

2016

The Parliament of the  
Commonwealth of Australia

HOUSE OF REPRESENTATIVES

*Presented and read a first time*

**Therapeutic Goods Amendment (2016  
Measures No. 1) Bill 2016**

**No.     , 2016**

*(Health and Aged Care)*

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



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

3     The Parliament of Australia enacts:

4     **1 Short title**

5                     This Act is the *Therapeutic Goods Amendment (2016 Measures*  
6                     *No. 1) Act 2016*.

7     **2 Commencement**

8                     (1) Each provision of this Act specified in column 1 of the table  
9                     commences, or is taken to have commenced, in accordance with  
10                    column 2 of the table. Any other statement in column 2 has effect  
11                    according to its terms.  
12

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**Commencement information**

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<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<b>Provisions</b>	<b>Commencement</b>	<b>Date/Details</b>
1. Sections 1 to 3 and anything in this Act not elsewhere covered by this table	The day this Act receives the Royal Assent.	
2. Schedule 1	A single day to be fixed by Proclamation. However, if the provisions do not commence within the period of 6 months beginning on the day this Act receives the Royal Assent, they commence on the day after the end of that period.	
3. Schedules 2 to 8	The day after this Act receives the Royal Assent.	
4. Schedule 9	A single day to be fixed by Proclamation. However, if the provisions do not commence within the period of 6 months beginning on the day this Act receives the Royal Assent, they commence on the day after the end of that period.	
5. Schedules 10 to 12	The day after this Act receives the Royal Assent.	

1 Note: This table relates only to the provisions of this Act as originally  
2 enacted. It will not be amended to deal with any later amendments of  
3 this Act.

4 (2) Any information in column 3 of the table is not part of this Act.  
5 Information may be inserted in this column, or information in it  
6 may be edited, in any published version of this Act.

### 7 **3 Schedules**

8 Legislation that is specified in a Schedule to this Act is amended or  
9 repealed as set out in the applicable items in the Schedule  
10 concerned, and any other item in a Schedule to this Act has effect  
11 according to its terms.

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## **Schedule 1—Variation of entries in Register**

### ***Therapeutic Goods Act 1989***

#### **1 Before subsection 9D(3)**

Insert:

(2C) If:

- (a) the person in relation to whom therapeutic goods are registered or listed has requested the Secretary to vary the entry in the Register that relates to the goods; and
- (b) the variation is of a kind specified in the regulations; and
- (c) the conditions (if any) specified in the regulations are satisfied;

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

#### **2 After paragraph 9D(3)(b)**

Insert:

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

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

Insert:

(3AC) If:

- (a) the person in relation to whom a biological is included in the Register has requested the Secretary to vary the entry in the Register that relates to the biological; and
- (b) the variation is of a kind specified in the regulations; and
- (c) the conditions (if any) specified in the regulations are satisfied;

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

#### **4 After paragraph 9D(3A)(aa)**

Insert:

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

#### **5 Before subsection 9D(3D)**

Insert:

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- 1           (3CB) If:
- 2                   (a) the person in relation to whom a kind of medical device is
- 3                   included in the Register has requested the Secretary to vary
- 4                   the entry in the Register that relates to the kind of medical
- 5                   device; and
- 6                   (b) the variation is of a kind specified in the regulations; and
- 7                   (c) the conditions (if any) specified in the regulations are
- 8                   satisfied;
- 9           the Secretary must vary the entry in accordance with the request.

10   **6 After paragraph 9D(3D)(b)**

- 11           Insert:
- 12                   (ba) subsection (3CB) does not apply to the request; and



1 **Schedule 2—Conformity assessment of**  
2 **medical devices**  
3

4 ***Therapeutic Goods Act 1989***

5 **1 Subsection 3(1)**

6 Insert:

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

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

12 **2 Subsection 3(1) (paragraph (a) of the definition of**  
13 ***authorised person*)**

14 After “this Act”, insert “or the regulations”.

15 **3 Subsection 3(1)**

16 Insert:

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

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

23 **4 After Part 4-4**

24 Insert:

1 **Part 4-4A—Australian conformity assessment**  
2 **bodies**  
3

4 **41EWA Conformity assessment body determinations**

- 5 (1) The regulations may make provision for and in relation to  
6 empowering the Secretary to make conformity assessment body  
7 determinations.
- 8 (2) A *conformity assessment body determination* is a determination  
9 that a specified Australian corporation is an *Australian conformity*  
10 *assessment body* for the purposes of this Act.
- 11 (3) The regulations may make provision for and in relation to the  
12 following matters:  
13 (a) applications for conformity assessment body determinations;  
14 (b) the approval by the Secretary of a form for such an  
15 application;  
16 (c) information that must accompany such an application;  
17 (d) the application fee for such an application;  
18 (e) the lapsing of such an application;  
19 (f) the assessment by the Secretary of whether a conformity  
20 assessment body determination should be made in response  
21 to such an application;  
22 (g) the assessment fee for such an assessment;  
23 (h) the duration of conformity assessment body determinations.
- 24 (4) A conformity assessment body determination:  
25 (a) may be of general application; or  
26 (b) may be limited to either or both of the following:  
27 (i) one or more specified kinds of medical devices;  
28 (ii) one or more specified kinds of conformity assessment  
29 procedures.
- 30 (5) The regulations may provide that a conformity assessment body  
31 determination is subject to:  
32 (a) the conditions prescribed by the regulations; and  
33 (b) such other conditions (if any) as are specified in the  
34 determination.

- 
- 1 (6) The following are examples of conditions that may be prescribed:  
2 (a) a condition that the body will allow an authorised person:  
3 (i) to enter, at any reasonable time, premises used by the  
4 body to carry on certification-related activities; and  
5 (ii) while on those premises, to inspect those premises and  
6 anything on those premises that concerns  
7 certification-related activities carried on by the body;  
8 and  
9 (iii) while on those premises, to make any still or moving  
10 image or any recording of those premises or anything on  
11 those premises that concerns certification-related  
12 activities carried on by the body; and  
13 (iv) while on those premises, to inspect, and make copies of,  
14 any documents that concern certification-related  
15 activities carried on by the body;  
16 (b) a condition that the body will, if requested to do so by the  
17 Secretary, give the Secretary information, or produce to the  
18 Secretary documents, that concern certification-related  
19 activities carried on by the body.
- 20 (7) The regulations may make provision for and in relation to  
21 empowering the Secretary to revoke or vary a conformity  
22 assessment body determination.
- 23 (8) Subsections (3) to (7) do not limit subsection (1).
- 24 (9) The express references in this section to the Secretary do not, by  
25 implication, prevent the regulations from empowering the  
26 Secretary to delegate any or all of the Secretary's functions or  
27 powers under regulations made for the purposes of this section.
- 28 (10) If a conformity assessment body determination is in force under the  
29 regulations, the determination must be published on the  
30 Department's website.
- 31 (11) A conformity assessment body determination made under the  
32 regulations is not a legislative instrument.
- 33 (12) Subsection 33(3AB) of the *Acts Interpretation Act 1901* does not  
34 apply to the specification of an Australian corporation in a  
35 conformity assessment body determination.

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

3 **5 After section 41FI**

4 Insert:

5 **41FIA Certificates issued by Australian conformity assessment**  
6 **bodies**

7 (1) If:

- 8 (a) a section 41FC application is made for a kind of medical  
9 device to be included in the Register; and  
10 (b) the application has been selected for audit; and  
11 (c) a person has obtained a certificate issued by an Australian  
12 conformity assessment body to the effect that the body is  
13 satisfied that devices of that kind comply with the essential  
14 principles; and  
15 (d) the certificate was issued under a contract between the person  
16 and the body; and  
17 (e) the certificate has been given to the Secretary;  
18 then, in auditing the application, the Secretary may have regard to  
19 the certificate.

20 (2) If:

- 21 (a) a section 41FC application is made for a kind of medical  
22 device to be included in the Register; and  
23 (b) the application has been selected for audit; and  
24 (c) a person has obtained a certificate issued by an Australian  
25 conformity assessment body to the effect that the body is  
26 satisfied that an appropriate conformity assessment procedure  
27 has been applied to devices of that kind; and  
28 (d) the certificate was issued under a contract between the person  
29 and the body; and  
30 (e) the certificate has been given to the Secretary;  
31 then, in auditing the application, the Secretary may have regard to  
32 the certificate.

33 (3) If a conformity assessment body determination that relates to an  
34 Australian conformity assessment body is limited to one or more  
35 specified kinds of medical devices, subsection (1) does not apply to

1 a certificate issued by the body unless the certificate relates to one  
2 of those kinds of medical devices.

3 (4) If a conformity assessment body determination that relates to an  
4 Australian conformity assessment body is limited to one or more  
5 specified kinds of conformity assessment procedures,  
6 subsection (2) does not apply to a certificate issued by the body  
7 unless the certificate relates to one of those kinds of conformity  
8 assessment procedures.

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

1  
2

## Schedule 3—Exemptions

3

### *A New Tax System (Goods and Services Tax) Act 1999*

4

#### **1 After paragraph 38-50(6)(b)**

5

Insert:

6

(ba) the supply of the drug or medicinal preparation is authorised  
by rules under subsection 19(7A) of that Act; or

7

8

### *Therapeutic Goods Act 1989*

9

#### **2 Subsection 3(1)**

10

Insert:

11

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

12

13

14

(a) Aboriginal and Torres Strait Islander health practice;

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(b) dental (not including the professions of dental therapist,

16

dental hygienist, dental prosthetist or oral health therapist);

17

(c) medical;

18

(d) medical radiation practice;

19

(e) nursing;

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(f) midwifery;

21

(g) occupational therapy;

22

(h) optometry;

23

(i) pharmacy;

24

(j) physiotherapy;

25

(k) podiatry;

26

(l) psychology.

27

#### **3 Section 19 (heading)**

28

Repeal the heading, substitute:

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**19 Exemptions for certain uses****4 After subsection 19(7)**

Insert:

- (7A) The Minister may, by legislative instrument, make rules authorising any health practitioner who is included in a specified class of health practitioners to supply:
- (a) specified therapeutic goods for use in the treatment of humans; or
  - (b) a specified class of such goods;
- to the class or classes of recipients specified in those rules, so long as:
- (c) the goods are supplied in the circumstances specified in those rules; and
  - (d) the conditions (if any) specified in those rules are satisfied.
- (7B) In making rules under subsection (7A), the Minister must comply with:
- (a) such requirements (if any) as are prescribed by the regulations; and
  - (b) such restrictions (if any) as are prescribed by the regulations; and
  - (c) such limitations (if any) as are prescribed by the regulations.
- (7C) If:
- (a) a person is authorised, by subsection (7A) rules, to supply therapeutic goods; and
  - (b) the person supplies those goods in accordance with those rules;
- the person must:
- (c) notify the supply to the Secretary; and
  - (d) do so within 28 days after the supply.
- (7D) A notification under subsection (7C) must:
- (a) be in accordance with a form that is approved, in writing, by the Secretary; and
  - (b) contain such information as is prescribed by the regulations.

- 1 (7E) An approval of a form may require or permit information to be  
2 given in accordance with specified software requirements:  
3 (a) on a specified kind of data processing device; or  
4 (b) by way of a specified kind of electronic transmission.

- 5 (7F) A person commits an offence if:  
6 (a) the person is subject to a requirement under subsection (7C);  
7 and  
8 (b) the person omits to do an act; and  
9 (c) the omission breaches the requirement.

10 Penalty: 10 penalty units.

- 11 (7G) An offence against subsection (7F) is an offence of strict liability.

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

- 13 (7H) In recommending to the Governor-General that regulations should  
14 be made for the purposes of paragraph (7D)(b), the Minister must  
15 have regard to the principle that information should only be  
16 prescribed for the purposes of that paragraph if the information is  
17 reasonably required for the responsible scrutiny by the Secretary of  
18 the operation of the scheme embodied in subsection (7A).

## 19 **5 After subsection 21A(11)**

20 Insert:

- 21 (11A) A person commits an offence if:  
22 (a) the person is a health practitioner; and  
23 (b) the person is included in a class of health practitioners  
24 specified in subsection 19(7A) rules; and  
25 (c) the person supplies:  
26 (i) therapeutic goods specified in those rules; or  
27 (ii) therapeutic goods included in a class of therapeutic  
28 goods specified in those rules; and  
29 (d) any of the following applies:  
30 (i) the supply is not in accordance with those rules;  
31 (ii) the supply is not in the circumstances specified in those  
32 rules;  
33 (iii) the supply is not in accordance with the conditions  
34 specified in those rules; and



- 
- 1 (e) either:
- 2 (i) the use of the goods has resulted in, or will result in,
- 3 harm or injury to any person; or
- 4 (ii) the use of the goods, if the goods were used, would
- 5 result in harm or injury to any person; and
- 6 (f) the harm or injury has resulted, will result, or would result,
- 7 because:
- 8 (i) the supply is not in accordance with those rules; or
- 9 (ii) the supply is not in the circumstances specified in those
- 10 rules; or
- 11 (iii) the supply is not in accordance with the conditions
- 12 specified in those rules.

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

- 14 (11B) A person commits an offence if:
- 15 (a) the person is a health practitioner; and
- 16 (b) the person is included in a class of health practitioners
- 17 specified in subsection 19(7A) rules; and
- 18 (c) the person supplies:
- 19 (i) therapeutic goods specified in those rules; or
- 20 (ii) therapeutic goods included in a class of therapeutic
- 21 goods specified in those rules; and
- 22 (d) any of the following applies:
- 23 (i) the supply is not in accordance with those rules;
- 24 (ii) the supply is not in the circumstances specified in those
- 25 rules;
- 26 (iii) the supply is not in accordance with the conditions
- 27 specified in those rules; and
- 28 (e) the use of the goods, if goods were used, would be likely to
- 29 result in harm or injury to any person; and
- 30 (f) the harm or injury would be likely to result because:
- 31 (i) the supply is not in accordance with those rules; or
- 32 (ii) the supply is not in the circumstances specified in those
- 33 rules; or
- 34 (iii) the supply is not in accordance with the conditions
- 35 specified in those rules.

36 Penalty: 2,000 penalty units.

- 1 (11C) A person commits an offence if:  
2 (a) the person is a health practitioner; and  
3 (b) the person is included in a class of health practitioners  
4 specified in subsection 19(7A) rules; and  
5 (c) the person supplies:  
6 (i) therapeutic goods specified in those rules; or  
7 (ii) therapeutic goods included in a class of therapeutic  
8 goods specified in those rules; and  
9 (d) any of the following applies:  
10 (i) the supply is not in accordance with those rules;  
11 (ii) the supply is not in the circumstances specified in those  
12 rules;  
13 (iii) the supply is not in accordance with the conditions  
14 specified in those rules.

15 Penalty: 500 penalty units.

16 **6 After subsection 31B(3)**

17 Insert:

18 *Authority under subsection 19(7A) rules*

- 19 (3A) If a person is authorised, by subsection 19(7A) rules, to supply  
20 therapeutic goods, the Secretary may give the person a written  
21 notice requiring the person to give the Secretary specified  
22 information or documents relating to one or more of the following:  
23 (a) the supply of the goods;  
24 (b) the handling of the goods;  
25 (c) the monitoring of the supply of the goods;  
26 (d) the results of the supply of the goods;  
27 (e) any other matter prescribed by the regulations for the  
28 purposes of this paragraph in relation to goods of that kind.

29 **7 Subsections 31B(4) and (5)**

30 Omit “or (3)”, substitute “, (3) or (3A)”.

31 **8 Subparagraphs 32BD(1)(b)(v), (2)(b)(v) and (4)(b)(v)**

32 Omit “that is held”, substitute “or (7A) that covers the supply of the  
33 biological”.

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**9 Subparagraph 32BF(4)(b)(v)**

Omit “that is held”, substitute “or (7A) that covers the supply of the biological”.

**10 Subdivision D of Division 3 of Part 3-2A (heading)**

Repeal the heading, substitute:

**Subdivision D—Exempting biologicals for certain uses****11 Section 32CM (heading)**

Repeal the heading, substitute:

**32CM Exemptions for health practitioners****12 After subsection 32CM(7)**

Insert:

(7A) The Minister may, by legislative instrument, make rules authorising any health practitioner who is included in a specified class of health practitioners to supply a specified biological, for use in the treatment of humans, to the class or classes of recipients specified in those rules, so long as:

- (a) the biological is supplied in the circumstances specified in those rules; and
- (b) the conditions (if any) specified in those rules are satisfied.

(7B) In making rules under subsection (7A), the Minister must comply with:

- (a) such requirements (if any) as are prescribed by the regulations; and
- (b) such restrictions (if any) as are prescribed by the regulations; and
- (c) such limitations (if any) as are prescribed by the regulations.

(7C) If:

- (a) a person is authorised, by subsection (7A) rules, to supply a biological; and
- (b) the person supplies the biological in accordance with those rules;

the person must:

1 (c) notify the supply to the Secretary; and

2 (d) do so within 28 days after the supply.

3 (7D) A notification under subsection (7C) must:

4 (a) be in accordance with a form that is approved, in writing, by  
5 the Secretary; and

6 (b) contain such information as is prescribed by the regulations.

7 (7E) An approval of a form may require or permit information to be  
8 given in accordance with specified software requirements:

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

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

11 (7F) A person commits an offence if:

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

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

15 (c) the omission breaches the requirement.

16 Penalty: 10 penalty units.

17 (7G) An offence against subsection (7F) is an offence of strict liability.

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

19 (7H) In recommending to the Governor-General that regulations should  
20 be made for the purposes of paragraph (7D)(b), the Minister must  
21 have regard to the principle that information should only be  
22 prescribed for the purposes of that paragraph if the information is  
23 reasonably required for the responsible scrutiny by the Secretary of  
24 the operation of the scheme embodied in subsection (7A).

25 **13 Section 32CN (heading)**

26 Repeal the heading, substitute:

27 **32CN Criminal offences relating to the giving of an authority to a**  
28 **health practitioner**

29 **14 Subsection 32CN(4) (penalty)**

30 Omit “for contravention of this subsection”.

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**15 At the end of section 32CN**

Add:

- (5) A person commits an offence if:
- (a) the person is a health practitioner; and
  - (b) the person is included in a class of health practitioners specified in subsection 32CM(7A) rules; and
  - (c) the person supplies a biological specified in those rules; and
  - (d) any of the following applies:
    - (i) the supply is not in accordance with those rules;
    - (ii) the supply is not in the circumstances specified in those rules;
    - (iii) the supply is not in accordance with the conditions specified in those rules; and
  - (e) either:
    - (i) the use of the biological has resulted in, or will result in, harm or injury to any person; or
    - (ii) the use of the biological, if the biological were used, would result in harm or injury to any person; and
  - (f) the harm or injury has resulted, will result, or would result, because:
    - (i) the supply is not in accordance with those rules; or
    - (ii) the supply is not in the circumstances specified in those rules; or
    - (iii) the supply is not in accordance with the conditions specified in those rules.

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

- (6) A person commits an offence if:
- (a) the person is a health practitioner; and
  - (b) the person is included in a class of health practitioners specified in subsection 32CM(7A) rules; and
  - (c) the person supplies a biological specified in those rules; and
  - (d) any of the following applies:
    - (i) the supply is not in accordance with those rules;
    - (ii) the supply is not in the circumstances specified in those rules;

- 1 (iii) the supply is not in accordance with the conditions  
2 specified in those rules; and  
3 (e) the use of the biological, if the biological were used, would  
4 be likely to result in harm or injury to any person; and  
5 (f) the harm or injury would be likely to result because:  
6 (i) the supply is not in accordance with those rules; or  
7 (ii) the supply is not in the circumstances specified in those  
8 rules; or  
9 (iii) the supply is not in accordance with the conditions  
10 specified in those rules.

11 Penalty: 2,000 penalty units.

- 12 (7) A person commits an offence if:  
13 (a) the person is a health practitioner; and  
14 (b) the person is included in a class of health practitioners  
15 specified in subsection 32CM(7A) rules; and  
16 (c) the person supplies a biological specified in those rules; and  
17 (d) any of the following applies:  
18 (i) the supply is not in accordance with those rules;  
19 (ii) the supply is not in the circumstances specified in those  
20 rules;  
21 (iii) the supply is not in accordance with the conditions  
22 specified in those rules.

23 Penalty for contravention of this subsection: 500 penalty units.

## 24 **16 After subsection 32JG(3)**

25 Insert:

26 *Authority under subsection 32CM(7A) rules*

- 27 (3A) If a person is authorised, by subsection 32CM(7A) rules, to supply  
28 a biological, the Secretary may give the person a written notice  
29 requiring the person to give the Secretary specified information, or  
30 to produce to the Secretary specified documents, relating to one or  
31 more of the following:  
32 (a) the supply of the biological;  
33 (b) the handling of the biological;  
34 (c) the monitoring of the supply of the biological;
-

- 
- 1 (d) the results of the supply of the biological;  
2 (e) any other matter prescribed by the regulations for the  
3 purposes of this paragraph in relation to a biological of that  
4 kind.

5 **17 Subsection 32JG(4)**

6 Omit “or (3)”, substitute “, (3) or (3A)”.

7 **18 Section 41H**

8 Omit “particular medical practitioners”, substitute “health  
9 practitioners”.

10 **19 Section 41HC (heading)**

11 Repeal the heading, substitute:

12 **41HC Exemptions for health practitioners**

13 **20 Subsection 41HC(2)**

14 After “An authority”, insert “under subsection (1)”.

15 **21 Subsection 41HC(3)**

16 Omit “a person’s authority”, substitute “the authority given to a person  
17 under subsection (1)”.

18 **22 Subsection 41HC(4)**

19 After “authority”, insert “under subsection (1)”.

20 **23 At the end of subsection 41HC(5)**

21 Add “under subsection (1)”.

22 **24 After subsection 41HC(5)**

23 Insert:

- 24 (6) The Minister may, by legislative instrument, make rules  
25 authorising any health practitioner who is included in a specified  
26 class of health practitioners to supply a specified kind of medical  
27 device, for use in the treatment of humans, to the class or classes of  
28 recipients specified in those rules, so long as:

- 1 (a) that kind of medical device is supplied in the circumstances  
2 specified in those rules; and  
3 (b) the conditions (if any) specified in those rules are satisfied.
- 4 (6A) In making rules under subsection (6), the Minister must comply  
5 with:  
6 (a) such requirements (if any) as are prescribed by the  
7 regulations; and  
8 (b) such restrictions (if any) as are prescribed by the regulations;  
9 and  
10 (c) such limitations (if any) as are prescribed by the regulations.
- 11 (6B) If:  
12 (a) a person is authorised, by subsection (6) rules, to supply a  
13 specified kind of medical device; and  
14 (b) the person supplies a medical device of that kind in  
15 accordance with those rules;  
16 the person must:  
17 (c) notify the supply to the Secretary; and  
18 (d) do so within 28 days after the supply.
- 19 (6C) A notification under subsection (6B) must:  
20 (a) be in accordance with a form that is approved, in writing, by  
21 the Secretary; and  
22 (b) contain such information as is prescribed by the regulations.
- 23 (6D) An approval of a form may require or permit information to be  
24 given in accordance with specified software requirements:  
25 (a) on a specified kind of data processing device; or  
26 (b) by way of a specified kind of electronic transmission.
- 27 (6E) A person commits an offence if:  
28 (a) the person is subject to a requirement under subsection (6B);  
29 and  
30 (b) the person omits to do an act; and  
31 (c) the omission breaches the requirement.
- 32 Penalty: 10 penalty units.
- 33 (6F) An offence against subsection (6E) is an offence of strict liability.  
34 Note: For strict liability, see section 6.1 of the *Criminal Code*.
-



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1 (6G) In recommending to the Governor-General that regulations should  
2 be made for the purposes of paragraph (6C)(b), the Minister must  
3 have regard to the principle that information should only be  
4 prescribed for the purposes of that paragraph if the information is  
5 reasonably required for the responsible scrutiny by the Secretary of  
6 the operation of the scheme embodied in subsection (6).

7 **25 Section 41JF (heading)**

8 Repeal the heading, substitute:

9 **41JF Secretary may require information relating to health**  
10 **practitioner authorisations**

11 **26 Subsection 41JF(1)**

12 Omit “section 41HC”, substitute “subsection 41HC(1)”.

13 **27 After subsection 41JF(1)**

14 Insert:

15 (1A) If a person is authorised, by subsection 41HC(6) rules, to supply a  
16 specified kind of medical device, the Secretary may give the  
17 person a written notice requiring the person to give the Secretary  
18 specified information or documents relating to one or more of the  
19 following:

- 20 (a) the supply of devices of that kind;  
21 (b) the handling of devices of that kind;  
22 (c) the monitoring of the supply of devices of that kind;  
23 (d) the results of the supply of devices of that kind;  
24 (e) any other matter prescribed by the regulations for the  
25 purposes of this paragraph in relation to devices of that kind.

26 **28 Subsection 41JF(2)**

27 Omit “The notice”, substitute “A notice under subsection (1) or (1A)”.

28 **29 Subsection 41JF(3)**

29 Omit “The notice”, substitute “A notice under subsection (1) or (1A)”.

30 **30 Paragraphs 41MO(1)(a), (2)(a) and (4)(a)**

31 Omit “section 41HC”, substitute “subsection 41HC(1)”.

---

1 **31 After subsection 41MO(4)**

2 Insert:

3 (4A) A person commits an offence if:

- 4 (a) the person is a health practitioner; and
- 5 (b) the person is included in a class of health practitioners
- 6 specified in subsection 41HC(6) rules; and
- 7 (c) the person supplies a medical device of a kind specified in
- 8 those rules; and
- 9 (d) any of the following applies:
- 10 (i) the supply is not in accordance with those rules;
- 11 (ii) the supply is not in the circumstances specified in those
- 12 rules;
- 13 (iii) the supply is not in accordance with the conditions
- 14 specified in those rules; and
- 15 (e) 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 (f) the harm or injury has resulted, will result, or would result,
- 21 because:
- 22 (i) the supply is not in accordance with those rules; or
- 23 (ii) the supply is not in the circumstances specified in those
- 24 rules; or
- 25 (iii) the supply is not in accordance with the conditions
- 26 specified in those rules.

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

28 (4B) A person commits an offence if:

- 29 (a) the person is a health practitioner; and
- 30 (b) the person is included in a class of health practitioners
- 31 specified in subsection 41HC(6) rules; and
- 32 (c) the person supplies a medical device of a kind specified in
- 33 those rules; and
- 34 (d) any of the following applies:
- 35 (i) the supply is not in accordance with those rules;

- 1 (ii) the supply is not in the circumstances specified in those  
 2 rules;
- 3 (iii) the supply is not in accordance with the conditions  
 4 specified in those rules; and
- 5 (e) the use of the device, if the device were used, would be likely  
 6 to result in harm or injury to any person; and
- 7 (f) the harm or injury would be likely to result because:
- 8 (i) the supply is not in accordance with those rules; or
- 9 (ii) the supply is not in the circumstances specified in those  
 10 rules; or
- 11 (iii) the supply is not in accordance with the conditions  
 12 specified in those rules.

13 Penalty: 2,000 penalty units.

- 14 (4C) A person commits an offence if:
- 15 (a) the person is a health practitioner; and
- 16 (b) the person is included in a class of health practitioners  
 17 specified in subsection 41HC(6) rules; and
- 18 (c) the person supplies a medical device of a kind specified in  
 19 those rules; and
- 20 (d) any of the following applies:
- 21 (i) the supply is not in accordance with those rules;
- 22 (ii) the supply is not in the circumstances specified in those  
 23 rules;
- 24 (iii) the supply is not in accordance with the conditions  
 25 specified in those rules.

26 Penalty: 500 penalty units.

27 **32 Section 53A (after table item 8)**

28 Insert:

29

8A	subsection 21A(11A)	subsection 21A(11C)
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30 **33 Section 53A (after table item 13F)**

31 Insert:

32

13FA	subsection 32CN(5)	subsection 32CN(7)
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1 **34 Section 53A (after table item 32)**

2           Insert:

3

                  32A           subsection 41MO(4A)           subsection 41MO(4C)

4 **35 Paragraph 56A(1)(b)**

5           After “approval”, insert “under subsection 19(1)”.

6 **36 Paragraph 56A(1)(b)**

7           Omit “section 19”, substitute “subsection 19(5)”.

8 **37 Paragraph 56A(1)(ba)**

9           Omit “41HC”, substitute “subsection 41HC(1)”.

1  
2

## **Schedule 4—Committees**

3

### ***Therapeutic Goods Act 1989***

4

#### **1 Subsection 10(4)**

5

Repeal the subsection.

6

#### **2 Subsection 36(3)**

7

Repeal the subsection.

1 **Schedule 5—Permissible ingredients**  
2

3 ***Therapeutic Goods Act 1989***

4 **1 Section 26BD**

5 Repeal the section.

6 **2 Before section 26C**

7 Insert:

8 **26BE Variation of section 26BB determination—application by**  
9 **person**

- 10 (1) A person may apply to the Secretary for a recommendation that the  
11 Minister vary a section 26BB determination.
- 12 (2) An application under subsection (1) must:
- 13 (a) be made in accordance with a form approved, in writing, by  
14 the Secretary; and
- 15 (b) set out the recommendation sought; and
- 16 (c) be delivered to an office of the Department specified in the  
17 form; and
- 18 (d) be accompanied by the prescribed application fee (if any).

19 *Decision by Secretary whether to make recommendation*

- 20 (3) If:
- 21 (a) an application is made under subsection (1); and
- 22 (b) any applicable prescribed evaluation fee has been paid;
- 23 the Secretary must carry out an evaluation of whether to make the  
24 recommendation.
- 25 (4) After carrying out the evaluation, the Secretary must:
- 26 (a) make the recommendation; or
- 27 (b) refuse to make the recommendation.
- 28 (5) In deciding whether to make the recommendation, the Secretary  
29 must have regard to:
- 30 (a) the quality and safety of the ingredients concerned; and

- 1 (b) such other matters (if any) as the Secretary considers  
2 relevant.

3 *Minister may vary determination*

- 4 (6) If the Secretary makes a recommendation under paragraph (4)(a),  
5 the Minister must:  
6 (a) by legislative instrument, vary the section 26BB  
7 determination; or  
8 (b) refuse to vary the section 26BB determination.
- 9 (7) In making a decision under subsection (6), the Minister must have  
10 regard to:  
11 (a) the recommendation made under paragraph (4)(a); and  
12 (b) such other matters (if any) as the Minister considers relevant.

13 *Further information*

- 14 (8) The Secretary may, by written notice given to a person who has  
15 made an application under subsection (1), require the person to:  
16 (a) give the Secretary such further information in connection  
17 with the application as is specified in the notice; and  
18 (b) do so within such reasonable time as is specified in the  
19 notice.

20 *Applications or information may be given electronically*

- 21 (9) An approval of a form mentioned in paragraph (2)(a), or a notice  
22 mentioned in subsection (8), may require or permit an application  
23 or information to be given in accordance with specified software  
24 requirements:  
25 (a) on a specified kind of data processing device; or  
26 (b) by way of a specified kind of electronic transmission.

27 **3 After subsection 60(2A)**

28 Insert:

- 29 (2B) If the Secretary decides, under paragraph 26BE(4)(b), to refuse to  
30 make a recommendation, a person is not entitled to request the  
31 Minister to reconsider the decision unless the person made an  
32 application under subsection 26BE(1) for the recommendation.

1 **4 Transitional provisions**

2 (1) If:

- 3 (a) an application was made under subsection 26BD(1) of the  
4 *Therapeutic Goods Act 1989* before the commencement of  
5 this item; and  
6 (b) no decision was made on the application before that  
7 commencement;

8 then, despite the repeal of section 26BD of the *Therapeutic Goods Act*  
9 *1989* by this Schedule, that section continues to apply, in relation to:

- 10 (c) the application; and  
11 (d) a variation of a determination in response to the application;

12 as if that repeal had not happened.

13 (2) The repeal of section 26BD of the *Therapeutic Goods Act 1989* by this  
14 Schedule does not affect the continuity of a variation made under that  
15 section before the commencement of this item.



1 **Schedule 6—Approval of therapeutic goods,**  
2 **biologicals and medical devices**  
3

4 ***Therapeutic Goods Act 1989***

5 **1 After section 25**

6 Insert:

7 **25AAA Therapeutic goods (priority applicant) determinations**

- 8 (1) The regulations may make provision for and in relation to  
9 empowering the Secretary to make therapeutic goods (priority  
10 applicant) determinations.
- 11 (2) A *therapeutic goods (priority applicant) determination* is a  
12 determination that, for the purposes of this Act, a specified person  
13 is a priority applicant in relation to any section 23 application that  
14 may be made by the person for the registration of therapeutic  
15 goods specified in the determination.
- 16 (3) The regulations may make provision for and in relation to the  
17 following matters:  
18 (a) applications for therapeutic goods (priority applicant)  
19 determinations;  
20 (b) the approval by the Secretary of a form for such an  
21 application;  
22 (c) information that must accompany such an application;  
23 (d) the application fee for such an application.
- 24 (4) The regulations may make provision for and in relation to the  
25 following matters:  
26 (a) empowering the Secretary to revoke a therapeutic goods  
27 (priority applicant) determination;  
28 (b) the consequences of the revocation of a therapeutic goods  
29 (priority applicant) determination.
- 30 (5) Subsections (3) and (4) do not limit subsection (1).
- 31 (6) A period prescribed under paragraph 63(2)(da) for the evaluation  
32 of therapeutic goods covered by a section 23 application for which

1 the applicant is a priority applicant may be shorter than the period  
2 prescribed under that paragraph for the evaluation of therapeutic  
3 goods covered by a section 23 application for which the applicant  
4 is not a priority applicant.

- 5 (7) The regulations may provide that, if:  
6 (a) a person is a priority applicant in relation to a section 23  
7 application made by the person; and  
8 (b) a decision is made on the application;  
9 a statement setting out the decision may be published on the  
10 Department's website.
- 11 (8) The express references in this section to the Secretary do not, by  
12 implication, prevent the regulations from empowering the  
13 Secretary to delegate any or all of the Secretary's functions or  
14 powers under regulations made for the purposes of this section.
- 15 (9) If a therapeutic goods (priority applicant) determination is in force  
16 under the regulations, the determination may be published on the  
17 Department's website.
- 18 (10) A therapeutic goods (priority applicant) determination made under  
19 the regulations is not a legislative instrument.
- 20 (11) Subsection 33(3AB) of the *Acts Interpretation Act 1901* does not  
21 apply to the specification of a person in a therapeutic goods  
22 (priority applicant) determination.

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

## 25 **2 After section 32DE**

26 Insert:

### 27 **32DEA Biologicals (priority applicant) determinations**

- 28 (1) The regulations may make provision for and in relation to  
29 empowering the Secretary to make biologicals (priority applicant)  
30 determinations.
- 31 (2) A ***biologicals (priority applicant) determination*** is a determination  
32 that, for the purposes of this Act, a specified person is a priority  
33 applicant in relation to any section 32DD application that may be

- 1                   made by the person for the inclusion in the Register of a biological  
2                   specified in the determination.
- 3                   (3) The regulations may make provision for and in relation to the  
4                   following matters:
- 5                   (a) applications for biologicals (priority applicant)  
6                   determinations;
- 7                   (b) the approval by the Secretary of a form for such an  
8                   application;
- 9                   (c) information that must accompany such an application;
- 10                  (d) the application fee for such an application.
- 11                  (4) The regulations may make provision for and in relation to the  
12                  following matters:
- 13                  (a) empowering the Secretary to revoke a biologicals (priority  
14                  applicant) determination;
- 15                  (b) the consequences of the revocation of a biologicals (priority  
16                  applicant) determination.
- 17                  (5) Subsections (3) and (4) do not limit subsection (1).
- 18                  (6) A period prescribed under paragraph 63(2)(daa) for the evaluation  
19                  of a biological covered by a section 32DD application for which  
20                  the applicant is a priority applicant may be shorter than the period  
21                  prescribed under that paragraph for the evaluation of a biological  
22                  covered by a section 32DD application for which the applicant is  
23                  not a priority applicant.
- 24                  (7) The regulations may provide that, if:
- 25                  (a) a person is a priority applicant in relation to a section 32DD  
26                  application made by the person; and
- 27                  (b) a decision is made on the application;
- 28                  a statement setting out the decision may be published on the  
29                  Department's website.
- 30                  (8) The express references in this section to the Secretary do not, by  
31                  implication, prevent the regulations from empowering the  
32                  Secretary to delegate any or all of the Secretary's functions or  
33                  powers under regulations made for the purposes of this section.

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

4 (10) A biologicals (priority applicant) determination made under the  
5 regulations is not a legislative instrument.

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

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

### 11 3 After section 41EC

12 Insert:

#### 13 41ECA Conformity assessment (priority applicant) determinations

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

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

23 (3) The regulations may make provision for and in relation to the  
24 following matters:  
25 (a) applications for conformity assessment (priority applicant)  
26 determinations;  
27 (b) the approval by the Secretary of a form for such an  
28 application;  
29 (c) information that must accompany such an application;  
30 (d) the application fee for such an application.

31 (4) The regulations may make provision for and in relation to the  
32 following matters:  
33 (a) empowering the Secretary to revoke a conformity assessment  
34 (priority applicant) determination;

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- 1 (b) the consequences of the revocation of a conformity  
2 assessment (priority applicant) determination.
- 3 (5) Subsections (3) and (4) do not limit subsection (1).
- 4 (6) The regulations may make provision for and in relation to the  
5 priority to be given by the Secretary to consideration of a  
6 section 41EB application where the applicant is a priority  
7 applicant.
- 8 (7) The regulations may provide that, if:  
9 (a) a person is a priority applicant in relation to a section 41EB  
10 application made by the person; and  
11 (b) a decision is made on the application;  
12 a statement setting out the decision may be published on the  
13 Department's website.
- 14 (8) The express references in this section to the Secretary do not, by  
15 implication, prevent the regulations from empowering the  
16 Secretary to delegate any or all of the Secretary's functions or  
17 powers under regulations made for the purposes of this section.
- 18 (9) If a conformity assessment (priority applicant) determination is in  
19 force under the regulations, the determination may be published on  
20 the Department's website.
- 21 (10) A conformity assessment (priority applicant) determination made  
22 under the regulations is not a legislative instrument.
- 23 (11) Subsection 33(3AB) of the *Acts Interpretation Act 1901* does not  
24 apply to the specification of a person in a conformity assessment  
25 (priority applicant) determination.

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

#### 28 **4 Before section 41FL**

29 Insert:

#### 30 **41FKA Medical devices (priority applicant) determinations**

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

- 1 (2) A *medical devices (priority applicant) determination* is a  
2 determination that, for the purposes of this Act, a specified person  
3 is a priority applicant in relation to any section 41FC application  
4 that may be made by the person for the inclusion in the Register of  
5 a medical device of a kind specified in the determination.
- 6 (3) The regulations may make provision for and in relation to the  
7 following matters:  
8 (a) applications for medical devices (priority applicant)  
9 determinations;  
10 (b) the approval by the Secretary of a form for such an  
11 application;  
12 (c) information that must accompany such an application;  
13 (d) the application fee for such an application.
- 14 (4) The regulations may make provision for and in relation to the  
15 following matters:  
16 (a) empowering the Secretary to revoke a medical devices  
17 (priority applicant) determination;  
18 (b) the consequences of the revocation of a medical devices  
19 (priority applicant) determination.
- 20 (5) Subsections (3) and (4) do not limit subsection (1).
- 21 (6) The regulations may make provision for and in relation to the  
22 priority to be given by the Secretary to consideration of a  
23 section 41FC application where the applicant is a priority  
24 applicant.
- 25 (7) The regulations may provide that, if:  
26 (a) a person is a priority applicant in relation to a section 41FC  
27 application made by the person; and  
28 (b) a decision is made on the application;  
29 a statement setting out the decision may be published on the  
30 Department's website.
- 31 (8) The express references in this section to the Secretary do not, by  
32 implication, prevent the regulations from empowering the  
33 Secretary to delegate any or all of the Secretary's functions or  
34 powers under regulations made for the purposes of this section.

- 1 (9) If a medical devices (priority applicant) determination is in force  
2 under the regulations, the determination may be published on the  
3 Department's website.
- 4 (10) A medical devices (priority applicant) determination made under  
5 the regulations is not a legislative instrument.
- 6 (11) Subsection 33(3AB) of the *Acts Interpretation Act 1901* does not  
7 apply to the specification of a person in a medical devices (priority  
8 applicant) determination.
- 9 Note: Subsection 33(3AB) of the *Acts Interpretation Act 1901* deals with  
10 specification by class.

1  
2

## Schedule 7—Time limits

3

### *Therapeutic Goods Act 1989*

4

#### **1 After paragraph 63(2)(dd)**

5

Insert:

6

(de) provide for the periods within which the performance of specified functions conferred on the Secretary by this Act is to be completed; and

7

8

9

(df) provide for the periods within which specified decisions under this Act are to be made by the Secretary; and

10



1 **Schedule 8—Record-keeping etc.**  
2

3 ***Therapeutic Goods Act 1989***

4 **1 At the end of subparagraph 28(5)(a)(i)**

5 Add “, complies with record-keeping requirements covered by  
6 paragraph (c) or (ca), or keeps documents that relate to the subject  
7 goods”.

8 **2 At the end of paragraph 28(5)(a)**

9 Add:

- 10 (iv) while on those premises, to inspect, and make copies of,  
11 any records kept in compliance with paragraph (c) or  
12 (ca); and  
13 (v) while on those premises, to inspect, and make copies of,  
14 any documents that relate to the subject goods; and

15 **3 After paragraph 28(5)(c)**

16 Insert:

- 17 (ca) comply, in relation to the subject goods, with any  
18 record-keeping requirements that are prescribed; and

19 **4 Paragraph 28(5)(d)**

20 Omit “such record”, substitute “record kept in compliance with  
21 paragraph (c) or (ca)”.

22 **5 Paragraph 46A(4)(a)**

23 Omit all the words from and including “being” to and including “goods;  
24 and”, substitute:

25 being premises connected with:

- 26 (iv) the importation, export, manufacture or supply of  
27 therapeutic goods; or  
28 (v) the keeping of documents relating to the importation,  
29 export, manufacture or supply of therapeutic goods; or  
30 (vi) the keeping of records in compliance with  
31 paragraph 28(5)(c) or (ca); and

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## **Schedule 9—Applications for variations of entries in Register**

### ***Therapeutic Goods Act 1989***

#### **1 At the end of subsection 9D(7)**

Add:

; and (g) the request is accompanied by information that is:

(i) of a kind determined under subsection (8); and

(ii) in a form approved, in writing, by the Secretary.

#### **2 At the end of section 9D**

Add:

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

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

#### **3 Application of amendments**

The amendments of section 9D of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to requests made after the commencement of this item.

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## Schedule 10—Public notification and recalls

### *Therapeutic Goods Act 1989*

#### **1 Division 2A of Part 3-2 (heading)**

Repeal the heading, substitute:

#### **Division 2A—Public notification, and recall, of therapeutic goods**

#### **2 Section 30EA (heading)**

Repeal the heading, substitute:

#### **30EA Public notification, and recall, of therapeutic goods**

#### **3 Subsection 30EA(1) (table items 1, 2, 3 and 4, column headed “Circumstance relating to therapeutic goods”)**

After “but”, insert “the Secretary is satisfied that”.

#### **4 Subsection 30EA(1) (table item 5, column headed “Circumstance relating to therapeutic goods”)**

Omit “, 19D(1) or 42E(1) or section 42EA”, substitute “or 19D(1)”.

#### **5 Subsection 30EA(1) (at the end of the table)**

Add:

8.       The goods are counterfeit (within       The person supplying the goods  
the meaning of section 42E)

#### **6 Paragraph 30EA(2)(a)**

Omit “recover”, substitute “recall”.

#### **7 After paragraph 30EA(2)(b)**

Insert:

- (ba) to inform the public or a specified class of persons, in the specified manner and within such reasonable period as is specified, of specified information, or of information of a specified kind, relating to either or both of the following:

- 1 (i) therapeutic goods;  
2 (ii) the circumstances referred to in paragraph (1)(a) in  
3 relation to therapeutic goods;

4 **8 At the end of subsection 30EA(2)**

5 Add:  
6 ; (d) to notify the Secretary, in the specified manner and within  
7 such reasonable period as is specified, of specified  
8 information, or of information of a specified kind, relating to  
9 the persons to whom therapeutic goods have been supplied.

10 **9 Subsection 30EA(4)**

11 Omit “recover”, substitute “recall”.

12 **10 Subsection 30EA(4)**

13 Omit “recovered”, substitute “recalled”.

14 **11 At the end of Division 2A of Part 3-2**

15 Add:

16 **30EE Saving of other laws**

17 This Division is not intended to exclude or limit the operation of  
18 any other law of the Commonwealth or any law of a State or  
19 Territory.

20 **12 Subsection 30F(2)**

21 Omit “recover”, substitute “recall”.

22 **13 Subsection 30F(2)**

23 Omit “recovered”, substitute “recalled”.

24 **14 Paragraph 30F(3)(a)**

25 Omit “recover”, substitute “recall”.

26 **15 At the end of section 30F**

27 Add:

1 *Saving of other laws*

2 (7) This section is not intended to exclude or limit the operation of any  
3 other law of the Commonwealth or any law of a State or Territory.

4 **16 Section 32**

5 Omit “recovery”, substitute “recall”.

6 **17 Subsection 32CJ(2)**

7 Omit “recover”, substitute “recall”.

8 **18 Subsection 32CJ(2)**

9 Omit “recovered”, substitute “recalled”.

10 **19 Paragraph 32CJ(3)(a)**

11 Omit “recover”, substitute “recall”.

12 **20 At the end of section 32CJ**

13 Add:

14 *Saving of other laws*

15 (12) This section is not intended to exclude or limit the operation of any  
16 other law of the Commonwealth or any law of a State or Territory.

17 **21 Division 8 of Part 3-2A (heading)**

18 Repeal the heading, substitute:

19 **Division 8—Public notification, and recall, of biologicals**

20 **22 Section 32H**

21 Omit “recover”, substitute “recall”.

22 **23 Section 32HA (heading)**

23 Repeal the heading, substitute:

1 **32HA Public notification, and recall, of biologicals**

2 **24 Subsection 32HA(1) (table item 1, column headed**  
3 **“Circumstance relating to biological”)**

4 After “but”, insert “the Secretary is satisfied that”.

5 **25 Subsection 32HA(1) (table item 2, column headed**  
6 **“Circumstance relating to biological”)**

7 After “but”, insert “the Secretary is satisfied that”.

8 **26 Subsection 32HA(1) (table item 3, column headed**  
9 **“Circumstance relating to biological”)**

10 After “but”, insert “the Secretary is satisfied that”.

11 **27 Subsection 32HA(1) (table item 4, column headed**  
12 **“Circumstance relating to biological”)**

13 After “but”, insert “the Secretary is satisfied that”.

14 **28 Subsection 32HA(1) (table item 7, column headed**  
15 **“Circumstance relating to biological”)**

16 Omit “supplied in contravention of subsection 42E(1) or section 42EA”,  
17 substitute “counterfeit goods (within the meaning of section 42E)”.

18 **29 Subsection 32HA(1) (table item 8, column headed**  
19 **“Circumstance relating to biological”)**

20 After “but”, insert “the Secretary is satisfied that”.

21 **30 Paragraph 32HA(2)(a)**

22 Omit “recover”, substitute “recall”.

23 **31 After paragraph 32HA(2)(b)**

24 Insert:

25 (ba) to inform the public or a specified class of persons, in the  
26 specified manner and within such reasonable period as is  
27 specified, of specified information, or of information of a  
28 specified kind, relating to either or both of the following:

29 (i) the biological;

30 (ii) the circumstances referred to in paragraph (1)(a);

---

1 **32 At the end of subsection 32HA(2)**

2 Add:

3 ; (d) to notify the Secretary, in the specified manner and within  
4 such reasonable period as is specified, of specified  
5 information, or of information of a specified kind, relating to  
6 the persons to whom the biological has been supplied.

7 **33 Subsection 32HA(4)**

8 Omit “recover”, substitute “recall”.

9 **34 Subsection 32HA(4)**

10 Omit “recovered”, substitute “recalled”.

11 **35 At the end of Division 8 of Part 3-2A**

12 Add:

13 **32HF Saving of other laws**

14 This Division is not intended to exclude or limit the operation of  
15 any other law of the Commonwealth or any law of a State or  
16 Territory.

17 **36 Paragraph 41BB(f)**

18 Omit “recovery”, substitute “recall”.

19 **37 Section 41GR (paragraph (b) of note 2)**

20 Omit “recovery”, substitute “recall”.

21 **38 Part 4-9 (heading)**

22 Repeal the heading, substitute:

23 **Part 4-9—Public notification, and recall, of medical**  
24 **devices**

25 **39 Section 41K**

26 Omit “recover”, substitute “recall”.

1 **40 Section 41KA (heading)**

2 Repeal the heading, substitute:

3 **41KA Public notification, and recall, of medical devices**

4 **41 Subsection 41KA(1) (table item 1, column headed**  
5 **“Circumstance relating to a kind of medical device”)**

6 After “but”, insert “the Secretary is satisfied that”.

7 **42 Subsection 41KA(1) (table item 2, column headed**  
8 **“Circumstance relating to a kind of medical device”)**

9 After “but”, insert “the Secretary is satisfied that”.

10 **43 Subsection 41KA(1) (table item 3, column headed**  
11 **“Circumstance relating to a kind of medical device”)**

12 After “but”, insert “the Secretary is satisfied that”.

13 **44 Subsection 41KA(1) (table item 4, column headed**  
14 **“Circumstance relating to a kind of medical device”)**

15 After “but”, insert “the Secretary is satisfied that”.

16 **45 Subsection 41KA(1) (at the end of the table)**

17 Add:

- |    |   |   |
|----|---|---|
| 8. | It is counterfeit goods (within the meaning of section 42E) | The person supplying the kind of medical device |
|----|---|---|

18 **46 Subsection 41KA(2)**

19 Omit “one or both”, substitute “one or more”.

20 **47 Paragraph 41KA(2)(a)**

21 Omit “recover”, substitute “recall”.

22 **48 At the end of subsection 41KA(2)**

23 Add:

24 ; (c) to inform the public or a specified class of persons, in the  
25 specified manner and within such reasonable period as is  
26 specified, of specified information, or of information of a  
27 specified kind, relating to either or both of the following:

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- 1 (i) medical devices of that kind;  
2 (ii) the circumstances referred to in paragraph (1)(a);  
3 (d) to publish, in the specified manner and within such  
4 reasonable period as is specified, specified information, or  
5 information of a specified kind, relating to the manufacture  
6 or distribution of medical devices of that kind;  
7 (e) to notify the Secretary, in the specified manner and within  
8 such reasonable period as is specified, of specified  
9 information, or of information of a specified kind, relating to  
10 the persons to whom medical devices of that kind have been  
11 supplied.

12 **49 Subsection 41KA(4)**

13 Omit “recover”, substitute “recall”.

14 **50 Subsection 41KA(4)**

15 Omit “recovered”, substitute “recalled”.

16 **51 At the end of Part 4-9**

17 Add:

18 **41KE Saving of other laws**

19 This Part is not intended to exclude or limit the operation of any  
20 other law of the Commonwealth or any law of a State or Territory.

21 **52 Paragraph 41MP(2)(b)**

22 Omit “recover”, substitute “recall”.

23 **53 Paragraph 41MPA(2)(b)**

24 Omit “recover”, substitute “recall”.

25 **54 Section 42V (heading)**

26 Repeal the heading, substitute:

1 **42V Recall of therapeutic goods because of actual or potential**  
2 **tampering**

3 **55 Paragraph 42V(2)(a)**

4 Omit “recover”, substitute “recall”.

5 **56 Subsection 42V(3)**

6 Omit “recovered”, substitute “recalled”.

7 **57 Section 42VA (heading)**

8 Repeal the heading, substitute:

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

11 **58 Section 42VB (heading)**

12 Repeal the heading, substitute:

13 **42VB Relief from liability for contraventions relating to the recall of**  
14 **therapeutic goods because of actual or potential**  
15 **tampering**

16 **59 Section 42W (heading)**

17 Repeal the heading, substitute:

18 **42W Supply etc. of therapeutic goods that are subject to recall**  
19 **requirements**

20 **60 Subparagraphs 42W(1)(b)(i) and (2)(b)(i)**

21 Omit “recover”, substitute “recall”.

22 **61 Paragraph 61(4A)(da)**

23 Omit “recovery”, substitute “recall”.

24 **62 After paragraph 61(4A)(da)**

25 Insert:

26 (db) action taken by the Secretary under section 32HA (about  
27 notification and recall of biologicals);

---

(dc) action taken by the Secretary under section 41KA (about notification and recall of medical devices);

### **63 Application of amendments**

#### *Therapeutic goods*

- (1) The amendments of section 30EA of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to requirements imposed after the commencement of this item.
- (2) The amendments of sections 30F and 32CJ of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to notices given after the commencement of this item.

#### *Biologicals*

- (3) The amendments of section 32HA of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to requirements imposed after the commencement of this item.

#### *Medical devices*

- (4) The amendments of section 41KA of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to requirements imposed after the commencement of this item.
- (5) The amendments of sections 41MP and 41MPA of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to steps taken after the commencement of this item.

#### *Product tampering*

- (6) The amendments of sections 42V, 42VA, 42VB and 42W of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to requirements imposed after the commencement of this item.

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2

## Schedule 11—Obtaining information etc.

3

### *Therapeutic Goods Act 1989*

4

#### **1 Paragraph 31(2)(fa)**

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6  
7

Omit “the matters covered by a certification by the person under paragraph 26A(2)(j)”, substitute “any of the matters covered by a certification by the person under subsection 26A(2) or (2A)”.

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#### **2 Application of amendments**

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The amendment of section 31 of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to notices given under section 31 of that Act after the commencement of this item, whether:

- (a) if the notice is given to an applicant for the registration or listing of therapeutic goods—the application is made before or after that commencement; or
- (b) if the notice is given to a person in relation to whom therapeutic goods are or were registered or listed—the goods are registered or listed before or after that commencement.

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## Schedule 12—Miscellaneous amendments

### *Therapeutic Goods Act 1989*

#### **1 Subsection 3(1) (definition of *National Manager of the Therapeutic Goods Administration*)**

Repeal the definition.

#### **2 After subsection 19A(1)**

Insert:

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

- (a) registered goods that could act as a substitute for the goods are unavailable or are in short supply; and
- (b) either:
  - (i) the goods that are the subject of the application are not registered or approved for general marketing in any of the foreign countries specified by the Secretary in a determination under subsection (3); or
  - (ii) the goods that are the subject of the application are registered or approved for general marketing in at least one foreign country specified by the Secretary in a determination under subsection (3), but are not readily available for importation into, and supply in, Australia; and
- (c) the goods are registered or approved for general marketing in a foreign country; and
- (d) the manufacturing and quality control procedures used in the manufacture of the goods are acceptable; and
- (e) the goods are of a kind:
  - (i) included in Schedule 10 of the Therapeutic Goods Regulations; or
  - (ii) specified by the Secretary in a determination under subsection (4); and
- (f) the approval is necessary in the interests of public health.

1 **3 Subsection 19A(3)**

2 Omit “this section”, substitute “subsection (1)”.

3 **4 Paragraph 19A(9)(a)**

4 After “(d),” (first occurring), insert “paragraph (1A)(a), (b), (c), (d), (e)  
5 or (f),”.

6 **5 At the end of section 19A**

7 Add:

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

10 **6 At the end of subsection 30(1)**

11 Add:

12 ; or (g) the Secretary is satisfied that a statement made in, or in  
13 connection with, the application for registration or listing of  
14 the goods was false or misleading in a material particular; or  
15 (h) the annual registration or listing charge is not paid within 28  
16 days after it becomes payable.

17 **7 Subparagraph 30(2)(ea)(ii)**

18 Omit “regulations; or”, substitute “regulations.”.

19 **8 Paragraph 30(2)(f)**

20 Repeal the paragraph.

21 **9 After section 30A**

22 Insert:

23 **30AA Revocation of cancellation of registration or listing—payment**  
24 **of annual registration or listing charge**

25 (1) If:

26 (a) the Secretary cancels the registration or listing of therapeutic  
27 goods because the annual registration or listing charge was  
28 not paid within 28 days after it became payable (see  
29 paragraph 30(1)(h)); and

- 
- 1 (b) before the end of the period of 90 days beginning on the day  
2 the goods ceased to be registered or listed, the person  
3 requests, in writing, the Secretary to revoke the cancellation;  
4 and  
5 (c) the annual registration or listing charge has been paid; and  
6 (d) the request is accompanied by the prescribed application fee;  
7 the Secretary may, by notice in writing given to the person, revoke  
8 the cancellation.
- 9 (2) If the cancellation is revoked, the cancellation is taken never to  
10 have occurred.

11 **10 At the end of subsection 30F(4)**

12 Add “or on the Department’s website”.

13 **11 After section 31B**

14 Insert:

15 **31BA Secretary may require information about therapeutic goods**  
16 **approved under section 19A**

- 17 (1) The Secretary may give to a person who is granted an approval  
18 under subsection 19A(1), (1A) or (2) in relation to specified  
19 therapeutic goods a written notice requiring the person to give to  
20 the Secretary specified information, or to produce to the Secretary  
21 specified documents, relating to one or more of the following:  
22 (a) the supply of the goods;  
23 (b) the handling of the goods;  
24 (c) the monitoring of the supply of the goods;  
25 (d) the results of the supply of the goods;  
26 (e) any other matter prescribed by the regulations.
- 27 *Compliance*
- 28 (2) A person given a notice under subsection (1) must give the  
29 information, or produce the documents, to the Secretary:  
30 (a) within the period specified in the notice (which must not be  
31 less than 14 days after the day the notice is given); and  
32 (b) in the form specified in the notice.

1 (3) The form may require or permit the information to be given, or the  
2 documents to be produced, in accordance with specified software  
3 requirements:

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

6 **12 Section 31C (heading)**

7 Repeal the heading, substitute:

8 **31C Criminal offence for failing to give information or documents**  
9 **sought under section 31A, 31AA, 31B or 31BA**

10 **13 Paragraph 31C(a)**

11 Omit “or 31B”, substitute “, 31B or 31BA”.

12 **14 Subsection 31D(1)**

13 Omit “or 31B”, substitute “, 31B or 31BA”.

14 **15 Paragraph 31E(1)(c)**

15 Omit “or 31B”, substitute “, 31B or 31BA”.

16 **16 Subsection 31F(1)**

17 Omit “or 31B”, substitute “, 31B or 31BA”.

18 **17 Subparagraphs 32BA(1)(b)(v), (2)(b)(v) and (4)(b)(v)**

19 After “32CO(1)”, insert “, (1A)”.

20 **18 Subparagraphs 32BD(1)(b)(vi), (2)(b)(vi) and (4)(b)(vi)**

21 After “32CO(1)”, insert “, (1A)”.

22 **19 Subparagraphs 32BF(1)(b)(v) and (4)(b)(vi)**

23 After “32CO(1)”, insert “, (1A)”.

24 **20 Subparagraph 32BH(b)(vi)**

25 After “32CO(1)”, insert “, (1A)”.

26 **21 Subparagraphs 32BI(1)(c)(iv), (2)(c)(iv) and (4)(c)(iv)**

27 After “32CO(1)”, insert “, (1A)”.

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**22 Subparagraph 32BJ(4)(b)(vi)**

After “32CO(1)”, insert “, (1A)”.

**23 Paragraph 32BK(2)(f)**

After “32CO(1)”, insert “, (1A)”.

**24 At the end of subsection 32CJ(4)**

Add “or on the Department’s website”.

**25 After subsection 32CO(1)**

Insert:

(1A) The Secretary may, by notice in writing, grant an approval to a person for:

- (a) the importation into Australia of a specified biological; or
- (b) the importation into Australia of a specified biological and the supply in Australia of that biological;

if the Secretary is satisfied that:

- (c) therapeutic goods included in the Register that could act as a substitute for the biological are unavailable or are in short supply; and

(d) either:

- (i) the biological that is the subject of the application for approval is not registered or approved for general marketing in any of the foreign countries specified by the Secretary under subsection (5); or
- (ii) the biological that is the subject of the application for approval is registered or approved for general marketing in at least one foreign country specified by the Secretary under subsection (5), but is not readily available for importation into, and supply in, Australia; and

(e) the biological is registered or approved for general marketing in a foreign country; and

(f) the manufacturing and quality control procedures used in the manufacture of the biological are acceptable; and

(g) the biological is of a kind specified by the Secretary in a determination under subsection (6); and

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

1 **26 Paragraph 32CO(8)(b)**

2 After “(1)”, insert “, (1A)”.

3 **27 Paragraph 32CO(11)(a)**

4 After “(f),” (first occurring), insert “paragraph (1A)(c), (d), (e), (f), (g)  
5 or (h),”.

6 **28 Subsection 32CO(13)**

7 After “(1)”, insert “, (1A)”.

8 **29 After section 32GD**

9 Insert:

10 **32GDA Revocation of cancellation of biological upon request—**  
11 **payment of annual charge**

12 (1) If:

- 13 (a) the Secretary cancels the entry of a biological from the  
14 Register because the annual charge payable under the  
15 *Therapeutic Goods (Charges) Act 1989* in respect of the  
16 inclusion of the biological in the Register was not paid within  
17 28 days after it becomes payable; and  
18 (b) before the end of the period of 90 days beginning on the day  
19 the biological ceased to be included in the Register, the  
20 person requests, in writing, the Secretary to revoke the  
21 cancellation; and  
22 (c) the annual charge payable under the *Therapeutic Goods*  
23 *(Charges) Act 1989* in respect of the inclusion of the  
24 biological in the Register has been paid; and  
25 (d) the request is accompanied by the prescribed application fee;  
26 the Secretary may, by notice in writing given to the person, revoke  
27 the cancellation.

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

30 **30 Subsection 32HA(1) (table item 3, column headed**  
31 **“Circumstance relating to biological”, paragraph (e))**

32 After “32CO(1)”, insert “, (1A)”.

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1 **31 Subsection 32HA(1) (table item 4, column headed**  
2 **“Circumstance relating to biological”, paragraph (e))**

3 After “32CO(1)”, insert “, (1A)”.

4 **32 Subsection 32HA(1) (table item 5, column headed**  
5 **“Circumstance relating to biological”, paragraph (f))**

6 After “32CO(1)”, insert “, (1A)”.

7 **33 Subsection 32JH(1)**

8 After “32CO(1)”, insert “, (1A)”.

9 **34 After section 41AA**

10 Insert:

11 **41AB Secretary may require information or documents**

12 (1) If:

- 13 (a) a person is the holder of a licence; and  
14 (b) the person has carried out, or is carrying out, one or more  
15 steps in the manufacture of therapeutic goods;

16 the Secretary may, by written notice given to the person, require  
17 the person to:

- 18 (c) give the Secretary information, or produce to the Secretary  
19 documents, relating to one or more of the following:  
20 (i) the therapeutic goods;  
21 (ii) if the therapeutic goods consist of a mixture of  
22 ingredients—those ingredients;  
23 (iii) if the therapeutic goods consist of a mixture of  
24 ingredients—the suppliers of those ingredients;  
25 (iv) if the therapeutic goods consist of a combination of  
26 component parts—those component parts;  
27 (v) if the therapeutic goods consist of a combination of  
28 component parts—the suppliers of those component  
29 parts;  
30 (vi) the containers or packages used, or proposed to be used,  
31 to contain the therapeutic goods;  
32 (vii) the batch numbers of the therapeutic goods;  
33 (viii) the expiry dates of the therapeutic goods;
-

- 1 (ix) the distribution of the therapeutic goods;  
2 (x) the conformity of the therapeutic goods to a standard  
3 applicable to the goods;  
4 (xi) the step or steps that the person has carried out, or is  
5 carrying out, in the manufacture of the therapeutic  
6 goods;  
7 (xii) the premises used to carry out one or more steps in the  
8 manufacture of the therapeutic goods;  
9 (xiii) the observance of the manufacturing principles;  
10 (xiv) the names, qualifications and experience of individuals  
11 who have control of any of the steps that have been  
12 carried out, or are being carried out, in the manufacture  
13 of the therapeutic goods;  
14 (xv) the measures for quality assurance and quality control  
15 employed in the taking of any of the steps that have  
16 been carried out, or are being carried out, in the  
17 manufacture of the therapeutic goods;  
18 (xvi) compliance with the conditions of the licence;  
19 (xvii) whether there are grounds for revoking or suspending  
20 the licence;  
21 (xviii) any other matter that is prescribed by the regulations  
22 and that relates to the manufacture of the therapeutic  
23 goods; and  
24 (d) do so:  
25 (i) within such reasonable time as is specified in the notice;  
26 and  
27 (ii) in such form as is specified in the notice.
- 28 (2) The time specified in the notice must not be shorter than 14 days  
29 after the notice is given.
- 30 (3) The rule in subsection (2) does not apply if the Secretary is  
31 satisfied that, because of circumstances of urgency, the time  
32 specified in the notice should be shorter than 14 days after the  
33 notice is given.
- 34 (4) An approval of a form may require or permit the information to be  
35 given, or the documents to be produced, in accordance with  
36 specified software requirements:  
37 (a) on a specified kind of data processing device; or
-

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

2 **41AC Criminal offence for contravening a requirement in a notice**  
3 **under section 41AB**

4 A person commits an offence if:

- 5 (a) the person has been given a notice under section 41AB; and  
6 (b) the person omits to do an act; and  
7 (c) the omission contravenes a requirement in the notice.

8 Penalty: 400 penalty units.

9 **41AD False or misleading information—offence**

10 (1) A person commits an offence if:

- 11 (a) the person is given a notice under section 41AB; and  
12 (b) the person gives information to the Secretary in compliance,  
13 or purported compliance, with the notice; and  
14 (c) the person does so knowing that the information:  
15 (i) is false or misleading; or  
16 (ii) omits any matter or thing without which the information  
17 is misleading.

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

20 (2) Subsection (1) does not apply as a result of subparagraph (1)(c)(i)  
21 if the information is not false or misleading in a material particular.

22 Note: A defendant bears an evidential burden in relation to the matter in  
23 subsection (2).

24 (3) Subsection (1) does not apply as a result of subparagraph (1)(c)(ii)  
25 if the information did not omit any matter or thing without which  
26 the information is misleading in a material particular.

27 Note: A defendant bears an evidential burden in relation to the matter in  
28 subsection (3).

29 **41AE False or misleading documents—offence**

30 (1) A person commits an offence if:

- 1 (a) the person produces a document to the Secretary; and  
2 (b) the person does so knowing that the document is false or  
3 misleading; and  
4 (c) the document is produced in compliance, or purported  
5 compliance, with a notice given under section 41AB.

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

- 8 (2) Subsection (1) does not apply if the document is not false or  
9 misleading in a material particular.

10 Note: A defendant bears an evidential burden in relation to the matter in  
11 subsection (2).

- 12 (3) Subsection (1) does not apply to a person who produces a  
13 document if the document is accompanied by a written statement  
14 signed by the person or, in the case of a body corporate, by a  
15 competent officer of the body corporate:

- 16 (a) stating that the document is, to the knowledge of the  
17 first-mentioned person, false or misleading in a material  
18 particular; and  
19 (b) setting out, or referring to, the material particular in which  
20 the document is, to the knowledge of the first-mentioned  
21 person, false or misleading.

22 Note: A defendant bears an evidential burden in relation to the matter in  
23 subsection (3).

24 **41AF False or misleading information or documents—civil penalty**

- 25 (1) A person contravenes this section if:  
26 (a) the person is given a notice under section 41AB; and  
27 (b) the person gives information, or produces a document, in  
28 compliance or purported compliance with the notice; and  
29 (c) the information or document is false or misleading in a  
30 material particular.

31 Maximum civil penalty:

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

- 
- 1 (2) Subsection (1) does not apply to a person who produces a  
2 document if the document is accompanied by a written statement  
3 signed by the person or, in the case of a body corporate, by a  
4 competent officer of the body corporate:
- 5 (a) stating that the document is, to the knowledge of the  
6 first-mentioned person, false or misleading in a material  
7 particular; and
- 8 (b) setting out, or referring to, the material particular in which  
9 the document is, to the knowledge of the first-mentioned  
10 person, false or misleading.

#### 11 **41AG Self-incrimination**

- 12 (1) A person is not excused from giving information or a producing a  
13 document under a section 41AB notice on the ground that the  
14 giving of the information or the production of the document would  
15 tend to incriminate the person or expose the person to a penalty.
- 16 (2) However, in the case of an individual:
- 17 (a) the information given or the document produced; or  
18 (b) the giving of the information or the production of the  
19 document; or  
20 (c) any information, document or thing obtained as a direct or  
21 indirect consequence of giving the information or producing  
22 the document;
- 23 is not admissible in evidence in:
- 24 (d) criminal proceedings against the individual, except  
25 proceedings under, or arising out of, section 41AD or 41AE;  
26 or  
27 (e) proceedings for a pecuniary penalty order against the  
28 individual for a contravention of a civil penalty provision.

#### 29 **35 After subsection 41FN(5)**

30 Insert:

31 *Conditions prescribed by the regulations*

- 32 (5A) The inclusion of a kind of medical device in the Register is subject  
33 to such conditions (if any) as are prescribed by the regulations.

1                                    *Conditions determined by the Minister*

2                    (5B) The inclusion of a kind of medical device in the Register is subject  
3                    to such conditions (if any) as are determined under  
4                    subsection (5C).

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

7                    **36 After section 41GLA**

8                    Insert:

9                    **41GLB Revocation of cancellation of entries—payment of annual**  
10                    **charge**

11                    (1) If:

12                                    (a) the Secretary cancels the entry of a kind of medical device  
13                                    because the annual charge payable by a person under  
14                                    subsection 4(1B) of the *Therapeutic Goods (Charges) Act*  
15                                    *1989* in respect of the inclusion of the kind of device in the  
16                                    Register was not paid within 20 working days after it  
17                                    becomes payable; and

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

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

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

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

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

33                    **37 After subsection 41HD(1)**

34                    Insert:

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1 (1A) The Secretary may, by notice in writing, grant an approval to a  
2 person for:

3 (a) the importation into Australia of a specified medical device;  
4 or

5 (b) the importation into Australia of a specified medical device  
6 and the supply in Australia of that device;

7 if the Secretary is satisfied that:

8 (c) the kinds of medical devices included in the Register that  
9 could act as a substitute for the medical device are  
10 unavailable or are in short supply; and

11 (d) either:

12 (i) the medical device is not registered or approved for  
13 general marketing in any of the foreign countries  
14 specified in a determination under subsection (5); or

15 (ii) the medical device is registered or approved for general  
16 marketing in at least one foreign country specified in a  
17 determination under subsection (5), but is not readily  
18 available for importation into, and supply in, Australia;  
19 and

20 (e) the medical device is registered or approved for general  
21 marketing in a foreign country; and

22 (f) the manufacturing and quality control procedures used in the  
23 manufacture of the medical device are acceptable; and

24 (g) the medical device is specified in a determination under  
25 subsection (6); and

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

27 Note: For specification by class, see the *Acts Interpretation Act 1901* and  
28 subsection 13(3) of the *Legislation Act 2003*.

29 **38 Paragraph 41HD(10)(a)**

30 After “(f),” (first occurring), insert “paragraph (1A)(c), (d), (e), (f), (g)  
31 or (h),”.

32 **39 Subsection 41HD(12)**

33 After “(1),” insert “, (1A)”.

34 **40 Subsection 41JFA(1)**

35 After “41HD(1),” insert “, (1A)”.

1 **41 Subsection 41KA(1) (table item 3, column headed**  
2 **“Circumstance relating to a kind of medical device”,**  
3 **paragraph (d))**

4 After “41HD(1)”, insert “, (1A)”.

5 **42 Subsection 41KA(1) (table item 4, column headed**  
6 **“Circumstance relating to a kind of medical device”,**  
7 **paragraph (d))**

8 After “41HD(1)”, insert “, (1A)”.

9 **43 Subsection 41KA(1) (table item 5, column headed**  
10 **“Circumstance relating to a kind of medical device”,**  
11 **paragraph (e))**

12 After “41HD(1)”, insert “, (1A)”.

13 **44 Subparagraphs 41MI(1)(b)(iv), (2)(b)(iv) and (4)(b)(iv)**

14 After “41HD(1)”, insert “, (1A)”.

15 **45 Subparagraph 41MIB(1)(b)(iv)**

16 After “41HD(1)”, insert “, (1A)”.

17 **46 Subparagraph 41MK(b)(iv)**

18 After “41HD(1)”, insert “, (1A)”.

19 **47 Paragraph 41MLA(2)(d)**

20 After “41HD(1)”, insert “, (1A)”.

21 **48 Subparagraph 41MN(9)(b)(iv)**

22 After “41HD(1)”, insert “, (1A)”.

23 **49 Paragraphs 42T(1)(c) and (2)(d)**

24 Omit “or the National Manager of the Therapeutic Goods  
25 Administration”.

26 **50 Subparagraph 46A(4)(a)(iiaac)**

27 After “32CO(1)”, insert “, (1A)”.

**51 Subparagraph 46A(4)(a)(iib)**

After “41HD(1)”, insert “, (1A)”.

**52 Section 54BA (after table item 27)**

Insert:

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27A Subsection 41AD(1)

27B Subsection 41AE(1)

**53 Paragraph 56A(1)(bb)**

After “41HD(1)”, insert “, (1A)”.

**54 Paragraph 56A(1)(ca)**

After “32CO(1)”, insert “, (1A)”.

**55 Subsections 57(8) and (9)**

Repeal the subsections, substitute:

(8) The powers of the Secretary under section 19A or 32CO may be delegated only to a person who holds, occupies or performs the duties of a position in the Department prescribed by the regulations.

(9) The powers of the Secretary under section 41HD may be delegated only to a person who holds, occupies or performs the duties of a position in the Department prescribed by the regulations.

**56 Subsection 61(3A)**

After “31B,”, insert “31BA,”.

**57 Subsection 61(3A)**

After “32JH,”, insert “41AB,”.

**58 Transitional provisions**

(1) If:

(a) a determination was made under subsection 19A(3) of the *Therapeutic Goods Act 1989*; and

1 (b) the determination was in force immediately before the  
2 commencement of this item;  
3 the determination has effect, after the commencement of this item, as if  
4 a reference in the determination to a prerequisite for approval by the  
5 Secretary under that section 19A of that Act were a reference to a  
6 prerequisite for approval by the Secretary under subsection 19A(1) of  
7 that Act.

8 (2) If:  
9 (a) regulations were made for the purposes of paragraph 57(8)(b)  
10 of the *Therapeutic Goods Act 1989*; and  
11 (b) the regulations were in force immediately before the  
12 commencement of this item;  
13 the regulations have effect, after the commencement of this item, as if  
14 they had been made for the purposes of subsection 57(8) of the  
15 *Therapeutic Goods Act 1989* as amended by this Act.

16 (3) If:  
17 (a) regulations were made for the purposes of paragraph 57(9)(b)  
18 of the *Therapeutic Goods Act 1989*; and  
19 (b) the regulations were in force immediately before the  
20 commencement of this item;  
21 the regulations have effect, after the commencement of this item, as if  
22 they had been made for the purposes of subsection 57(9) of the  
23 *Therapeutic Goods Act 1989* as amended by this Act.