 - 9 before the goods are supplied in Australia.

10 Maximum civil penalty:

- 11 (a) for an individual—200 penalty units; and
- 12 (b) for a body corporate—2,000 penalty units.

13 *Civil penalty relating to the supply of registered or listed goods*

- 14 (4) A person contravenes this subsection if:
- 15 (a) therapeutic goods are registered or listed in relation to the
 - 16 person (other than listed goods that are therapeutic devices);
 - 17 and
 - 18 (b) the person supplies the goods in Australia; and
 - 19 (c) the registration number or listing number of the goods is not
 - 20 set out on the label of the goods in the prescribed manner.

21 Maximum civil penalty:

- 22 (a) for an individual—200 penalty units; and
- 23 (b) for a body corporate—2,000 penalty units.

24 *Application of Customs Act 1901*

- 25 (5) Where:
- 26 (a) the importation or exportation of goods contravenes
 - 27 subsection (1); and
 - 28 (b) the Secretary notifies the Chief Executive Officer of Customs
 - 29 in writing that the Secretary wishes the *Customs Act 1901* to
 - 30 apply to that importation or exportation;
 - 31 the *Customs Act 1901* has effect as if the goods included in that
 - 32 importation or exportation were goods described as forfeited to the
 - 33 Crown under section 229 of that Act because they were:
 - 34 (c) prohibited imports within the meaning of that Act; or
-

1 (d) prohibited exports within the meaning of that Act;
2 as the case requires.

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

4 Repeal the subsections.

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

7 **16 After section 20**

8 Insert:

9 **20A Civil penalty relating to the importation, exportation,**
10 **manufacture or supply of sponsored goods without**
11 **proper notification**

- 12 (1) A person contravenes this section if:
- 13 (a) the person does any of the following:
- 14 (i) imports therapeutic goods into Australia;
- 15 (ii) exports therapeutic goods from Australia;
- 16 (iii) manufactures therapeutic goods in Australia;
- 17 (iv) supplies therapeutic goods in Australia; and
- 18 (b) the person is the sponsor of the goods for use in humans; and
- 19 (c) the person has not, at or before the time of the importation,
- 20 exportation, manufacture or supply, properly notified to the
- 21 Secretary either or both of the following:
- 22 (i) the manufacturer of the goods;
- 23 (ii) premises used in the manufacture of the goods.

24 Maximum civil penalty:

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

27 *Meaning of properly notified*

- 28 (2) For the purposes of paragraph (1)(c):
- 29 (a) a manufacturer is *properly notified* to the Secretary if:
- 30 (i) the manufacturer was nominated, as a manufacturer of
- 31 the goods, in an application for the registration or listing
- 32 of the goods; or

- 1 (ii) the Secretary was subsequently informed in writing that
2 the manufacturer is a manufacturer of the goods; and
3 (b) premises are *properly notified* to the Secretary if:
4 (i) the premises were nominated, as premises used in the
5 manufacture of the goods, in an application for the
6 registration or listing of the goods; or
7 (ii) the Secretary was subsequently informed in writing that
8 the premises are used in the manufacture of the goods.

9 **17 After section 21**

10 Insert:

11 **21A General criminal offences relating to this Part**

12 *Offences for making a false or misleading statement*

- 13 (1) A person commits an offence if:
14 (a) the person makes a statement; and
15 (b) the statement is made in or in connection with a certification
16 of any matter under subsection 26A(2); and
17 (c) the statement is false or misleading in a material particular;
18 and
19 (d) either:
20 (i) the use of the medicine has resulted in, or will result in,
21 harm or injury to any person; or
22 (ii) the use of the medicine, if the medicine were used,
23 would result in harm or injury to any person.

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

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

- 29 (2) A person commits an offence if:
30 (a) the person makes a statement; and
31 (b) the statement is made in or in connection with a certification
32 of any matter under subsection 26A(2); and
33 (c) the statement is false or misleading in a material particular;
34 and

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

3 Maximum penalty: 2,000 penalty units.

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

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

6 (4) A person commits an offence if:

- 7 (a) the person makes a statement; and
8 (b) the statement is made in or in connection with a certification
9 of any matter under subsection 26A(2); and
10 (c) the statement is false or misleading in a material particular.

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

13 *Offences relating to breaching a condition of registration or listing*
14 *of therapeutic goods*

15 (5) A person commits an offence if:

- 16 (a) therapeutic goods are registered or listed in relation to the
17 person; and
18 (b) the person does an act or omits to do an act; and
19 (c) the act or omission breaches a condition of the registration or
20 listing of the goods; and
21 (d) the act or omission has resulted in, or will result in, harm or
22 injury to any person.

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

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

28 (6) A person commits an offence if:

- 29 (a) therapeutic goods are registered or listed in relation to the
30 person; and
31 (b) the person does an act or omits to do an act; and
32 (c) the act or omission breaches a condition of the registration or
33 listing of the goods; and
-

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

3 Maximum penalty: 2,000 penalty units.

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

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

6 (8) A person commits an offence if:

- 7 (a) therapeutic goods are registered or listed in relation to the
8 person; and
9 (b) the person does an act or omits to do an act; and
10 (c) the act or omission breaches a condition of the registration or
11 listing of the goods.

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

14 *Offences relating to the supply of therapeutic goods in breach of*
15 *authority etc.*

16 (9) A person commits an offence if:

- 17 (a) the Secretary has authorised, under subsection 19(5), the
18 person to supply therapeutic goods; and
19 (b) the person supplies those goods; and
20 (c) any of the following applies:
21 (i) the supply is not in accordance with the authority; or
22 (ii) the supply is not in accordance with the conditions to
23 which the authority is subject; or
24 (iii) the supply is not in accordance with regulations made
25 for the purpose of subsection 19(7); and
26 (d) either:
27 (i) the use of the goods has resulted in, or will result in,
28 harm or injury to any person; or
29 (ii) the use of the goods, if the goods were used, would
30 result in harm or injury to any person; and
31 (e) the harm or injury has resulted, will result, or would result,
32 because:
33 (i) the supply is not in accordance with the authority; or
34 (ii) the supply is not in accordance with the conditions to
35 which the authority is subject; or
-

1 (iii) the supply is not in accordance with regulations made
2 for the purpose of subsection 19(7).

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

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

8 (10) A person commits an offence if:

- 9 (a) the Secretary has authorised, under subsection 19(5), the
10 person to supply therapeutic goods; and
11 (b) the person supplies those goods; and
12 (c) any of the following applies:
13 (i) the supply is not in accordance with the authority; or
14 (ii) the supply is not in accordance with the conditions to
15 which the authority is subject; or
16 (iii) the supply is not in accordance with regulations made
17 for the purpose of subsection 19(7); and
18 (d) the use of the goods, if goods were used, would be likely to
19 result in harm or injury to any person; and
20 (e) the harm or injury would be likely to result because:
21 (i) the supply is not in accordance with the authority; or
22 (ii) the supply is not in accordance with the conditions to
23 which the authority is subject; or
24 (iii) the supply is not in accordance with regulations made
25 for the purpose of subsection 19(7).

26 **Maximum penalty:** 2,000 penalty units.

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

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

29 *Offences relating to using therapeutic goods without approval etc.*

30 (12) A person commits an offence if:

- 31 (a) the person uses therapeutic goods; and
32 (b) the goods are used:
33 (i) in the treatment of another person; or
34 (ii) solely for experimental purposes in humans; and
35 (c) the goods are not:

- 1 (i) exempt goods; or
- 2 (ii) listed goods; or
- 3 (iii) registered goods; or
- 4 (iv) goods exempt under section 18A; or
- 5 (v) goods that are the subject of an approval under
- 6 section 19A; and
- 7 (d) the goods are not used in accordance with:
 - 8 (i) an approval or authority under section 19; or
 - 9 (ii) a condition applicable under regulations made for the
 - 10 purposes of subsection 19(4A); and
- 11 (e) either:
 - 12 (i) if the person used the goods in the treatment of another
 - 13 person—the use of the goods has resulted in, or will
 - 14 result in, harm or injury to that person; or
 - 15 (ii) if the person used the goods solely for experimental
 - 16 purposes in humans—the use of the goods has resulted
 - 17 in, or will result in, harm or injury to any of those
 - 18 persons.

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

21 Note: A jury may acquit a person of an offence against this subsection and
22 may convict the person of an offence against subsection 22(8) instead:
23 see section 53A.

- 24 (13) A person commits an offence if:
 - 25 (a) the person uses therapeutic goods; and
 - 26 (b) the goods are used:
 - 27 (i) in the treatment of another person; or
 - 28 (ii) solely for experimental purposes in humans; and
 - 29 (c) the goods are not:
 - 30 (i) exempt goods; or
 - 31 (ii) listed goods; or
 - 32 (iii) registered goods; or
 - 33 (iv) goods exempt under section 18A; or
 - 34 (v) goods that are the subject of an approval under
 - 35 section 19A; and
 - 36 (d) the goods are not used in accordance with:
 - 37 (i) an approval or authority under section 19; or

- 1 (ii) a condition applicable under regulations made for the
2 purposes of subsection 19(4A); and
3 (e) either:
4 (i) if the person used the goods in the treatment of another
5 person—the use of the goods, if the goods were used, is
6 likely to result in harm or injury to that person; or
7 (ii) if the person used the goods solely for experimental
8 purposes in humans—the use of the goods, if the goods
9 were used, is likely to result in harm or injury to any of
10 those persons.

11 Maximum penalty: 2,000 penalty units.

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

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

14 **21B General civil penalties relating to this Part**

15 *Civil penalty for making a false or misleading statement*

- 16 (1) A person contravenes this subsection if the person, in or in
17 connection with a certification of any matter under subsection
18 26A(2), makes a statement that is false or misleading in a material
19 particular.

20 Maximum civil penalty:

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

23 *Civil penalty relating to breaching a condition of registration or* 24 *listing of therapeutic goods*

- 25 (2) A person contravenes this subsection if:
26 (a) therapeutic goods are registered or listed in relation to the
27 person; and
28 (b) the person does an act or omits to do an act that breaches a
29 condition of the registration or listing of the goods.

30 Maximum civil penalty:

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

Civil penalty for falsely representing therapeutic goods

- 1
- 2 (3) A person contravenes this subsection if:
- 3 (a) the person represents therapeutic goods that are not included
- 4 in the Register as being so included; or
- 5 (b) the person represents therapeutic goods that are not exempt
- 6 goods as being exempt goods; or
- 7 (c) the person represents therapeutic goods that are not goods
- 8 exempt under section 18A as being goods exempt under that
- 9 section; or
- 10 (d) the person represents therapeutic goods that are included in
- 11 one part of the Register as being included in another part of
- 12 the Register; or
- 13 (e) the person represents therapeutic goods that are not the
- 14 subject of an approval or authority under section 19 as being
- 15 the subject of such an approval or authority; or
- 16 (f) the person represents therapeutic goods that are not the
- 17 subject of an approval under section 19A as being the subject
- 18 of such an approval.

19 Maximum civil penalty:

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

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

23 Repeal the subsections.

24 **19 Subsection 22(7AB) (penalty)**

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

26 **20 Subsection 22(7AB) (note 1)**

27 Repeal the note, substitute:

28 Note 1: A person may commit an offence against subsection 20(2A) or (2C),
29 or contravene section 22AA (a civil penalty provision), by breaching a
30 condition of an exemption of therapeutic goods under section 18A that
31 relates to the importation of the goods.

32 **21 Subsection 22(7A) (penalty)**

33 Repeal the penalty, substitute:

34 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.

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

- 4 (2) A person commits an offence if:
5 (a) the person makes a statement; and
6 (b) the statement is made in or in connection with an application
7 for registration of therapeutic goods; and
8 (c) the statement is false or misleading in a material particular;
9 and
10 (d) the use of the goods, if the goods were used, would be likely
11 to result in harm or injury to any person.

12 Maximum penalty: 2,000 penalty units.

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

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

- 15 (4) A person commits an offence if:
16 (a) the person makes a statement; and
17 (b) the statement is made in or in connection with an application
18 for registration of therapeutic goods; and
19 (c) the statement is false or misleading in a material particular.

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

22 **22B Civil penalty for false statements in applications for registration**

23 A person contravenes this section if the person in or in connection
24 with an application for registration of therapeutic goods, makes a
25 statement that is false or misleading in a material particular.

26 Maximum civil penalty:

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

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

30 Repeal the penalty, substitute:

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

1 Note: The heading to section 29A is replaced by the heading “**Criminal offence for failing to**
2 **notify adverse effects etc. of goods**”.

3 **26 After section 29A**

4 Insert:

5 **29AA Civil penalty for failing to notify adverse effects etc. of goods**

6 (1) A person contravenes this section if:

- 7 (a) therapeutic goods are registered or listed in relation to a
8 person; and
9 (b) the person becomes aware of information of a kind
10 mentioned in subsection (2) relating to the goods; and
11 (c) the person does not give the information to the Secretary in
12 writing as soon as he or she becomes aware of it.

13 Maximum civil penalty:

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

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

- 18 (a) information that contradicts information already given by the
19 person under this Act;
20 (b) information that indicates that the use of the goods in
21 accordance with the recommendations for their use may have
22 an unintended harmful effect;
23 (c) information that indicates that the goods, when used in
24 accordance with the recommendations for their use, may not
25 be as effective as the application for registration or listing of
26 the goods or information already given by the person under
27 this Act suggests;
28 (d) information that indicates that the quality, safety or efficacy
29 of the goods is unacceptable.

30 **27 Paragraph 29B(1)(a)**

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

32 **28 Subsection 29B(3) (penalty)**

33 Repeal the penalty, substitute:

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

3 **29 Subsection 29B(4) (penalty)**

4 Repeal the penalty, substitute:

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

7 **30 After section 29B**

8 Insert:

9 **29C Civil penalties for failing to notify adverse effects etc. where**
10 **application withdrawn or lapses**

11 *Civil penalty for failing to comply with requirements of a notice*

12 (1) A person contravenes this subsection if the person does not comply
13 with the requirements of a notice under subsection 29B(1) within
14 30 days after the day on which the notice is given to the person.

15 Maximum civil penalty:

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

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

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

23 Maximum civil penalty:

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

26 **31 Paragraph 30(2)(ca)**

27 After “subsection 29A(1)”, insert “or 29AA(1)”.

28 **32 Subsection 30EA(1) (table item 5)**

1 Omit “20(1) or 42E(1)”, substitute “19B(1), (2) or (4), 19D(1), 42E(1)
2 or 42EA(1)”.

3 **33 Section 30EC**

4 Repeal the section, substitute:

5 **30EC Criminal offences for non-compliance with requirements**

6 (1) A person commits an offence if:

- 7 (a) the person does an act or omits to do an act; and
8 (b) the act or omission breaches a requirement imposed on the
9 person under section 30EA; and
10 (c) the act or omission has resulted in, or will result in, harm or
11 injury to any person.

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

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

17 (2) A person commits an offence if:

- 18 (a) the person does an act or omits to do an act; and
19 (b) the act or omission breaches a requirement imposed on the
20 person under section 30EA; and
21 (c) the act or omission is likely to result in harm or injury to any
22 person.

23 Maximum penalty: 2,000 penalty units.

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

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

26 (4) A person commits an offence if:

- 27 (a) the person does an act or omits to do an act; and
28 (b) the act or omission breaches a requirement imposed on the
29 person under section 30EA.

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

1 **30ECA Civil penalty for non-compliance with requirements**

2 A person contravenes this section if:

- 3 (a) the person does an act or omits to do an act; and
4 (b) the act or omission breaches a requirement imposed on the
5 person under section 30EA.

6 Maximum civil penalty:

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

9 **34 After subsection 30F(4)**

10 Insert:

11 *Written notice is not a legislative instrument*

- 12 (4A) A written notice given to a person by the Secretary under this
13 section is not a legislative instrument for the purposes of the
14 *Legislative Instruments Act 2003*.

15 *Offences*

16 (4B) A person commits an offence if:

- 17 (a) the Secretary gives a notice to the person under
18 subsection (2); and
19 (b) the notice specifies a particular requirement mentioned in
20 subsection (3); and
21 (c) the person fails to comply with that requirement; and
22 (d) either:
23 (i) the use of the goods has resulted in, or will result in,
24 harm or injury to any person; or
25 (ii) the use of the goods, if the goods were used, would
26 result in harm or injury to any person; and
27 (e) the harm or injury has resulted, will result, or would result,
28 because the person failed to comply with that requirement.

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

31 Note: A jury may acquit a person of an offence against this subsection and
32 may convict the person of an offence against subsection (5) instead:
33 see section 53A.

- 1 (4C) A person commits an offence if:
2 (a) the Secretary gives a notice to the person under
3 subsection (2); and
4 (b) the notice specifies a particular requirement mentioned in
5 subsection (3); and
6 (c) the person fails to comply with that requirement; and
7 (d) the use of the goods, if the goods were used, would be likely
8 to result in harm or injury to any person; and
9 (e) the harm or injury would be likely to result because the
10 person failed to comply with that requirement.

11 Maximum penalty: 2,000 penalty units.

12 (4D) Subsection (4C) is an offence of strict liability.

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

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

16 **35 Subsection 30F(5) (penalty)**

17 Repeal the penalty, substitute:

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

20 **36 After section 30F**

21 Insert:

22 **30FA Civil penalty for goods exempt under section 18A not**
23 **conforming to standards etc.**

- 24 A person contravenes this section if:
25 (a) the Secretary gives a notice to the person under subsection
26 30F(2); and
27 (b) the notice specifies a particular requirement mentioned in
28 subsection 30F(3); and
29 (c) the person does not comply with the requirement.

30 Maximum civil penalty:

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

1 **37 Subsection 31(4) (penalty)**

2 Repeal the penalty, substitute:

3 Maximum penalty: 500 penalty units.

4 **38 After subsection 31(5)**

5 Insert:

6 (5A) A person commits an offence if:

- 7 (a) a medicine is listed under section 26A in relation to the
8 person; and
9 (b) the person provides information in purported compliance
10 with a notice under section 31 relating to the medicine; and
11 (c) the information is false or misleading in a material particular;
12 and
13 (d) either:
14 (i) the use of the medicine has resulted in, or will result in,
15 harm or injury to any person; or
16 (ii) the use of the medicine, if the medicine were used,
17 would result in harm or injury to any person.

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

20 Note: A jury may acquit a person of an offence against this subsection and
21 may convict the person of an offence against subsection (6) instead:
22 see section 53A.

23 (5B) A person commits an offence if:

- 24 (a) a medicine is listed under section 26A in relation to the
25 person; and
26 (b) the person provides information in purported compliance
27 with a notice under section 31 relating to the medicine; and
28 (c) the information is false or misleading in a material particular;
29 and
30 (d) the use of the medicine, if the medicine were used, would be
31 likely to result in harm or injury to any person.

32 Maximum penalty: 2,000 penalty units.

33 (5C) Subsection (5B) is an offence of strict liability.

34 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:

1 *Information may need to be given in accordance with specified*
2 *software requirements*

- 3 (4) The notice may require information to be given in accordance with
4 specified software requirements:
5 (a) on a specified kind of data processing device; or
6 (b) by way of a specified kind of electronic transmission.

7 **43 At the end of section 31B**

8 Add:

9 *Information may need to be given in accordance with specified*
10 *software requirements*

- 11 (5) A notice under subsection (1), (2) or (3) may require information to
12 be given in accordance with specified software requirements:
13 (a) on a specified kind of data processing device; or
14 (b) by way of a specified kind of electronic transmission.

15 **44 Section 31C**

16 Repeal the section, substitute:

17 **31C Criminal offence for failing to give information or documents**
18 **sought under section 31A, 31AA or 31B**

19 A person commits an offence if:

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

23 Maximum penalty: 400 penalty units.

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

30 **45 Paragraph 31D(1)(a)**

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

32 **46 Subsection 31D(1) (penalty)**

1 Repeal the penalty, substitute:

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

4 **47 Paragraph 31E(1)(c)**

5 Omit “subsection 31C(1)”, substitute “a notice given under section 31A,
6 31AA or 31B”.

7 **48 Subsection 31E(1) (penalty)**

8 Repeal the penalty, substitute:

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

11 **49 Subsection 31F(1)**

12 Omit “section 31C”, substitute “a notice given under section 31A,
13 31AA or 31B”.

14 **50 Subsection 31F(2)**

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

16 is not admissible in evidence in:

17 (d) criminal proceedings against the individual, except
18 proceedings under, or arising out of, section 31D or 31E; or

19 (e) proceedings for a pecuniary penalty order against the
20 individual for a contravention of a civil penalty provision.

21 **51 Section 35**

22 Repeal the section, substitute:

23 **35 Criminal offences relating to manufacturing therapeutic goods**

24 (1) A person commits an offence if:

25 (a) the person, at premises in Australia, carries out a step in the
26 manufacture of therapeutic goods (other than goods exempt
27 under section 18A); and

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

29 (c) none of the following applies:

30 (i) the goods are exempt goods;

- 1 (ii) the person is an exempt person in relation to the
2 manufacture of the goods;
3 (iii) the person is the holder of a licence that is in force that
4 authorises the carrying out of that step in relation to the
5 goods at those premises; and
6 (d) either:
7 (i) the use of the goods has resulted in, or will result in,
8 harm or injury to any person; or
9 (ii) the use of the goods, if the goods were used, would
10 result in harm or injury to any person; and
11 (e) the harm or injury has resulted, will result, or would result,
12 because the person carried out the step in the manufacture of
13 the goods.

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

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

- 19 (2) A person commits an offence if:
20 (a) the person, at premises in Australia, carries out a step in the
21 manufacture of therapeutic goods (other than goods exempt
22 under section 18A); and
23 (b) the goods are for supply for use in humans; and
24 (c) none of the following applies:
25 (i) the goods are exempt goods;
26 (ii) the person is an exempt person in relation to the
27 manufacture of the goods;
28 (iii) the person is the holder of a licence that is in force that
29 authorises the carrying out of that step in relation to the
30 goods at those premises; and
31 (d) the use of the goods, if the goods were used, would be likely
32 to result in harm or injury to any person; and
33 (e) the harm or injury would be likely to result because the
34 person carried out the step in the manufacture of the goods.

35 Maximum penalty: 2,000 penalty units.

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

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

-
- 1 (4) A person commits an offence if:
2 (a) the person, at premises in Australia, carries out a step in the
3 manufacture of therapeutic goods (other than goods exempt
4 under section 18A); and
5 (b) the goods are for supply for use in humans; and
6 (c) none of the following applies:
7 (i) the goods are exempt goods;
8 (ii) the person is an exempt person in relation to the
9 manufacture of the goods;
10 (iii) the person is the holder of a licence that is in force that
11 authorises the carrying out of that step in relation to the
12 goods at those premises.

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

- 15 (5) A person commits an offence if:
16 (a) the person, at premises in Australia, carries out a step in the
17 manufacture of therapeutic goods; and
18 (b) the goods are for supply for use in humans; and
19 (c) the goods are exempt under section 18A; and
20 (d) the person is not the holder of a licence that:
21 (i) is in force; and
22 (ii) authorises the carrying out of that step in relation to the
23 goods at those premises; and
24 (e) either:
25 (i) the use of the goods has resulted in, or will result in,
26 harm or injury to any person; or
27 (ii) the use of the goods, if the goods were used, would
28 result in harm or injury to any person; and
29 (f) the harm or injury has resulted, will result, or would result,
30 because the person carried out the step in the manufacture of
31 the goods.

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

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

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

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

- 2 (7) A person commits an offence if:
- 3 (a) the person, at premises in Australia, carries out a step in the
 - 4 manufacture of therapeutic goods; and
 - 5 (b) the goods are for supply for use in humans; and
 - 6 (c) the goods are exempt under section 18A; and
 - 7 (d) the person is not the holder of a licence that:
 - 8 (i) is in force; and
 - 9 (ii) authorises the carrying out of that step in relation to the
 - 10 goods at those premises; and
 - 11 (e) the use of the goods, if the goods were used, would be likely
 - 12 to result in harm or injury to any person; and
 - 13 (f) the harm or injury would be likely to result because the
 - 14 person carried out the step in the manufacture of the goods.

15 Maximum penalty: 2,000 penalty units.

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

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

- 18 (9) A person commits an offence if:
- 19 (a) the person, at premises in Australia, carries out a step in the
 - 20 manufacture of therapeutic goods; and
 - 21 (b) the goods are for supply for use in humans; and
 - 22 (c) the goods are exempt under section 18A; and
 - 23 (d) the person is not the holder of a licence that:
 - 24 (i) is in force; and
 - 25 (ii) authorises the carrying out of that step in relation to the
 - 26 goods at those premises.

27 Maximum penalty: Imprisonment for 12 months or 1,000 penalty

28 units, or both.

- 29 (10) Strict liability applies to paragraph (9)(c).

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

31 **35A Civil penalties relating to manufacturing therapeutic goods**

- 32 (1) A person contravenes this subsection if:
-

-
- 1 (a) the person carries out a step in the manufacture of therapeutic
2 goods at premises in Australia; and
3 (b) the goods are for supply for use in humans; and
4 (c) the goods are not exempt under section 18A; and
5 (d) none of the following applies:
6 (i) the goods are exempt goods;
7 (ii) the person is an exempt person in relation to the
8 manufacture of the goods;
9 (iii) the person is the holder of a licence that is in force that
10 authorises the carrying out of that step in relation to the
11 goods at those premises.

12 Maximum civil penalty:

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

15 (2) A person contravenes this subsection if:

- 16 (a) the person carries out a step in the manufacture of therapeutic
17 goods at premises in Australia; and
18 (b) the goods are for supply for use in humans; and
19 (c) the goods are exempt under section 18A; and
20 (d) the person is not the holder of a licence that:
21 (i) is in force; and
22 (ii) authorises the carrying out of that step in relation to the
23 goods at those premises.

24 Maximum civil penalty:

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

27 **35B Criminal offences relating to breaching a condition of a licence**

28 (1) A person commits an offence if:

- 29 (a) the person holds a licence; and
30 (b) the person does an act or omits to do an act; and
31 (c) the act or omission breaches a condition of the licence; and
32 (d) the act or omission has resulted in, or will result in, harm or
33 injury to any person.

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

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

- 6 (2) A person commits an offence if:
7 (a) the person holds a licence; and
8 (b) the person does an act or omits to do an act; and
9 (c) the act or omission breaches a condition of the licence; and
10 (d) the act or omission is likely to result in harm or injury to any
11 person.

12 Maximum penalty: 2,000 penalty units.

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

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

- 15 (4) A person commits an offence if:
16 (a) the person holds a licence; and
17 (b) the person does an act or omits to do an act; and
18 (c) the act or omission breaches a condition of the licence.

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

21 **35C Civil penalty relating to breaching a condition of a licence**

22 A person contravenes this section if:
23 (a) the person holds a licence; and
24 (b) the person does an act, or omits to do an act, that breaches a
25 condition of the licence.

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

29 **52 After paragraph 38(1A)(b)**

30 Insert:

- 1 (ba) an order requiring any of the following persons to pay a
- 2 pecuniary penalty for the contravention of a civil penalty
- 3 provision:
- 4 (i) the applicant or person;
- 5 (ii) another person who controls the applicant or person
- 6 (whether directly, or indirectly through one or more
- 7 interposed entities);
- 8 (iii) another person whom the applicant or person controlled
- 9 (whether directly, or indirectly through one or more
- 10 interposed entities) at the time civil penalty provision
- 11 was contravened or at the time of the order; or

12 **53 Paragraphs 41(1)(aa), (ab) and (ac)**

13 Repeal the paragraphs, substitute:

- 14 (aa) the holder has been ordered to pay a pecuniary penalty for the
- 15 contravention of a civil penalty provision; or
- 16 (ab) the holder controls another person (whether directly, or
- 17 indirectly through one or more interposed entities) and that
- 18 other person:
- 19 (i) has been convicted of an offence against this Act or a
- 20 law of a State or Territory relating to therapeutic goods;
- 21 or
- 22 (ii) has been ordered to pay a pecuniary penalty for the
- 23 contravention of a civil penalty provision; or
- 24 (ac) the holder controlled another person (whether directly, or
- 25 indirectly through one or more interposed entities) when that
- 26 other person:
- 27 (i) committed an offence against this Act or a law of a
- 28 State or Territory relating to therapeutic goods, being an
- 29 offence for which the person was convicted; or
- 30 (ii) contravened a civil penalty provision, being a
- 31 contravention for which the person was ordered to pay a
- 32 pecuniary penalty; or
- 33 (ad) the holder is controlled by another person (whether directly,
- 34 or indirectly through one or more interposed entities) when
- 35 that other person:
- 36 (i) has been convicted of an offence against this Act or a
- 37 law of a State or Territory relating to therapeutic goods;
- 38 or

1 (ii) has been ordered to pay a pecuniary penalty for the
2 contravention of a civil penalty provision; or

3 **54 Subsection 41(1A)**

4 After “(b)”, insert “, (ba)”.

5 **55 At the end of paragraph 41B(c)**

6 Add “and civil penalty provisions”.

7 **56 Section 41BC**

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

9 **57 Section 41BC (note)**

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

11 **58 Section 41C (note)**

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

13 **59 Section 41D (note 1)**

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

15 **60 Subsection 41EB(2) (note)**

16 Repeal the note, substitute:

17 Note: A person might also commit an offence, or contravene a civil penalty
18 provision, if the person makes a statement in an application that is
19 false or misleading in a material particular: see sections 41EI and
20 41EIA.

21 **61 After paragraph 41EC(4)(b)**

22 Insert:

23 (ba) an order requiring any of the following persons to pay a
24 pecuniary penalty for the contravention of a civil penalty
25 provision:

26 (i) the applicant or person;

27 (ii) another person who controls the applicant or person
28 (whether directly, or indirectly through one or more
29 interposed entities);

30 (iii) another person whom the applicant or person controlled
31 (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.

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

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

3 (4) A person commits an offence if:

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

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

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

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

12 **41E1A Civil penalty for making a false statement**

13 A person contravenes this section if:

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

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

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

20 Maximum civil penalty:

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

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

23 **63 Division 2 of Part 4-4 (note under the heading to the** 24 **Division)**

25 Repeal the note, substitute:

26 Note: Breaching conditions of the conformity assessment certificate may lead to suspension or
27 revocation of the certificate (see Divisions 3 and 4), may be an offence (see subsections
28 41MN(5), (6) and (8)), and may contravene a civil penalty provision (see subsection
29 41MNA(2)).

30 **64 Subsection 41ET(1A)**

31 After “(b)”, insert “, (ba)”.

32 **65 Section 41FA (note 2)**

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

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) 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.

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

- 1 (i) an application for including a kind of medical device in
2 the Register under this Chapter; or
3 (ii) a certification or purported certification under
4 section 41FD; and
5 (d) the use of the kind of medical device, if the kind of medical
6 device were used, would be likely to result in harm or injury
7 to any person.

8 Maximum penalty: 2,000 penalty units.

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

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

11 (4) A person commits an offence if:

- 12 (a) the person makes a statement (whether orally, in a document
13 or in any other way); and
14 (b) the person knows that the statement is false or misleading in
15 a material particular; and
16 (c) the statement is in or in connection with:
17 (i) an application for including a kind of medical device in
18 the Register under this Chapter; or
19 (ii) a certification or purported certification under
20 section 41FD.

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

23 **41FEA Civil penalty for making a false statement**

24 A person contravenes this section if:

- 25 (a) the person makes a statement (whether orally, in a document
26 or in any other way); and
27 (b) the statement is false or misleading in a material particular;
28 and
29 (c) the statement is in or in connection with:
30 (i) an application for including a kind of medical device in
31 the Register under this Chapter; or
32 (ii) a certification or purported certification under
33 section 41FD.

34 Maximum civil penalty:

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

3 **68 Division 2 of Part 4-5 (note under the heading to the**
4 **Division)**

5 Repeal the note, substitute:

6 Note: Breaching conditions of the inclusion of a kind of medical device may lead to
7 suspension or cancellation of the entry of the kind of device from the Register (see
8 Part 4-6), may be an offence (see subsections 41MN(1), (2) and (4)), and may
9 contravene a civil penalty provision (see subsection 41MNA(1)).

10 **69 Paragraph 41FN(3)(d)**

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

12 **70 Section 41GI (note)**

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

14 **71 Paragraph 41GN(1)(d)**

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

16 **72 Subsection 41HA(1) (note)**

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

18 **73 Subsection 41HA(2) (note)**

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

20 **74 Subsections 41HB(2) and (7) (note)**

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

22 **75 Section 41J (note)**

23 Omit “sections 41MP and 41MQ”, substitute “sections 41MP, 41MPA,
24 41MQ and 41MR”.

25 **76 Subsections 41JB(3) and (4)**

26 Repeal the subsections, substitute:

27 *Offence for failing to comply with a notice*

28 (3) A person commits an offence if:

29 (a) the person is given a notice under section 41JA; and

1 (b) the person fails to comply with the notice.

2 Maximum penalty: 500 penalty units.

3 Note: Failure to comply with the notice might also lead to suspension or
4 revocation of a conformity assessment certificate (see Divisions 3 and
5 4 of Part 4-4) or suspension or cancellation of the entry of a kind of
6 medical device in the Register (see Part 4-6).

7 *Offences for giving false or misleading information in purported*
8 *compliance with a notice*

9 (4) A person commits an offence if:

- 10 (a) the person is given a notice under section 41JA in relation to
11 a kind of medical device; and
12 (b) the person gives information in purported compliance with
13 the notice; and
14 (c) the information is false or misleading in a material particular;
15 and
16 (d) either:
17 (i) the use of the kind of medical device has resulted in, or
18 will result in, harm or injury to any person; or
19 (ii) the use of the kind of medical device, if the kind of
20 medical device were used, would result in harm or
21 injury to any person.

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

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

27 (5) A person commits an offence if:

- 28 (a) the person is given a notice under section 41JA in relation to
29 a kind of medical device; and
30 (b) the person gives information in purported compliance with
31 the notice; and
32 (c) the information is false or misleading in a material particular;
33 and
34 (d) the use of the kind of medical device, if the kind of medical
35 device were used, would be likely to result in harm or injury
36 to any person.

1 Maximum penalty: 2,000 penalty units.

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

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

4 (7) A person commits an offence if:

- 5 (a) the person is given a notice under section 41JA; and
6 (b) the person gives information in purported compliance with
7 the notice; and
8 (c) the information is false or misleading in a material particular.

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

11 **77 After section 41JB**

12 Insert:

13 **41JBA Civil penalty for giving false or misleading information in** 14 **purported compliance with a notice**

15 A person contravenes this section if:

- 16 (a) the person is given a notice under section 41JA; and
17 (b) the person gives information in purported compliance with
18 the notice; and
19 (c) the information is false or misleading in a material particular.

20 Maximum civil penalty:

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

23 **78 Subsection 41JC(2)**

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

25 is not admissible in evidence in:

- 26 (d) criminal proceedings against the individual, except
27 proceedings under, or arising out of, subsection 41JB(4), (5)
28 or (7); or
29 (e) proceedings for a pecuniary penalty order against the
30 individual for a contravention of a civil penalty provision,
31 except civil proceedings under, or arising out of,
32 section 41JBA.
-

1 **79 At the end of section 41JD**

2 Add:

- 3 (4) A notice under this section may require information to be given in
4 accordance with specified software requirements:
5 (a) on a specified kind of data processing device; or
6 (b) by way of a specified kind of electronic transmission.

7 **80 At the end of section 41JE**

8 Add:

9 *Information may need to be given in accordance with specified*
10 *software requirements*

- 11 (4) A notice under this section may require information to be given in
12 accordance with specified software requirements:
13 (a) on a specified kind of data processing device; or
14 (b) by way of a specified kind of electronic transmission.

15 **81 At the end of section 41JF**

16 Add:

- 17 (3) The notice may require information to be given in accordance with
18 specified software requirements:
19 (a) on a specified kind of data processing device; or
20 (b) by way of a specified kind of electronic transmission.

21 **82 Section 41JG**

22 Repeal the section, substitute:

23 **41JG Criminal offences for failing to give information or documents**
24 **sought under this Division**

25 A person commits an offence if:

- 26 (a) the person is given a notice under section 41JD, 41JE or
27 41JF; and
28 (b) the person fails to comply with the notice.

29 Maximum penalty: 400 penalty units.

30 Note: The privilege against self incrimination is not a reasonable excuse for
31 the purposes of this section. However, section 41JJ limits the use in

1 prosecutions of information etc. obtained under sections 41JD, 41JE
2 and 41JF.

3 **83 Paragraph 41JH(c)**

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

5 **84 Section 41JH (penalty)**

6 Repeal the penalty, substitute:

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

9 **85 Paragraph 41JI(1)(c)**

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

12 **86 Subsection 41JI(1) (penalty)**

13 Repeal the penalty, substitute:

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

16 **87 Subsection 41JJ(1)**

17 Omit “section 41JG”, substitute “a notice given under section 41JD,
18 41JE or 41JF”.

19 **88 Subsection 41JJ(2)**

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

21 is not admissible in evidence in:

22 (d) criminal proceedings against the individual, except
23 proceedings under, or arising out of, section 41JH or 41JI; or

24 (e) proceedings for a pecuniary penalty order against the
25 individual for a contravention of a civil penalty provision.

26 **89 Section 41KC**

27 Repeal the section, substitute:

1 **41KC Criminal offences for failing to comply with requirements**
2 **relating to a kind of medical device**

- 3 (1) A person commits an offence if:
4 (a) the person does an act or omits to do an act; and
5 (b) the act or omission breaches a requirement imposed on the
6 person under section 41KA; and
7 (c) the act or omission has resulted in, or will result in, harm or
8 injury to any person.

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

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

- 14 (2) A person commits an offence if:
15 (a) the person does an act or omits to do an act; and
16 (b) the act or omission breaches a requirement imposed on the
17 person under section 41KA; and
18 (c) the act or omission is likely to result in harm or injury to any
19 person.

20 Maximum penalty: 2,000 penalty units.

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

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

- 23 (4) A person commits an offence if:
24 (a) the person does an act or omits to do an act; and
25 (b) the act or omission breaches a requirement imposed on the
26 person under section 41KA.

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

29 **41KCA Civil penalty for failing to comply with requirements**
30 **relating to a kind of medical device**

- 31 A person contravenes this section if:
32 (a) the person does an act or omits to do an act; and
-

1 (b) the act or omission contravenes a requirement imposed on
2 the person under section 41KA.

3 Maximum civil penalty:

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

6 **90 Part 4-11 (heading)**

7 Repeal the heading, substitute:

8 **Part 4-11—Offences and civil penalty provisions** 9 **relating to medical devices**

10 **91 Section 41M**

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

12 **92 Section 41M (note)**

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

14 **93 Section 41MA**

15 Repeal the section, substitute:

16 **41MA Criminal offences for importing, supplying or exporting a** 17 **medical device that does not comply with essential** 18 **principles**

19 *Offences relating to importing a medical device*

- 20 (1) A person commits an offence if:
- 21 (a) the person imports a medical device into Australia; and
22 (b) the medical device does not comply with the essential
23 principles relating to matters other than the labelling of the
24 device; and
25 (c) the Secretary has not consented to the importation; and
26 (d) either:
27 (i) the use of the device has resulted in, or will result in,
28 harm or injury to any person; or
29 (ii) the use of the device, if the device were used, would
30 result in harm or injury to any person; and

1 (e) the harm or injury has resulted, will result, or would result,
2 because the device does not comply with the essential
3 principles.

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

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

9 (2) A person commits an offence if:

- 10 (a) the person imports a medical device into Australia; and
11 (b) the medical device does not comply with the essential
12 principles relating to matters other than the labelling of the
13 device; and
14 (c) the Secretary has not consented to the importation; and
15 (d) the use of the device, if the device were used, would be likely
16 to result in harm or injury to any person; and
17 (e) the harm or injury would be likely to result because the
18 device does not comply with the essential principles.

19 Maximum penalty: 2,000 penalty units.

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

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

22 (4) A person commits an offence if:

- 23 (a) the person imports a medical device into Australia; and
24 (b) the medical device does not comply with the essential
25 principles relating to matters other than the labelling of the
26 device; and
27 (c) the Secretary has not consented to the importation.

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

30 *Offences relating to supplying a medical device*

31 (5) A person commits an offence if:

- 32 (a) the person supplies a medical device for use in Australia; and
33 (b) the medical device does not comply with the essential
34 principles; and
-

- 1 (c) the Secretary has not consented to the supply; and
2 (d) either:
3 (i) the use of the device has resulted in, or will result in,
4 harm or injury to any person; or
5 (ii) the use of the device, if device were used, would result
6 in harm or injury to any person; and
7 (e) the harm or injury has resulted, will result, or would result,
8 because the device does not comply with the essential
9 principles.

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

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

- 15 (6) A person commits an offence if:
16 (a) the person supplies a medical device for use in Australia; and
17 (b) the medical device does not comply with the essential
18 principles; and
19 (c) the Secretary has not consented to the supply; and
20 (d) the use of the device, if the device were used, would be likely
21 to result in harm or injury to any person; and
22 (e) the harm or injury would be likely to result because the
23 device does not comply with the essential principles.

24 Maximum penalty: 2,000 penalty units.

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

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

- 27 (8) A person commits an offence if:
28 (a) the person supplies a medical device for use in Australia; and
29 (b) the medical device does not comply with the essential
30 principles; and
31 (c) the Secretary has not consented to the supply.

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

1 (c) the Secretary has not consented to the exportation.

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

4 *Exception*

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

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

10 **41MAA Civil penalties for importing, supplying or exporting a**
11 **medical device that does not comply with essential**
12 **principles**

13 *Civil penalty relating to importing a medical device*

- 14 (1) A person contravenes this subsection if:
15 (a) the person imports a medical device into Australia; and
16 (b) the medical device does not comply with the essential
17 principles relating to matters other than the labelling of the
18 device; and
19 (c) the Secretary has not consented to the importation.

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

23 *Civil penalty relating to supplying a medical device*

- 24 (2) A person contravenes this subsection if:
25 (a) the person supplies a medical device for use in Australia; and
26 (b) the medical device does not comply with the essential
27 principles; and
28 (c) the Secretary has not consented to the supply.

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

1 *Civil penalty relating to exporting a medical device*

- 2 (3) A person contravenes this subsection if:
3 (a) the person exports a medical device from Australia; and
4 (b) the medical device does not comply with the essential
5 principles; and
6 (c) the Secretary has not consented to the exportation.

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

10 **94 Subsection 41MB(1)**

11 Omit “Section 41MA does”, substitute “Sections 41MA and 41MAA
12 do”.

13 **95 Subsection 41MB(2) (note)**

14 Repeal the note, substitute:

- 15 Note 1: In the prosecution for an offence, the defendant bears an evidential
16 burden in relation to the matters in this section (see subsection 13.3(3)
17 of the *Criminal Code*).
- 18 Note 2: In proceedings for the contravention of a civil penalty provision, the
19 defendant must prove the matters in this section.

20 **96 Section 41MC**

21 Repeal the section, substitute:

22 **41MC Criminal offences relating to breaching a condition of a
23 consent**

- 24 (1) The consent of the Secretary under section 41MA or 41MAA may
25 be given:
26 (a) unconditionally or subject to conditions; or
27 (b) in respect of particular medical devices or kinds of medical
28 devices.
- 29 (2) A person commits an offence if:
30 (a) the person does an act or omits to do an act; and
31 (b) the act or omission breaches a condition of a consent; and

1 (c) the act or omission has resulted, or will result in, harm or
2 injury to any person.

3 Maximum penalty: 2,000 penalty units.

4 Note: A jury may acquit a person of an offence against this subsection and
5 may convict the person of an offence against subsection (5) instead:
6 see section 53A.

7 (3) A person commits an offence if:

- 8 (a) the person does an act or omits to do an act; and
9 (b) the act or omission breaches a condition of a consent; and
10 (c) the act or omission is likely to result in harm or injury to any
11 person.

12 Maximum penalty: 1,000 penalty units.

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

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

15 (5) A person commits an offence if:

- 16 (a) the person does an act or omits to do an act; and
17 (b) the act or omission breaches a condition of a consent.

18 Maximum penalty: 500 penalty units.

19 **41MCA Civil penalty relating to breaching a condition of a consent**

20 (1) The consent of the Secretary under section 41MA or 41MAA may
21 be given:

- 22 (a) unconditionally or subject to conditions; or
23 (b) in respect of particular medical devices or kinds of medical
24 devices.

25 (2) A person contravenes this section if:

- 26 (a) the person does an act or omits to do an act; and
27 (b) the act or omission breaches a condition of a consent.

28 Maximum civil penalty:

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

31 **97 Paragraph 41MD(a)**

1 Repeal the paragraph, substitute:

- 2 (a) the importation or exportation of a medical device is an
3 offence under subsection 41MA(1), (2), (4), (9), (10) or (12)
4 or a contravention of subsection 41MAA(1) or (3); and

5 **98 Section 41ME**

6 Repeal the section, substitute:

7 **41ME Criminal offences for failing to apply conformity assessment**
8 **procedures—manufacturers**

9 *Offences relating to supplying a medical device*

- 10 (1) A person commits an offence if:
- 11 (a) the person manufactures a medical device; and
- 12 (b) the person supplies the device in Australia; and
- 13 (c) the conformity assessment procedures have not been applied
14 to the device; and
- 15 (d) either:
- 16 (i) the use of the device has resulted in, or will result in,
17 harm or injury to any person; or
- 18 (ii) the use of the device, if the device were used, would
19 result in harm or injury to any person; and
- 20 (e) the harm or injury has resulted, will result, or would result,
21 because the conformity assessment procedures have not been
22 applied to the device.

23 **Maximum penalty:** Imprisonment for 5 years or 4,000 penalty
24 units, or both.

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

- 28 (2) A person commits an offence if:
- 29 (a) the person manufactures a medical device; and
- 30 (b) the person supplies the device in Australia; and
- 31 (c) the conformity assessment procedures have not been applied
32 to the device; and
- 33 (d) the use of the device, if the device were used, would be likely
34 to result in harm or injury to any person; and

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

4 Maximum penalty: 2,000 penalty units.

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

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

7 (4) A person commits an offence if:

- 8 (a) the person manufactures a medical device; and
- 9 (b) the person supplies the device in Australia; and
- 10 (c) the conformity assessment procedures have not been applied
11 to the device.

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

14 *Offences relating to exporting a medical device*

15 (5) A person commits an offence if:

- 16 (a) the person manufactures a medical device; and
- 17 (b) the person exports the device from Australia; and
- 18 (c) the conformity assessment procedures have not been applied
19 to the device; and
- 20 (d) either:
 - 21 (i) the use of the device has resulted in, or will result in,
22 harm or injury to any person; or
 - 23 (ii) the use of the device, if the device were used, would
24 result in harm or injury to any person; and
- 25 (e) the harm or injury has resulted, will result, or would result,
26 because the conformity assessment procedures have not been
27 applied to the device.

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

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

33 (6) A person commits an offence if:

- 34 (a) the person manufactures a medical device; and
-

- 1 (b) the person exports the device from Australia; and
2 (c) the conformity assessment procedures have not been applied
3 to the device; and
4 (d) the use of the device, if the device were used, would be likely
5 to result in harm or injury to any person; and
6 (e) the harm or injury would be likely to result because the
7 conformity assessment procedures have not been applied to
8 the device.

9 Maximum penalty: 2,000 penalty units.

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

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

12 (8) A person commits an offence if:

- 13 (a) the person manufactures a medical device; and
14 (b) the person exports the device from Australia; and
15 (c) the conformity assessment procedures have not been applied
16 to the device.

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

19 **41MEA Civil penalties for failing to apply conformity assessment**
20 **procedures—manufacturers**

21 *Civil penalty relating to supplying a medical device*

22 (1) A person contravenes this subsection if:

- 23 (a) the person supplies a medical device in Australia; and
24 (b) the person has manufactured the device; and
25 (c) the conformity assessment procedures have not been applied
26 to the device.

27 Maximum civil penalty:

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

30 *Civil penalty relating to exporting a medical device*

31 (2) A person contravenes this subsection if:

- 32 (a) the person exports a medical device from Australia; and
-

-
- 1 (b) the person has manufactured the device; and
2 (c) the conformity assessment procedures have not been applied
3 to the device.

4 Maximum civil penalty:

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

7 **99 Section 41MF**

8 Repeal the section, substitute:

9 **41MF Criminal offences for failing to apply conformity assessment**
10 **procedures—sponsors**

11 *Offences relating to supplying a medical device*

- 12 (1) A person commits an offence if:
13 (a) the person supplies a medical device in Australia; and
14 (b) the conformity assessment procedures have not been applied
15 to the device; and
16 (c) either:
17 (i) the use of the device has resulted in, or will result in,
18 harm or injury to any person; or
19 (ii) the use of the device, if the device were used, would
20 result in harm or injury to any person; and
21 (d) the harm or injury has resulted, will result, or would result,
22 because the conformity assessment procedures have not been
23 applied to the device.

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

26 Note: A jury may acquit a person of an offence against this subsection and
27 may convict the person of an offence against subsection (2) instead:
28 see section 53A.

- 29 (2) A person commits an offence if:
30 (a) the person supplies a medical device in Australia; and
31 (b) the conformity assessment procedures have not been applied
32 to the device.

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

3 *Offences relating to exporting a medical device*

- 4 (3) A person commits an offence if:
5 (a) the person exports a medical device from Australia; and
6 (b) the conformity assessment procedures have not been applied
7 to the device; and
8 (c) either:
9 (i) the use of the device has resulted in, or will result in,
10 harm or injury to any person; or
11 (ii) the use of the device, if the device were used, would
12 result in harm or injury to any person; and
13 (d) the harm or injury has resulted, will result, or would result,
14 because the conformity assessment procedures have not been
15 applied to the device.

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

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

- 21 (4) A person commits an offence if:
22 (a) the person exports a medical device from Australia; and
23 (b) the conformity assessment procedures have not been applied
24 to the device.

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

27 *Exception*

- 28 (5) This section does not apply if the defendant was not the sponsor of
29 the device at the time of the supply or exportation, as the case may
30 be.

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

33 **100 Subsection 41MG(1)**

34 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

- 1 (b) none of the following subparagraphs applies in relation to the
2 device:
3 (i) the device is of a kind included in the Register in
4 relation to the person;
5 (ii) the device is an exempt device;
6 (iii) the device is the subject of an approval under
7 section 41HB or an authority under section 41HC; and
8 (c) either:
9 (i) the use of the device has resulted in, or will result in,
10 harm or injury to any person; or
11 (ii) the use of the device, if the device were used, would
12 result in harm or injury to any person.

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

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

- 18 (2) A person commits an offence if:
19 (a) the person:
20 (i) imports a medical device into Australia; or
21 (ii) exports a medical device from Australia; or
22 (iii) supplies a medical device in Australia; or
23 (iv) manufactures a medical device in Australia; and
24 (b) none of the following subparagraphs applies in relation to the
25 device:
26 (i) the device is of a kind included in the Register in
27 relation to the person;
28 (ii) the device is an exempt device;
29 (iii) the device is the subject of an approval under
30 section 41HB or an authority under section 41HC; and
31 (c) the use of the device, if the device were used, would be likely
32 to result in harm or injury to any person.

33 Maximum penalty: 2,000 penalty units.

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

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

- 36 (4) A person commits an offence if:
-

- 1 (a) the person:
2 (i) imports a medical device into Australia; or
3 (ii) exports a medical device from Australia; or
4 (iii) supplies a medical device in Australia; or
5 (iv) manufactures a medical device in Australia; and
6 (b) none of the following subparagraphs applies in relation to the
7 device:
8 (i) the device is of a kind included in the Register in
9 relation to the person;
10 (ii) the device is an exempt device;
11 (iii) the device is the subject of an approval under
12 section 41HB or an authority under section 41HC.

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

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

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

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

18 (6) It is a defence to a prosecution under subsection (1), (2) or (4) if
19 the defendant proves that the defendant was not the sponsor of the
20 device at the time of the importation, exportation, supply, or
21 manufacture, as the case may be.

22 Note: A defendant bears a legal burden in relation to the matters in
23 subsection (6): see section 13.4 of the *Criminal Code*.

24 *Exception*

25 (7) Subsection (1) does not apply if:

- 26 (a) harm or injury did not, or will not, directly result from:
27 (i) the quality, safety or performance of the medical device;
28 or
29 (ii) a matter relating to the labelling or packaging of the
30 medical device; or
31 (iii) the improper use of the medical device; or
32 (b) harm or injury would not directly result from:
33 (i) the quality, safety or performance of the medical device;
34 or

- 1 (ii) a matter relating to the labelling or packaging of the
2 medical device; or
3 (iii) the improper use of the medical device.

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

6 **41MIA Notice required to adduce evidence in support of exception**
7 **under subsection 41MI(7)**

- 8 (1) If:
9 (a) a defendant is committed for trial for an offence against
10 subsection 41MI(1); or
11 (b) an offence against subsection 41MI(1) is to be heard and
12 determined by a court of summary jurisdiction;
13 the committing magistrate or the court must:
14 (c) inform the defendant of the requirements of this section; and
15 (d) cause a copy of this section to be given to the defendant.
- 16 (2) A defendant must not, without leave of the court, adduce evidence
17 in support of the exception under subsection 41MI(7) unless:
18 (a) if paragraph (1)(a) applies—more than 21 days before the
19 trial begins; or
20 (b) if paragraph (1)(b) applies—more than 21 days before the
21 hearing of the offence begins;
22 he or she gives notice of particulars of the exception.
- 23 (3) A defendant must not, without leave of the court, call any other
24 person to give evidence in support of the exception unless:
25 (a) the notice under subsection (2) includes the name and
26 address of the person or, if the name and address is not
27 known to the defendant at the time he or she gives the notice,
28 any information in his or her possession that might be of
29 material assistance in finding the person; and
30 (b) if the name or the address is not included in the notice—the
31 court is satisfied that the defendant before giving the notice
32 took, and after giving the notice continued to take, all
33 reasonable steps to ascertain the name or address; and
34 (c) if the name or address is not included in the notice, but the
35 defendant subsequently ascertains the name or address or
36 receives information that might be of material assistance in

- 1 finding the person—the defendant immediately gives notice
2 of the name, address or other information, as the case may
3 be; and
- 4 (d) if the defendant is told by or on behalf of the prosecutor that
5 the person has not been found by the name, or at the address,
6 given by the defendant:
- 7 (i) the defendant immediately gives notice of any
8 information in the defendant’s possession that might be
9 of material assistance in finding the person; or
- 10 (ii) if the defendant later receives any such information—
11 the defendant immediately gives notice of the
12 information.
- 13 (4) A notice purporting to be given under this section on behalf of the
14 defendant by his or her legal practitioner is, unless the contrary is
15 proved, taken as having been given with the authority of the
16 defendant.
- 17 (5) Any evidence tendered to disprove that the exception applies may,
18 subject to direction by the court, be given before or after evidence
19 is given in support of the exception.
- 20 (6) A notice of particulars of the exception must be given, in writing,
21 to the Director of Public Prosecutions. A notice is taken as having
22 been given if it is:
- 23 (a) delivered to or left at the Office of the Director of Public
24 Prosecutions; or
- 25 (b) sent by certified mail addressed to the Director of Public
26 Prosecutions at the Office of the Director of Public
27 Prosecutions.
- 28 (7) In this section:
- 29 *Director of Public Prosecutions* means a person holding office as,
30 or acting as, the Director of Public Prosecutions under the *Director*
31 *of Public Prosecutions Act 1983*.

32 **41MIB Civil penalty for importing, exporting, supplying or**
33 **manufacturing a medical device not included in the**
34 **Register**

- 35 (1) A person contravenes this section if:

- 1 (a) the person does any of the following:
2 (i) imports a medical device into Australia;
3 (ii) exports a medical device from Australia;
4 (iii) supplies a medical device in Australia;
5 (iv) manufactures a medical device in Australia; and
6 (b) none of the following paragraphs apply in relation to the
7 device:
8 (i) the device is of a kind included in the Register in
9 relation to the person;
10 (ii) the device is an exempt device;
11 (iii) the device is the subject of an approval under
12 section 41HB or an authority under section 41HC.

13 Maximum civil penalty:

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

16 *Exception*

- 17 (2) Subsection (1) does not apply if the defendant proves that the
18 defendant was not the sponsor of the device at the time of the
19 importation, exportation, supply, or manufacture, as the case may
20 be.

21 **104 Paragraph 41MJ(a)**

22 Repeal the paragraph, substitute:

- 23 (a) the importation or exportation of a medical device is an
24 offence under subsection 41MI(1), (2) or (4) or a
25 contravention of section 41MIB; and

26 **105 Subsections 41ML(1) and (2)**

27 Repeal the subsections.

28 Note: The heading to section 41ML is replaced by the heading “**False advertising about**
29 **medical devices**”.

30 **106 After section 41ML**

31 Insert:

1 **41MLA Civil penalty for making misrepresentations about medical**
2 **devices**

- 3 (1) A person contravenes this section if:
4 (a) the person makes a representation of a kind referred to in
5 subsection (2); and
6 (b) the representation is false or misleading.

7 Maximum civil penalty:

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

- 10 (2) Subsection (1) applies to the following representations:
11 (a) representations that medical devices are of a kind included in
12 the Register;
13 (b) representations that medical devices are exempt devices;
14 (c) representations that medical devices are the subject of an
15 approval under section 41HB or an authority under
16 section 41HC.

17 **107 Section 41MN**

18 Repeal the section, substitute:

19 **41MN Criminal offences relating to breaches of conditions**

20 *Offences relating to breaching a condition of the inclusion of a*
21 *kind of medical device in the Register*

- 22 (1) A person commits an offence if:
23 (a) a kind of medical device is included in the Register in
24 relation to the person; and
25 (b) the person does an act or omits to do an act; and
26 (c) the act or omission breaches a condition of the inclusion of
27 the kind of device in the Register; and
28 (d) the act or omission has resulted in, or will result in, harm or
29 injury to any person.

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

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

- 4 (2) A person commits an offence if:
5 (a) a kind of medical device is included in the Register in
6 relation to the person; and
7 (b) the person does an act or omits to do an act; and
8 (c) the act or omission breaches a condition of the inclusion of
9 the kind of device in the Register; and
10 (d) the act or omission is likely to result in harm or injury to any
11 person.

12 Maximum penalty: 2,000 penalty units.

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

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

- 15 (4) A person commits an offence if:
16 (a) a kind of medical device is included in the Register in
17 relation to the person; and
18 (b) the person does an act or omits to do an act; and
19 (c) the act or omission breaches a condition of the inclusion of
20 the kind of device in the Register.

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

23 *Offences relating to breaching a condition of a conformity*
24 *assessment certificate*

- 25 (5) A person commits an offence if:
26 (a) a conformity assessment certificate is issued in respect of the
27 person; and
28 (b) the person does an act or omits to do an act; and
29 (c) the act or omission breaches a condition of the conformity
30 assessment certificate; and
31 (d) the act or omission has resulted in, or will result in, harm or
32 injury to a person.

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

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

- 4 (6) A person commits an offence if:
5 (a) a conformity assessment certificate is issued in respect of the
6 person; and
7 (b) the person does an act or omits to do an act; and
8 (c) the act or omission breaches a condition of the conformity
9 assessment certificate; and
10 (d) the act or omission is likely to result in harm or injury to a
11 person.

12 Maximum penalty: 2,000 penalty units.

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

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

- 15 (8) A person commits an offence if:
16 (a) a conformity assessment certificate is issued in respect of the
17 person; and
18 (b) the person does an act or omits to do an act; and
19 (c) the act or omission breaches a condition of the conformity
20 assessment certificate.

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

23 *Offence relating to breaching a condition of an exemption or*
24 *approval, or a condition applicable under regulations*

- 25 (9) A person commits an offence if:
26 (a) the person does an act or omits to do an act; and
27 (b) the act or omission breaches:
28 (i) a condition of an exemption applicable under
29 regulations made for the purposes of section 41HA; or
30 (ii) a condition of an approval under section 41HB; or
31 (iii) a condition applicable under regulations made for the
32 purposes of subsection 41HB(7).

33 Maximum penalty: 60 penalty units.

1 **41MNA Civil penalties for breaching conditions**

- 2 (1) A person contravenes this subsection if:
3 (a) a kind of medical device is included in the Register in
4 relation to the person; and
5 (b) the person does an act or omits to do an act; and
6 (c) the act or omission breaches a condition of the inclusion of
7 the kind of device in the Register.

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

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

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

20 **108 Division 4 of Part 4-11 (heading)**

21 Repeal the heading, substitute:

22 **Division 4—Other offences and civil penalty provisions**

23 **109 Section 41MO**

24 Repeal the section, substitute:

25 **41MO Criminal offences for misusing medical devices exempted for**
26 **special or experimental uses**

- 27 (1) A person commits an offence if:
28 (a) the person has been granted an authority under section 41HC
29 relating to a specified kind of medical device; and
30 (b) the person supplies a medical device of that kind:
31 (i) otherwise than in accordance with the authority; or
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- 1 (ii) otherwise than in accordance with any conditions to
2 which the authority is subject; or
3 (iii) otherwise than in accordance with any regulations made
4 for the purpose of subsection 41HC(5); and
5 (c) either:
6 (i) the use of the device has resulted in, or will result in,
7 harm or injury to any person; or
8 (ii) the use of the device, if the device were used, would
9 result in harm or injury to any person; and
10 (d) the harm or injury has resulted, will result, or would result,
11 because:
12 (i) the supply is not in accordance with the authority; or
13 (ii) the supply is not in accordance with the conditions to
14 which the authority is subject; or
15 (iii) the supply is not in accordance with regulations made
16 for the purpose of subsection 41HC(5).

17 **Maximum penalty:** Imprisonment for 5 years or 4,000 penalty
18 units, or both.

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

- 22 (2) A person commits an offence if:
23 (a) the person has been granted an authority under section 41HC
24 relating to a specified kind of medical device; and
25 (b) the person supplies a medical device of that kind:
26 (i) otherwise than in accordance with the authority; or
27 (ii) otherwise than in accordance with any conditions to
28 which the authority is subject; or
29 (iii) otherwise than in accordance with any regulations made
30 for the purpose of subsection 41HC(5); and
31 (c) the use of the device, if the device were used, would be likely
32 to result in harm or injury to any person; and
33 (d) the harm or injury would be likely to result because:
34 (i) the supply is not in accordance with the authority; or
35 (ii) the supply is not in accordance with the conditions to
36 which the authority is subject; or
37 (iii) the supply is not in accordance with regulations made
38 for the purpose of subsection 41HC(5).

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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

- 1 (b) the person uses a medical device of that kind:
- 2 (i) in the treatment of another person; or
- 3 (ii) solely for experimental purposes in humans;
- 4 otherwise than in accordance with the approval; and
- 5 (c) the use of the device, if the device were used, would be likely
- 6 to result in harm or injury to any person.

7 Maximum penalty: 2,000 penalty units.

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

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

10 (8) A person commits an offence if:

- 11 (a) the person has been granted an approval under section 41HB
- 12 relating to a specified medical device or specified kind of
- 13 medical device; and
- 14 (b) the person uses a medical device of that kind:
- 15 (i) in the treatment of another person; or
- 16 (ii) solely for experimental purposes in humans;
- 17 otherwise than in accordance with the approval.

18 Maximum penalty: 500 penalty units.

19 **110 Subsection 41MP(1) (penalty)**

20 Repeal the penalty, substitute:

21 Maximum penalty: Imprisonment for 12 months or 1,000 penalty

22 units, or both.

23 Note: The heading to section 41MP is replaced by the heading “**Criminal offence for failing**

24 **to notify adverse events etc.**”.

25 **111 Subparagraphs 41MP(2)(a)(i) and (ii)**

26 Omit “a kind”, substitute “the kind”.

27 **112 After section 41MP**

28 Insert:

29 **41MPA Civil penalty for failing to notify adverse events etc.**

30 (1) A person contravenes this section if:

- 1 (a) a kind of medical device is included in the Register in
2 relation to the person; and
3 (b) the information is of a kind mentioned in subsection (2); and
4 (c) the person does not give information of a kind mentioned in
5 subsection (2) to the Secretary within the period specified in
6 the regulations (whether or not the person has already given
7 to the Secretary other information relating to the same
8 matter).

9 Maximum civil penalty:

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

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

- 14 (a) information relating to:
15 (i) any malfunction or deterioration in the characteristics or
16 performance of the kind of device; or
17 (ii) any inadequacy in the design, production, labelling,
18 instructions for use or advertising materials of the kind
19 of device; or
20 (iii) any use in accordance with, or contrary to, the use
21 intended by the manufacturer of the kind of device;
22 that might lead, or might have led, to the death of a patient or
23 user of the device, or to a serious deterioration in his or her
24 state of health;
- 25 (b) information relating to any technical or medical reason for a
26 malfunction or deterioration of a kind referred to in
27 subparagraph (a)(i) that has led the manufacturer to take steps
28 to recover devices of that kind that have been distributed;
- 29 (c) information that indicates that a device of that kind does not
30 comply with the essential principles;
- 31 (d) information that indicates that a certificate (other than one
32 issued under this Act) used for the purpose of an application
33 under subsection 41FC(1) to signify:
34 (i) compliance with the essential principles; or
35 (ii) the application of relevant conformity assessment
36 procedures to a particular device;
37 has been restricted, suspended, revoked or is no longer in
38 effect.
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1 **41MPB Relief from liability for contraventions for failing to notify**
2 **adverse events etc.**

3 (1) If:

4 (a) proceedings for the contravention of section 41MPA (a civil
5 penalty provision) are brought against a person; and

6 (b) in the proceedings it appears to the court that the person has,
7 or may have, contravened that section but that:

8 (i) the person has a reasonable excuse; and

9 (ii) having regard to all the circumstances of the case, the
10 person ought fairly to be excused for the contravention;

11 the court may relieve the person either wholly or partly from a
12 liability to which the person would otherwise be subject, or that
13 might otherwise be imposed on the person, because of the
14 contravention.

15 (2) If a person thinks that proceedings for the contravention of
16 section 41MPA will or may be begun against them, they may apply
17 to the Court for relief.

18 (3) On an application under subsection (2), the Court may grant relief
19 under subsection (1) as if proceedings had been begun in the Court.

20 (4) For the purposes of subsection (2) as applying for the purposes of a
21 case tried by a judge with a jury:

22 (a) a reference in that subsection to the Court is a reference to
23 the judge; and

24 (b) the relief that may be granted includes withdrawing the case
25 in whole or in part from the jury and directing judgment to be
26 entered for the person on such terms as to costs as the judge
27 thinks appropriate.

28 **113 Paragraph 41MQ(1)(a)**

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

30 **114 Subsection 41MQ(3) (penalty)**

31 Repeal the penalty, substitute:

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

1 **115 Subsection 41MQ(4) (penalty)**

2 Repeal the penalty, substitute:

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

5 **116 At the end of Division 4 of Part 4-11**

6 Add:

7 **41MR Civil penalties for failing to notify adverse effects etc. where**
8 **application withdrawn or lapses**

9 *Civil penalty for failing to comply with requirements of a notice*

- 10 (1) A person contravenes this subsection if the person does not comply
11 with the requirements of a notice under subsection 41MQ(1) within
12 20 working days after the day on which the notice is given to the
13 person.

14 Maximum civil penalty:

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

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

- 19 (2) A person contravenes this subsection if:
20 (a) the person gives information in purported compliance with a
21 notice under subsection 41MQ(1); and
22 (b) the information is false or misleading in a material particular.

23 Maximum civil penalty:

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

26 **117 At the end of subsections 42C(1) and (2)**

27 Add:

28 Note: Advertising that requires approval under Part 2 of the *Therapeutic*
29 *Goods Regulations 1990* must also comply with the Therapeutic
30 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 Goods Advertising Code.

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.

1 **42EB Relief from liability for certain contraventions relating to**
2 **dealing with counterfeit therapeutic goods**

3 (1) If:

- 4 (a) proceedings for the contravention of section 42EA (a civil
5 penalty provision) are brought against a person; and
6 (b) in the proceedings it appears to the court that the person has,
7 or may have, contravened that section but that:
8 (i) the person has a reasonable excuse; and
9 (ii) having regard to all the circumstances of the case, the
10 person ought fairly to be excused for the contravention;

11 the court may relieve the person either wholly or partly from a
12 liability to which the person would otherwise be subject, or that
13 might otherwise be imposed on the person, because of the
14 contravention.

15 (2) If a person thinks that proceedings for the contravention of
16 section 42EA will or may be begun against them, they may apply
17 to the Court for relief.

18 (3) On an application under subsection (2), the Court may grant relief
19 under subsection (1) as if proceedings had been begun in the Court.

20 (4) For the purposes of subsection (2) as applying for the purposes of a
21 case tried by a judge with a jury:

- 22 (a) a reference in that subsection to the Court is a reference to
23 the judge; and
24 (b) the relief that may be granted includes withdrawing the case
25 in whole or in part from the jury and directing judgment to be
26 entered for the person on such terms as to costs as the judge
27 thinks appropriate.

28 *Exception*

29 (5) This section does not apply to civil proceedings against a person
30 for manufacturing therapeutic goods in Australia that are
31 counterfeit (see subparagraph 42EA(1)(a)(i)).

32 **123 Subsection 42T(1) (penalty)**

33 Repeal the penalty, substitute:

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

3 **124 Subsection 42T(2) (penalty)**

4 Repeal the penalty, substitute:

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

7 **125 Subsection 42V(6)**

8 Repeal the subsection, substitute:

9 (6) A person commits an offence if:

10 (a) the person fails to comply with a requirement under
11 subsection (1) in relation to a supply of therapeutic goods;
12 and

13 (b) either:

14 (i) the use of the goods has resulted in, or will result in,
15 harm or injury to any person; or

16 (ii) the use of the goods, if the goods were used, would
17 result in harm or injury to any person; and

18 (c) the harm or injury has resulted, will result, or would result,
19 because the person failed to comply with the requirement.

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

22 Note: A jury may acquit a person of an offence against this subsection and
23 may convict the person of an offence against subsection (6C) instead:
24 see section 53A.

25 (6A) A person commits an offence if:

26 (a) the person fails to comply with a requirement under
27 subsection (1) in relation to a supply of therapeutic goods;
28 and

29 (b) the use of the goods, if the goods were used, would be likely
30 to result in harm or injury to any person; and

31 (c) the harm or injury would be likely to result because the
32 person failed to comply with the requirement.

33 Maximum penalty: 2,000 penalty units.

34 (6B) Subsection (6A) is an offence of strict liability.

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

2 (6C) A person commits an offence if the person fails to comply with a
3 requirement under subsection (1) in relation to a supply of
4 therapeutic goods.

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

7 **126 After section 42V**

8 Insert:

9 **42VA Civil penalty relating to the recovery of therapeutic goods**
10 **because of actual or potential tampering**

11 A person contravenes this section if the person fails to comply with
12 a requirement under subsection 42V(1) in relation to a supply of
13 therapeutic goods.

14 Maximum civil penalty:

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

17 **42VB Relief from liability for contraventions relating to the**
18 **recovery of therapeutic goods because of actual or**
19 **potential tampering**

20 (1) If:

- 21 (a) proceedings for the contravention of section 42VA (a civil
22 penalty provision) are brought against a person; and
23 (b) in the proceedings it appears to the court that the person has,
24 or may have, contravened that section but that:
25 (i) the person has acted honestly; and
26 (ii) having regard to all the circumstances of the case, the
27 person ought fairly to be excused for the contravention;

28 the court may relieve the person either wholly or partly from a
29 liability to which the person would otherwise be subject, or that
30 might otherwise be imposed on the person, because of the
31 contravention.

- 1 (2) If a person thinks that proceedings for the contravention of
2 section 42VA will or may be begun against them, they may apply
3 to the Court for relief.
- 4 (3) On an application under subsection (2), the Court may grant relief
5 under subsection (1) as if proceedings had been begun in the Court.
- 6 (4) For the purposes of subsection (2) as applying for the purposes of a
7 case tried by a judge with a jury:
8 (a) a reference in that subsection to the Court is a reference to
9 the judge; and
10 (b) the relief that may be granted includes withdrawing the case
11 in whole or in part from the jury and directing judgment to be
12 entered for the person on such terms as to costs as the judge
13 thinks appropriate.

14 **127 Subsection 42W(1) (penalty)**

15 Repeal the penalty, substitute:

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

18 **128 Subsection 42W(2) (penalty)**

19 Repeal the penalty, substitute:

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

22 **129 After Chapter 5**

23 Insert:

1 **Chapter 5A—Enforcement**

2 **Part 5A-1—Civil penalties**

3 **Division 1—Obtaining an order for a civil penalty**

4 **42Y Federal Court may order person to pay pecuniary penalty for**
5 **contravening civil penalty provision**

6 *Application for order*

- 7 (1) Within 6 years of a person (the *wrongdoer*) contravening a civil
8 penalty provision, the Secretary may apply on behalf of the
9 Commonwealth to the Federal Court for an order that the
10 wrongdoer pay the Commonwealth a pecuniary penalty.

11 *Court may order wrongdoer to pay pecuniary penalty*

- 12 (2) If the Court is satisfied that the wrongdoer has contravened a civil
13 penalty provision, the Court may order the wrongdoer to pay to the
14 Commonwealth for each contravention the pecuniary penalty that
15 the Court determines is appropriate (but not more than the
16 maximum amount specified for the provision).

17 *Determining amount of pecuniary penalty*

- 18 (3) In determining the pecuniary penalty, the Court must have regard
19 to all relevant matters, including:
20 (a) the nature and extent of the contravention; and
21 (b) the nature and extent of any loss or damage suffered as a
22 result of the contravention; and
23 (c) the circumstances in which the contravention took place; and
24 (d) whether the person has previously been found by the Court in
25 proceedings under this Act to have engaged in any similar
26 conduct.

27 *Civil evidence and procedure rules apply*

- 28 (4) The Court must apply the rules of evidence and procedure for civil
29 matters when hearing and determining an application for an order
30 under this section.

1 Note: The standard of proof in civil proceedings is the balance of
2 probabilities: see section 140 of the *Evidence Act 1995*.

3 *Conduct contravening more than one civil penalty provision*

4 (5) If conduct constitutes a contravention of 2 or more civil penalty
5 provisions, proceedings may be instituted under this Act against a
6 person in relation to the contravention of any one or more of those
7 provisions. However, the person is not liable to more than one
8 pecuniary penalty under this section in respect of the same
9 conduct.

10 **42YA What is a *civil penalty provision*?**

11 A subsection of this Act (or a section of this Act that is not divided
12 into subsections) is a ***civil penalty provision*** if the words “civil
13 penalty” and one or more amounts in penalty units are set out at the
14 foot of the subsection (or section).

15 **42YB Meaning of penalty unit**

16 In this Act, ***penalty unit***, in relation to a civil penalty provision, has
17 the same meaning as given by section 4AA of the *Crimes Act*
18 *1914*.

19 **42YC Persons involved in contravening civil penalty provision**

- 20 (1) A person must not:
- 21 (a) aid, abet, counsel or procure a contravention of a civil
22 penalty provision; or
 - 23 (b) induce (by threats, promises or otherwise) a contravention of
24 a civil penalty provision; or
 - 25 (c) conspire to contravene a civil penalty provision.
- 26 (2) This Act applies to a person who contravenes subsection (1) in
27 relation to a civil penalty provision as if the person had
28 contravened the civil penalty provision.

29 **42YD Recovery of a pecuniary penalty**

30 If the Federal Court orders a person to pay a pecuniary penalty:
31 (a) the penalty is payable to the Commonwealth; and

1 (b) the Commonwealth may enforce the order as if it were a
2 judgment of the Court.

3 **42YE Gathering information for application for pecuniary penalty**

4 (1) This section applies if it appears to the Secretary that a person (the
5 *wrongdoer*) may have contravened a civil penalty provision.

6 (2) If the Secretary, on reasonable grounds, suspects or believes that a
7 person other than the wrongdoer can give information relevant to
8 an application for a civil penalty order in relation to the
9 contravention, whether or not such an application has been made,
10 the Secretary may, by writing given to the person, require the
11 person to give all reasonable assistance in connection with such an
12 application.

13 (3) Subsection (2) does not apply in relation to a duly qualified legal
14 practitioner who is acting, or has acted, for the wrongdoer.

15 (4) If a person fails to give assistance as required under subsection (2),
16 the Federal Court may, on the application of the Secretary, order
17 the person to comply with the requirement as specified in the order.

18 (5) If a person fails to give assistance as required under subsection (2),
19 the person commits an offence against this subsection.

20 Maximum penalty: 30 penalty units.

21 **Division 2—Civil penalty proceedings and criminal**
22 **proceedings**

23 **42YF Civil proceedings after criminal proceedings**

24 The Federal Court must not make a pecuniary penalty order against
25 a person for a contravention of a civil penalty provision if the
26 person has been convicted of an offence constituted by conduct
27 that is substantially the same as the conduct constituting the
28 contravention.

29 **42YG Criminal proceedings during civil proceedings**

30 (1) Proceedings for a pecuniary penalty order against a person for a
31 contravention of a civil penalty provision are stayed if:

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- 1 (a) criminal proceedings are started or have already been started
2 against the person for an offence; and
3 (b) the offence is constituted by conduct that is substantially the
4 same as the conduct alleged to constitute the contravention.
- 5 (2) The proceedings for the order may be resumed if the person is not
6 convicted of the offence. Otherwise, the proceedings for the order
7 are dismissed.

8 **42YH Criminal proceedings after civil proceedings**

9 Criminal proceedings may not be started against a person for
10 conduct that is substantially the same as conduct constituting a
11 contravention of a civil penalty provision if a pecuniary penalty
12 order has been made against the person in respect of that conduct.

13 **42YI Evidence given in proceedings for civil penalty not admissible** 14 **in criminal proceedings**

15 Evidence of information given or evidence of production of
16 documents by an individual is not admissible in criminal
17 proceedings against the individual if:

- 18 (a) the individual previously gave the evidence or produced the
19 documents in proceedings for a pecuniary penalty order
20 against the individual for a contravention of a civil penalty
21 provision (whether or not the order was made); and
22 (b) the conduct alleged to constitute the offence is substantially
23 the same as the conduct that was claimed to constitute the
24 contravention.

25 However, this does not apply to a criminal proceeding in respect of
26 the falsity of the evidence given by the individual in the
27 proceedings for the pecuniary penalty order.

28 **Part 5A-2—Infringement notices**

30 **42YJ Infringement notices in respect of offences**

- 31 (1) The regulations may make provision enabling a person who is
32 alleged to have committed an offence against this Act to pay to the
33 Commonwealth, as an alternative to prosecution, a specified
34 penalty.
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1 Note: An offence against this Act includes an offence against the
2 regulations: see subsection 3(7).

3 (2) The penalty must not exceed an amount equal to one-fifth of the
4 maximum penalty that could have been imposed on the person for
5 that offence.

6 **42YK Infringement notices in respect of civil penalty provisions**

7 (1) The regulations may make provision enabling a person who is
8 alleged to have contravened a civil penalty provision to pay to the
9 Commonwealth, as an alternative to civil penalty proceedings
10 against the person, a specified penalty.

11 (2) The penalty must not exceed an amount equal to one-tenth of the
12 maximum penalty prescribed for contravening that provision.

13 **Part 5A-3—Enforceable undertakings**
14

15 **42YL Enforcement of undertakings**

16 (1) The Secretary may accept a written undertaking given by a person
17 in connection with a matter in relation to which the Secretary has a
18 power or function under this Act or the regulations.

19 (2) The person may withdraw or vary the undertaking at any time, but
20 only with the consent of the Secretary.

21 (3) The Secretary must publish details of the undertaking, as in force
22 from time to time, on the Internet.

23 (4) If the Secretary considers that the person who gave the undertaking
24 has breached any of its terms, the Secretary may apply to the
25 Federal Court for an order under subsection (5).

26 (5) If the Court is satisfied that the person has breached a term of the
27 undertaking, the Court may make all or any of the following
28 orders:

29 (a) an order directing the person to comply with that term of the
30 undertaking;

31 (b) an order directing the person to pay to the Commonwealth an
32 amount up to the amount of any financial benefit that the

- 1 person has obtained directly or indirectly and that is
2 reasonably attributable to the breach;
- 3 (c) any order that the Court considers appropriate directing the
4 person to compensate any other person who has suffered loss
5 or damage as a result of the breach;
- 6 (d) any other order that the Court considers appropriate.

7 **130 Section 45A (definition of *evidential material*)**

8 Repeal the definition, substitute:

9 ***evidential material*** means:

- 10 (a) in respect of an offence against this Act:
- 11 (i) any thing with respect to which the offence has been
12 committed or is suspected, on reasonable grounds, to
13 have been committed; or
- 14 (ii) any thing as to which there are reasonable grounds for
15 suspecting that it will afford evidence as to the
16 commission of the offence; or
- 17 (iii) any thing as to which there are reasonable grounds for
18 suspecting that it is intended to be used for the purpose
19 of committing the offence; and
- 20 (b) in respect of a contravention of a civil penalty provision:
- 21 (i) any thing with respect to which the civil penalty
22 provision has been contravened or is suspected, on
23 reasonable grounds, of having been contravened; or
- 24 (ii) any thing as to which there are reasonable grounds for
25 suspecting that it will afford evidence as to the
26 contravention of the civil penalty provision; or
- 27 (iii) any thing as to which there are reasonable grounds for
28 suspecting that it is intended to be used for the purpose
29 of contravening the civil penalty provision.

30 **131 Subsection 47(1)**

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

33 **132 Paragraph 47(4)(a)**

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

1 **133 After section 47**

2 Insert:

3 **47A Searches and seizures related to contraventions of civil penalty**
4 **provisions**

5 (1) Subject to subsections (2) and (3), if an authorised person has
6 reasonable grounds for suspecting that there may be evidential
7 material (within the meaning of paragraph (b) of the definition of
8 that expression) on any premises, the authorised person may:

- 9 (a) enter the premises; and
10 (b) exercise the powers set out in subsection (4) and subsection
11 48(1); and
12 (c) if the authorised person finds the thing on the premises—
13 seize it.

14 (2) The authorised person must not enter the premises unless:
15 (a) the occupier of the premises has consented to the entry; or
16 (b) the entry is made under a warrant issued under section 51AA.

17 (3) An authorised person is not entitled to exercise any powers under
18 subsection (1) in relation to premises if:

- 19 (a) the occupier of the premises has required the authorised
20 person to produce his or her identity card for inspection by
21 the occupier; and
22 (b) the authorised person fails to comply with the requirement.

23 (4) If:

24 (a) in the course of searching, in accordance with a warrant, for a
25 particular thing, an authorised person finds another thing that
26 the authorised believes on reasonable grounds to be
27 evidential material (within the meaning of paragraph (b) of
28 the definition of that expression); and

29 (b) the authorised person believes, on reasonable grounds, that it
30 is necessary to seize that other thing in order to prevent its
31 concealment, loss or destruction, or its use in contravening,
32 continuing to contravene, or repeating a contravention of a
33 civil penalty provision;

34 the warrant is taken to authorise the authorised person to seize that
35 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)

1 Add "(within the meaning of paragraph (a) of the definition of that
2 expression)".

3 **140 After section 51**

4 Insert:

5 **51AA Civil penalty contravention warrants**

6 (1) An authorised person may apply to a magistrate for a warrant
7 under this section in relation to premises.

8 (2) Subject to subsection (3), the magistrate may issue the warrant if
9 the magistrate is satisfied, by information on oath, that there are
10 reasonable grounds for suspecting that there is, or there may be
11 within the next 72 hours, in or on the premises evidential material
12 (within the meaning of paragraph (b) of the definition of that
13 expression).

14 (3) The magistrate must not issue the warrant unless the authorised
15 person or some other person has given to the magistrate, either
16 orally or by affidavit, such further information (if any) as the
17 magistrate requires concerning the grounds on which the issue of
18 the warrant is being sought.

19 (4) The warrant must:

20 (a) name one or more authorised persons; and

21 (b) authorise the persons so named, with such assistance and by
22 such force as is necessary and reasonable:

23 (i) to enter the premises; and

24 (ii) to exercise the powers set out in subsections 47A(4) and
25 48(1); and

26 (iii) to seize the evidential material; and

27 (c) state whether the entry is authorised to be made at any time
28 of the day or night or during specified hours of the day or
29 night; and

30 (d) specify the day (not more than one week after the issue of the
31 warrant) on which the warrant ceases to have effect; and

32 (e) state the purpose for which the warrant is issued.

33 **141 After section 53**

34 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:

Alternative verdicts for various offences		
Column 1	Column 2	Column 3
Item	If a prosecution is for an offence against...	the jury may instead convict the person of an offence against...
1	subsection 14(1)	subsection 14(4)
2	subsection 14(6)	subsection 14(9)
3	subsection 14(10)	subsection 14(13)
4	subsection 15(2)	subsection 15(5)
5	subsection 19B(1)	subsection 19B(4)
6	subsection 21A(1)	subsection 21A(4)
7	subsection 21A(5)	subsection 21A(8)
8	subsection 21A(9)	subsection 22(7A)
9	subsection 21A(12)	subsection 22(8)
10	subsection 22A(1)	subsection 22A(4)
11	subsection 30EC(1)	subsection 30EC(4)
12	subsection 30F(4B)	subsection 30F(5)
13	subsection 31(5A)	subsection 31(6)
14	subsection 35(1)	subsection 35(4)
15	subsection 35(5)	subsection 35(9)
16	subsection 35B(1)	subsection 35B(4)
17	subsection 41EI(1)	subsection 41EI(4)
18	subsection 41FE(1)	subsection 41FE(4)
19	subsection 41JB(4)	subsection 41JB(7)
20	subsection 41KC(1)	subsection 41KC(4)
21	subsection 41MA(1)	subsection 41MA(4)
22	subsection 41MA(5)	subsection 41MA(8)
23	subsection 41MA(9)	subsection 41MA(12)

Alternative verdicts for various offences		
Column 1	Column 2	Column 3
Item	If a prosecution is for an offence against...	the jury may instead convict the person of an offence against...
24	subsection 41MC(2)	subsection 41MC(5)
25	subsection 41ME(1)	subsection 41ME(4)
26	subsection 41ME(5)	subsection 41ME(8)
27	subsection 41MF(1)	subsection 41MF(2)
28	subsection 41MF(3)	subsection 41MF(4)
29	subsection 41MI(1)	subsection 41MI(4)
30	subsection 41MN(1)	subsection 41MN(4)
31	subsection 41MN(5)	subsection 41MN(8)
32	subsection 41MO(1)	subsection 41MO(4)
33	subsection 41MO(5)	subsection 41MO(8)
34	subsection 42V(6)	subsection 42V(6C)

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

2 Repeal the subsections, substitute:

3 (3) If a court:

4 (a) convicts a person of an offence against this Act; or

5 (b) orders a person to pay a pecuniary penalty for the
6 contravention of a civil penalty provision;

7 in relation to any therapeutic goods, the court may order that the
8 goods be forfeited to the Commonwealth and, if an order is made,
9 the goods become the property of the Commonwealth.

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

11 **143 Section 54AB(1) (penalty)**

12 Repeal the penalty, substitute:

13 Maximum penalty: 7 years imprisonment or 2,000 penalty units,
14 or both.

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

17 **144 After section 54AB**

1 Insert:

2 **54AC Civil penalty for damaging etc. documents**

3 A person contravenes this section if:

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

12 Maximum civil penalty:

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

15 **145 After section 54A**

16 Insert:

17 **54B Application of this Act to an executive officer of a body**
18 **corporate**

- 19 (1) An executive officer of a body corporate commits an offence if:
 - 20 (a) the body corporate commits an offence against this Act; and
 - 21 (b) the officer knew that the offence would be committed; and
 - 22 (c) the officer was in a position to influence the conduct of the
 - 23 body in relation to the commission of the offence; and
 - 24 (d) the officer failed to take all reasonable steps to prevent the
 - 25 commission of the offence.

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

- 28 (2) The maximum penalty for an offence against subsection (1) is the
29 maximum penalty that a Court could impose in respect of an
30 individual for the offence committed by the body corporate.
 - 31 (3) An executive officer of a body corporate contravenes this
32 subsection if:
 - 33 (a) the body corporate contravenes a civil penalty provision; and
-

- 1 (b) the officer knew that the contravention would occur; and
2 (c) the officer was in a position to influence the conduct of the
3 body in relation to the contravention; and
4 (d) the officer failed to take all reasonable steps to prevent the
5 contravention.
- 6 (4) The maximum civil penalty for a contravention of subsection (3) is
7 the maximum civil penalty that a Court could impose in respect of
8 an individual for the civil penalty provision contravened by the
9 body corporate.
- 10 (5) In this section:
- 11 *executive officer* of a body corporate means a person, by whatever
12 name called and whether or not a director of the body, who is
13 concerned in, or takes part in, the management of the body.

14 **54C Establishing whether an executive officer took reasonable steps**
15 **to prevent the commission of an offence or the**
16 **contravention of a civil penalty provision**

- 17 (1) For the purposes of section 54B, in determining whether an
18 executive officer of a body corporate failed to take all reasonable
19 steps to prevent the commission of the offence or the contravention
20 of a civil penalty provision, a court is to have regard to:
- 21 (a) what action (if any) the officer took towards ensuring that the
22 body's employees, agents and contractors have a reasonable
23 knowledge and understanding of the requirements to comply
24 with this Act and the regulations, in so far as those
25 requirements affect the employees, agents or contractors
26 concerned; and
- 27 (b) what action (if any) the officer took when he or she became
28 aware that the body was committing an offence against, or
29 otherwise contravening, this Act or the regulations.
- 30 (2) This section does not, by implication, limit the generality of
31 section 54B.
- 32 (3) In this section, *executive officer* has the same meaning as in
33 section 54B.

34 **146 Subsections 55(1), (2), (3) and (4)**

1 After “this Act,” insert “or for a contravention of a civil penalty
2 provision.”

3 **147 Paragraph 56A(1)(a)**

4 After “section 18”, insert “or 18A”.

5 **148 Subsection 56A(3)**

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

8 **149 Subsection 56A(4)**

9 Repeal the subsection, substitute:

10 (4) In proceedings for:

- 11 (a) an offence against section 14 or 41MA; or
12 (b) the contravention of section 14A or 41MAA (civil penalty
13 provisions);

14 a certificate by the Secretary to the effect that:

- 15 (c) the Secretary did not consent to the importation, supply or
16 exportation that is the subject of the proceedings; or
17 (d) the Secretary consented to that importation, supply or
18 exportation subject to conditions specified in the certificate;
19 is prima facie evidence of the matters specified in the certificate.

20 **150 Subsection 56A(5)**

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

23 **151 Subsection 60(1) (paragraph (b) of the definition of *initial*
24 *decision*)**

25 After “section 14”, insert “or 14A”.

26 **152 Subsection 60(1) (paragraph (k) of the definition of *initial*
27 *decision*)**

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

29 **153 Subsection 61(3A)**

30 After “31A,”, insert “31AA,”.

1 **154 After paragraph 61(4A)(b)**

2 Insert:

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

5 **155 At the end of subsection 61(4A)**

6 Add:

7 ; (g) information relating to an offence committed against this
8 Act, or alleged to have been committed against this Act,
9 involving therapeutic goods;

10 (h) information relating to the contravention of a civil penalty
11 provision, or the alleged contravention of a civil penalty
12 provision, involving therapeutic goods;

13 (i) a breach of a requirement of this Act or the regulations.

14 **156 After subsection 61(4A)**

15 Insert:

16 (4B) The release of therapeutic goods information mentioned in
17 paragraphs (4A)(g), (h) and (i) is not taken, for the purposes of
18 paragraph 1(d) of Information Privacy Principle 11 in section 14 of
19 the *Privacy Act 1988*, to be authorised by law.

20 **157 After subsection 61(5)**

21 Insert:

22 (5A) The Secretary may release to the public therapeutic goods
23 information relating to any decision or action taken under this Act
24 or the regulations.

25 (5B) The release of therapeutic goods information under
26 subsection (5A) is not taken, for the purposes of paragraph 1(d) of
27 Information Privacy Principle 11 in section 14 of the *Privacy Act*
28 *1988*, to be authorised by law.

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

30 **158 Item 12 of Schedule 2**

31 Repeal the item, substitute:

1 **12 Paragraph 19D(3)(a) and (4)(a)**

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