Therapeutic Goods Amendment (2016 Measures No. 1) Act 2017

No. 47, 2017

An Act to amend the *Therapeutic Goods Act 1989*, and for related purposes

Note: An electronic version of this Act is available on the Federal Register of Legislation (https://www.legislation.gov.au/)

Contents

1 Short title 1
2 Commencement 2
3 Schedules 3

Schedule 1—Variation of entries in Register 4

Therapeutic Goods Act 1989 4

Schedule 2—Conformity assessment of medical devices 6

Therapeutic Goods Act 1989 6

Schedule 3—Exemptions 11

A New Tax System (Goods and Services Tax) Act 1999 11

Therapeutic Goods Act 1989 11

Schedule 4—Committees 26

Therapeutic Goods Act 1989 26

Schedule 5—Permissible ingredients 27

Therapeutic Goods Act 1989 27

Schedule 6—Approval of therapeutic goods, biologicals and medical devices 30

Therapeutic Goods Act 1989 30

Schedule 7—Time limits 37

Therapeutic Goods Act 1989 37

Schedule 8—Record-keeping etc. 38

Therapeutic Goods Act 1989 38

Schedule 9—Applications for variations of entries in Register 39

Therapeutic Goods Act 1989 39

Schedule 10—Public notification and recalls 40

Therapeutic Goods Act 1989 40

Schedule 11—Obtaining information etc. 49

Therapeutic Goods Act 1989 49

Schedule 12—Miscellaneous amendments 50

Therapeutic Goods Act 1989 50

Therapeutic Goods Amendment (2016 Measures No. 1) Act 2017

No. 47, 2017

An Act to amend the *Therapeutic Goods Act 1989*, and for related purposes

[*Assented to 19 June 2017*]

The Parliament of Australia enacts:

1 Short title

This Act is the *Therapeutic Goods Amendment (2016 Measures No. 1) Act 2017*.

2 Commencement

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

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. Sections 1 to 3 and anything in this Act not elsewhere covered by this table	The day this Act receives the Royal Assent.	19 June 2017
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.	1 July 2017 (F2017N00047)
3. Schedules 2 to 8	The day after this Act receives the Royal Assent.	20 June 2017
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.	1 July 2017 (F2017N00047)
5. Schedules 10 to 12	The day after this Act receives the Royal Assent.	20 June 2017

Note: This table relates only to the provisions of this Act as originally enacted.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

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

3 Schedules

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

Schedule 1—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:

(3CB) If:

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

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

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

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

6 After paragraph 9D(3D)(b)

Insert:

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

Schedule 2—Conformity assessment of medical devices

Therapeutic Goods Act 1989

1 Subsection 3(1)

Insert:

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

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

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

After "this Act", insert "or the regulations".

3 Subsection 3(1)

Insert:

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

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

4 After Part 4-4

Insert:

Part 4-4A—Australian conformity assessment bodies

41EWA Conformity assessment body determinations

(1) The regulations may make provision for and in relation to empowering the Secretary to make conformity assessment body determinations.

(2) A ***conformity assessment body determination*** is a determination that a specified Australian corporation is an ***Australian conformity assessment body*** for the purposes of this Act.

(3) The regulations may make provision for and in relation to the following matters:

(a) applications for conformity assessment body determinations;

(b) the approval by the Secretary of a form for such an application;

(c) information that must accompany such an application;

(d) the application fee for such an application;

(e) the lapsing of such an application;

(f) the assessment by the Secretary of whether a conformity assessment body determination should be made in response to such an application;

(g) the assessment fee for such an assessment;

(h) the duration of conformity assessment body determinations.

(4) A conformity assessment body determination:

(a) may be of general application; or

(b) may be limited to either or both of the following:

(i) one or more specified kinds of medical devices;

(ii) one or more specified kinds of conformity assessment procedures.

(5) The regulations may provide that a conformity assessment body determination is subject to:

(a) the conditions prescribed by the regulations; and

(b) such other conditions (if any) as are specified in the determination.

(6) The following are examples of conditions that may be prescribed:

(a) a condition that the body will allow an authorised person:

(i) to enter, at any reasonable time, premises used by the body to carry on certification-related activities; and

(ii) while on those premises, to inspect those premises and anything on those premises that concerns certification-related activities carried on by the body; and

(iii) while on those premises, to make any still or moving image or any recording of those premises or anything on those premises that concerns certification-related activities carried on by the body; and

(iv) while on those premises, to inspect, and make copies of, any documents that concern certification-related activities carried on by the body;

(b) a condition that the body will, if requested to do so by the Secretary, give the Secretary information, or produce to the Secretary documents, that concern certification-related activities carried on by the body.

(7) The regulations may make provision for and in relation to empowering the Secretary to revoke or vary a conformity assessment body determination.

(8) Subsections (3) to (7) do not limit subsection (1).

(9) The express references in this section to the Secretary do not, by implication, prevent the regulations from empowering the Secretary to delegate any or all of the Secretary's functions or powers under regulations made for the purposes of this section.

(10) If a conformity assessment body determination is in force under the regulations, the determination must be published on the Department's website.

(11) A conformity assessment body determination made under the regulations is not a legislative instrument.

(12) Subsection 33(3AB) of the *Acts Interpretation Act 1901* does not apply to the specification of an Australian corporation in a conformity assessment body determination.

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

5 After section 41FI

Insert:

41FIA Certificates issued by Australian conformity assessment bodies

(1) If:

(a) a section 41FC application is made for a kind of medical device to be included in the Register; and

(b) the application has been selected for audit; and

(c) a person has obtained a certificate issued by an Australian conformity assessment body to the effect that the body is satisfied that devices of that kind comply with the essential principles; and

(d) the certificate was issued under a contract between the person and the body; and

(e) the certificate has been given to the Secretary;

then, in auditing the application, the Secretary may have regard to the certificate.

(2) If:

(a) a section 41FC application is made for a kind of medical device to be included in the Register; and

(b) the application has been selected for audit; and

(c) a person has obtained a certificate issued by an Australian conformity assessment body to the effect that the body is satisfied that an appropriate conformity assessment procedure has been applied to devices of that kind; and

(d) the certificate was issued under a contract between the person and the body; and

(e) the certificate has been given to the Secretary;

then, in auditing the application, the Secretary may have regard to the certificate.

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

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

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

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

Schedule 3—Exemptions

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

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

Insert:

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

Therapeutic Goods Act 1989

2 Subsection 3(1)

Insert:

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

(a) Aboriginal and Torres Strait Islander health practice;
(b) dental (not including the professions of dental therapist, dental hygienist, dental prosthetist or oral health therapist);
(c) medical;
(d) medical radiation practice;
(e) nursing;
(f) midwifery;
(g) occupational therapy;
(h) optometry;
(i) pharmacy;
(j) physiotherapy;
(k) podiatry;
(l) psychology.

3 Section 19 (heading)

Repeal the heading, substitute:

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.

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

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

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

(7F) A person commits an offence if:

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

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

(c) the omission breaches the requirement.

Penalty: 10 penalty units.

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

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

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

5 After subsection 21A(11)

Insert:

(11A) A person commits an offence if:

(a) the person is a health practitioner; and

(b) the person is included in a class of health practitioners specified in subsection 19(7A) rules; and

(c) the person supplies:

(i) therapeutic goods specified in those rules; or

(ii) therapeutic goods included in a class of therapeutic goods specified in those rules; and

(d) any of the following applies:

(i) the supply is not in accordance with those rules;

(ii) the supply is not in the circumstances specified in those rules;

(iii) the supply is not in accordance with the conditions specified in those rules; and

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

(11B) A person commits an offence if:
(a) the person is a health practitioner; and
(b) the person is included in a class of health practitioners specified in subsection 19(7A) rules; and
(c) the person supplies:
  (i) therapeutic goods specified in those rules; or
  (ii) therapeutic goods included in a class of therapeutic goods specified in those rules; and
(d) any of the following applies:
  (i) the supply is not in accordance with those rules;
  (ii) the supply is not in the circumstances specified in those rules;
  (iii) the supply is not in accordance with the conditions specified in those rules; and
(e) the use of the goods, if goods were used, would be likely to result in harm or injury to any person; and
(f) the harm or injury would be likely to result because:
  (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: 2,000 penalty units.

(11C) A person commits an offence if:

(a) the person is a health practitioner; and

(b) the person is included in a class of health practitioners specified in subsection 19(7A) rules; and

(c) the person supplies:

(i) therapeutic goods specified in those rules; or

(ii) therapeutic goods included in a class of therapeutic goods specified in those rules; and

(d) any of the following applies:

(i) the supply is not in accordance with those rules;

(ii) the supply is not in the circumstances specified in those rules;

(iii) the supply is not in accordance with the conditions specified in those rules.

Penalty: 500 penalty units.

6 After subsection 31B(3)

Insert:

Authority under subsection 19(7A) rules

(3A) If a person is authorised, by subsection 19(7A) rules, to supply therapeutic goods, the Secretary may give the person a written notice requiring the person to give the Secretary specified information or documents relating to one or more of the following:

(a) the supply of the goods;

(b) the handling of the goods;

(c) the monitoring of the supply of the goods;

(d) the results of the supply of the goods;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to goods of that kind.

7 Subsections 31B(4) and (5)

Omit "or (3)", substitute ", (3) or (3A)".

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

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

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:

(c) notify the supply to the Secretary; and
(d) do so within 28 days after the supply.

(7D) A notification under subsection (7C) must:
(a) be in accordance with a form that is approved, in writing, by the Secretary; and
(b) contain such information as is prescribed by the regulations.

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

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

Penalty: 10 penalty units.

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

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

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

13 Section 32CN (heading)

Repeal the heading, substitute:

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

14 Subsection 32CN(4) (penalty)

Omit "for contravention of this subsection".

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;

(iii) the supply is not in accordance with the conditions specified in those rules; and

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

(f) the harm or injury would be likely to result because:

(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: 2,000 penalty units.

(7) A person commits an offence if:

(a) the person is a health practitioner; and

(b) the person is included in a class of health practitioners specified in subsection 32CM(7A) rules; and

(c) the person supplies a biological specified in those rules; and

(d) any of the following applies:

(i) the supply is not in accordance with those rules;

(ii) the supply is not in the circumstances specified in those rules;

(iii) the supply is not in accordance with the conditions specified in those rules.

Penalty for contravention of this subsection: 500 penalty units.

16 After subsection 32JG(3)

Insert:

Authority under subsection 32CM(7A) rules

(3A) If a person is authorised, by subsection 32CM(7A) rules, to supply a biological, the Secretary may give the person a written notice requiring the person to give the Secretary specified information, or to produce to the Secretary specified documents, relating to one or more of the following:

(a) the supply of the biological;

(b) the handling of the biological;

(c) the monitoring of the supply of the biological;

(d) the results of the supply of the biological;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to a biological of that kind.

17 Subsection 32JG(4)

Omit "or (3)", substitute ", (3) or (3A)".

18 Section 41H

Omit "particular medical practitioners", substitute "health practitioners".

19 Section 41HC (heading)

Repeal the heading, substitute:

41HC Exemptions for health practitioners

20 Subsection 41HC(2)

After "An authority", insert "under subsection (1)".

21 Subsection 41HC(3)

Omit "a person's authority", substitute "the authority given to a person under subsection (1)".

22 Subsection 41HC(4)

After "authority", insert "under subsection (1)".

23 At the end of subsection 41HC(5)

Add "under subsection (1)".

24 After subsection 41HC(5)

Insert:

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

(a) that kind of medical device is supplied in the circumstances specified in those rules; and

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

(6A) In making rules under subsection (6), the Minister must comply with:

(a) such requirements (if any) as are prescribed by the regulations; and

(b) such restrictions (if any) as are prescribed by the regulations; and

(c) such limitations (if any) as are prescribed by the regulations.

(6B) If:

(a) a person is authorised, by subsection (6) rules, to supply a specified kind of medical device; and

(b) the person supplies a medical device of that kind in accordance with those rules;

the person must:

(c) notify the supply to the Secretary; and

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

(6C) A notification under subsection (6B) must:

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

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

(6D) An approval of a form may require or permit information to be given in accordance with specified software requirements:

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

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

(6E) A person commits an offence if:

(a) the person is subject to a requirement under subsection (6B); and

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

(c) the omission breaches the requirement.

Penalty: 10 penalty units.

(6F) An offence against subsection (6E) is an offence of strict liability.

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

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

25 Section 41JF (heading)

Repeal the heading, substitute:

41JF Secretary may require information relating to health practitioner authorisations

26 Subsection 41JF(1)

Omit "section 41HC", substitute "subsection 41HC(1)".

27 After subsection 41JF(1)

Insert:

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

(a) the supply of devices of that kind;

(b) the handling of devices of that kind;

(c) the monitoring of the supply of devices of that kind;

(d) the results of the supply of devices of that kind;

(e) any other matter prescribed by the regulations for the purposes of this paragraph in relation to devices of that kind.

28 Subsection 41JF(2)

Omit "The notice", substitute "A notice under subsection (1) or (1A)".

29 Subsection 41JF(3)

Omit "The notice", substitute "A notice under subsection (1) or (1A)".

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

Omit "section 41HC", substitute "subsection 41HC(1)".

31 After subsection 41MO(4)

Insert:

(4A) A person commits an offence if:

(a) the person is a health practitioner; and

(b) the person is included in a class of health practitioners specified in subsection 41HC(6) rules; and

(c) the person supplies a medical device of a kind specified in those rules; and

(d) any of the following applies:

(i) the supply is not in accordance with those rules;

(ii) the supply is not in the circumstances specified in those rules;

(iii) the supply is not in accordance with the conditions specified in those rules; and

(e) either:

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

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

(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.

(4B) A person commits an offence if:

(a) the person is a health practitioner; and

(b) the person is included in a class of health practitioners specified in subsection 41HC(6) rules; and

(c) the person supplies a medical device of a kind specified in those rules; and

(d) any of the following applies:

(i) the supply is not in accordance with those rules;

(ii) the supply is not in the circumstances specified in those rules;

(iii) the supply is not in accordance with the conditions specified in those rules; and

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

(f) the harm or injury would be likely to result because:

(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: 2,000 penalty units.

(4C) A person commits an offence if:

(a) the person is a health practitioner; and

(b) the person is included in a class of health practitioners specified in subsection 41HC(6) rules; and

(c) the person supplies a medical device of a kind specified in those rules; and

(d) any of the following applies:

(i) the supply is not in accordance with those rules;

(ii) the supply is not in the circumstances specified in those rules;

(iii) the supply is not in accordance with the conditions specified in those rules.

Penalty: 500 penalty units.

32 Section 53A (after table item 8)

Insert:

8A	subsection 21A(11A)	subsection 21A(11C)

33 Section 53A (after table item 13F)

Insert:

13FA	subsection 32CN(5)	subsection 32CN(7)

34 Section 53A (after table item 32)

Insert:

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

35 Paragraph 56A(1)(b)

After "approval", insert "under subsection 19(1)".

36 Paragraph 56A(1)(b)

Omit "section 19", substitute "subsection 19(5)".

37 Paragraph 56A(1)(ba)

Omit "41HC", substitute "subsection 41HC(1)".

Schedule 4—Committees

Therapeutic Goods Act 1989

1 Subsection 10(4)

Repeal the subsection.

2 Subsection 36(3)

Repeal the subsection.

Schedule 5—Permissible ingredients

Therapeutic Goods Act 1989

1 Section 26BD

Repeal the section.

2 Before section 26C

Insert:

26BE Variation of section 26BB determination—application by person

(1) A person may apply to the Secretary for a recommendation that the Minister vary a section 26BB determination.

(2) An application under subsection (1) must:
  (a) be made in accordance with a form approved, in writing, by the Secretary; and
  (b) set out the recommendation sought; and
  (c) be delivered to an office of the Department specified in the form; and
  (d) be accompanied by the prescribed application fee (if any).

Decision by Secretary whether to make recommendation

(3) If:
  (a) an application is made under subsection (1); and
  (b) any applicable prescribed evaluation fee has been paid;

the Secretary must carry out an evaluation of whether to make the recommendation.

(4) After carrying out the evaluation, the Secretary must:
  (a) make the recommendation; or
  (b) refuse to make the recommendation.

(5) In deciding whether to make the recommendation, the Secretary must have regard to:
  (a) the quality and safety of the ingredients concerned; and

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

Minister may vary determination

(6) If the Secretary makes a recommendation under paragraph (4)(a), the Minister must:
(a) by legislative instrument, vary the section 26BB determination; or
(b) refuse to vary the section 26BB determination.

(7) In making a decision under subsection (6), the Minister must have regard to:
(a) the recommendation made under paragraph (4)(a); and
(b) such other matters (if any) as the Minister considers relevant.

Further information

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

Applications or information may be given electronically

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

3 After subsection 60(2A)

Insert:

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

4 Transitional provisions

(1) If:

(a) an application was made under subsection 26BD(1) of the *Therapeutic Goods Act 1989* before the commencement of this item; and

(b) no decision was made on the application before that commencement;

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

(c) the application; and

(d) a variation of a determination in response to the application;

as if that repeal had not happened.

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

Schedule 6—Approval of therapeutic goods, biologicals and medical devices

Therapeutic Goods Act 1989

1 After section 25

Insert:

25AAA Therapeutic goods (priority applicant) determinations

(1) The regulations may make provision for and in relation to empowering the Secretary to make therapeutic goods (priority applicant) determinations.

(2) A ***therapeutic goods (priority applicant) determination*** is a determination that, for the purposes of this Act, a specified person is a priority applicant in relation to any section 23 application that may be made by the person for the registration of therapeutic goods specified in the determination.

(3) The regulations may make provision for and in relation to the following matters:

(a) applications for therapeutic goods (priority applicant) determinations;

(b) the approval by the Secretary of a form for such an application;

(c) information that must accompany such an application;

(d) the application fee for such an application.

(4) The regulations may make provision for and in relation to the following matters:

(a) empowering the Secretary to revoke a therapeutic goods (priority applicant) determination;

(b) the consequences of the revocation of a therapeutic goods (priority applicant) determination.

(5) Subsections (3) and (4) do not limit subsection (1).

(6) A period prescribed under paragraph 63(2)(da) for the evaluation of therapeutic goods covered by a section 23 application for which

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

(7) The regulations may provide that, if:

(a) a person is a priority applicant in relation to a section 23 application made by the person; and

(b) a decision is made on the application;

a statement setting out the decision may be published on the Department's website.

(8) The express references in this section to the Secretary do not, by implication, prevent the regulations from empowering the Secretary to delegate any or all of the Secretary's functions or powers under regulations made for the purposes of this section.

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

(10) A therapeutic goods (priority applicant) determination made under the regulations is not a legislative instrument.

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

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

2 After section 32DE

Insert:

32DEA Biologicals (priority applicant) determinations

(1) The regulations may make provision for and in relation to empowering the Secretary to make biologicals (priority applicant) determinations.

(2) A ***biologicals (priority applicant) determination*** is a determination that, for the purposes of this Act, a specified person is a priority applicant in relation to any section 32DD application that may be

made by the person for the inclusion in the Register of a biological specified in the determination.

(3) The regulations may make provision for and in relation to the following matters:

(a) applications for biologicals (priority applicant) determinations;

(b) the approval by the Secretary of a form for such an application;

(c) information that must accompany such an application;

(d) the application fee for such an application.

(4) The regulations may make provision for and in relation to the following matters:

(a) empowering the Secretary to revoke a biologicals (priority applicant) determination;

(b) the consequences of the revocation of a biologicals (priority applicant) determination.

(5) Subsections (3) and (4) do not limit subsection (1).

(6) A period prescribed under paragraph 63(2)(daa) for the evaluation of a biological covered by a section 32DD application for which the applicant is a priority applicant may be shorter than the period prescribed under that paragraph for the evaluation of a biological covered by a section 32DD application for which the applicant is not a priority applicant.

(7) The regulations may provide that, if:

(a) a person is a priority applicant in relation to a section 32DD application made by the person; and

(b) a decision is made on the application;

a statement setting out the decision may be published on the Department's website.

(8) The express references in this section to the Secretary do not, by implication, prevent the regulations from empowering the Secretary to delegate any or all of the Secretary's functions or powers under regulations made for the purposes of this section.

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

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

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

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

3 After section 41EC

Insert:

41ECA Conformity assessment (priority applicant) determinations

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

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

(3) The regulations may make provision for and in relation to the following matters:

(a) applications for conformity assessment (priority applicant) determinations;

(b) the approval by the Secretary of a form for such an application;

(c) information that must accompany such an application;

(d) the application fee for such an application.

(4) The regulations may make provision for and in relation to the following matters:

(a) empowering the Secretary to revoke a conformity assessment (priority applicant) determination;

(b) the consequences of the revocation of a conformity assessment (priority applicant) determination.

(5) Subsections (3) and (4) do not limit subsection (1).

(6) The regulations may make provision for and in relation to the priority to be given by the Secretary to consideration of a section 41EB application where the applicant is a priority applicant.

(7) The regulations may provide that, if:

(a) a person is a priority applicant in relation to a section 41EB application made by the person; and

(b) a decision is made on the application;

a statement setting out the decision may be published on the Department's website.

(8) The express references in this section to the Secretary do not, by implication, prevent the regulations from empowering the Secretary to delegate any or all of the Secretary's functions or powers under regulations made for the purposes of this section.

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

(10) A conformity assessment (priority applicant) determination made under the regulations is not a legislative instrument.

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

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

4 Before section 41FL

Insert:

41FKA Medical devices (priority applicant) determinations

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

(2) A ***medical devices (priority applicant) determination*** is a determination that, for the purposes of this Act, a specified person is a priority applicant in relation to any section 41FC application that may be made by the person for the inclusion in the Register of a medical device of a kind specified in the determination.

(3) The regulations may make provision for and in relation to the following matters:
   (a) applications for medical devices (priority applicant) determinations;
   (b) the approval by the Secretary of a form for such an application;
   (c) information that must accompany such an application;
   (d) the application fee for such an application.

(4) The regulations may make provision for and in relation to the following matters:
   (a) empowering the Secretary to revoke a medical devices (priority applicant) determination;
   (b) the consequences of the revocation of a medical devices (priority applicant) determination.

(5) Subsections (3) and (4) do not limit subsection (1).

(6) The regulations may make provision for and in relation to the priority to be given by the Secretary to consideration of a section 41FC application where the applicant is a priority applicant.

(7) The regulations may provide that, if:
   (a) a person is a priority applicant in relation to a section 41FC application made by the person; and
   (b) a decision is made on the application;

   a statement setting out the decision may be published on the Department's website.

(8) The express references in this section to the Secretary do not, by implication, prevent the regulations from empowering the Secretary to delegate any or all of the Secretary's functions or powers under regulations made for the purposes of this section.

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

(10) A medical devices (priority applicant) determination made under the regulations is not a legislative instrument.

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

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

Schedule 7—Time limits

Therapeutic Goods Act 1989

1 After paragraph 63(2)(dd)

Insert:

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

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

Schedule 8—Record-keeping etc.

Therapeutic Goods Act 1989

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

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

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

Add:

(iv) while on those premises, to inspect, and make copies of, any records kept in compliance with paragraph (c) or (ca); and

(v) while on those premises, to inspect, and make copies of, any documents that relate to the subject goods; and

3 After paragraph 28(5)(c)

Insert:

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

4 Paragraph 28(5)(d)

Omit "such record", substitute "record kept in compliance with paragraph (c) or (ca)".

5 Paragraph 46A(4)(a)

Omit all the words from and including "being" to and including "goods; and", substitute:

being premises connected with:

(iv) the importation, export, manufacture or supply of therapeutic goods; or

(v) the keeping of documents relating to the importation, export, manufacture or supply of therapeutic goods; or

(vi) the keeping of records in compliance with paragraph 28(5)(c) or (ca); and

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.

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 meaning of section 42E)	The person supplying the goods

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:

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

8 At the end of subsection 30EA(2)

Add:

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

9 Subsection 30EA(4)

Omit "recover", substitute "recall".

10 Subsection 30EA(4)

Omit "recovered", substitute "recalled".

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

Add:

30EE Saving of other laws

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

12 Subsection 30F(2)

Omit "recover", substitute "recall".

13 Subsection 30F(2)

Omit "recovered", substitute "recalled".

14 Paragraph 30F(3)(a)

Omit "recover", substitute "recall".

15 At the end of section 30F

Add:

Saving of other laws

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

16 Section 32

Omit "recovery", substitute "recall".

17 Subsection 32CJ(2)

Omit "recover", substitute "recall".

18 Subsection 32CJ(2)

Omit "recovered", substitute "recalled".

19 Paragraph 32CJ(3)(a)

Omit "recover", substitute "recall".

20 At the end of section 32CJ

Add:

Saving of other laws

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

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

Repeal the heading, substitute:

Division 8—Public notification, and recall, of biologicals

22 Section 32H

Omit "recover", substitute "recall".

23 Section 32HA (heading)

Repeal the heading, substitute:

32HA Public notification, and recall, of biologicals

24 Subsection 32HA(1) (table item 1, column headed "Circumstance relating to biological")

After "but", insert "the Secretary is satisfied that".

25 Subsection 32HA(1) (table item 2, column headed "Circumstance relating to biological")

After "but", insert "the Secretary is satisfied that".

26 Subsection 32HA(1) (table item 3, column headed "Circumstance relating to biological")

After "but", insert "the Secretary is satisfied that".

27 Subsection 32HA(1) (table item 4, column headed "Circumstance relating to biological")

After "but", insert "the Secretary is satisfied that".

28 Subsection 32HA(1) (table item 7, column headed "Circumstance relating to biological")

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

29 Subsection 32HA(1) (table item 8, column headed "Circumstance relating to biological")

After "but", insert "the Secretary is satisfied that".

30 Paragraph 32HA(2)(a)

Omit "recover", substitute "recall".

31 After paragraph 32HA(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:

(i) the biological;

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

32 At the end of subsection 32HA(2)

Add:

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

33 Subsection 32HA(4)

Omit "recover", substitute "recall".

34 Subsection 32HA(4)

Omit "recovered", substitute "recalled".

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

Add:

32HF Saving of other laws

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

36 Paragraph 41BB(f)

Omit "recovery", substitute "recall".

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

Omit "recovery", substitute "recall".

38 Part 4-9 (heading)

Repeal the heading, substitute:

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

39 Section 41K

Omit "recover", substitute "recall".

40 Section 41KA (heading)

Repeal the heading, substitute:

41KA Public notification, and recall, of medical devices

41 Subsection 41KA(1) (table item 1, column headed "Circumstance relating to a kind of medical device")

After "but", insert "the Secretary is satisfied that".

42 Subsection 41KA(1) (table item 2, column headed "Circumstance relating to a kind of medical device")

After "but", insert "the Secretary is satisfied that".

43 Subsection 41KA(1) (table item 3, column headed "Circumstance relating to a kind of medical device")

After "but", insert "the Secretary is satisfied that".

44 Subsection 41KA(1) (table item 4, column headed "Circumstance relating to a kind of medical device")

After "but", insert "the Secretary is satisfied that".

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

Add:

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

46 Subsection 41KA(2)

Omit "one or both", substitute "one or more".

47 Paragraph 41KA(2)(a)

Omit "recover", substitute "recall".

48 At the end of subsection 41KA(2)

Add:

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

(i) medical devices of that kind;

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

(d) to publish, in the specified manner and within such reasonable period as is specified, specified information, or information of a specified kind, relating to the manufacture or distribution of medical devices of that kind;

(e) to notify the Secretary, in the specified manner and within such reasonable period as is specified, of specified information, or of information of a specified kind, relating to the persons to whom medical devices of that kind have been supplied.

49 Subsection 41KA(4)

Omit "recover", substitute "recall".

50 Subsection 41KA(4)

Omit "recovered", substitute "recalled".

51 At the end of Part 4-9

Add:

41KE Saving of other laws

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

52 Paragraph 41MP(2)(b)

Omit "recover", substitute "recall".

53 Paragraph 41MPA(2)(b)

Omit "recover", substitute "recall".

54 Section 42V (heading)

Repeal the heading, substitute:

42V Recall of therapeutic goods because of actual or potential tampering

55 Paragraph 42V(2)(a)

Omit "recover", substitute "recall".

56 Subsection 42V(3)

Omit "recovered", substitute "recalled".

57 Section 42VA (heading)

Repeal the heading, substitute:

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

58 Section 42VB (heading)

Repeal the heading, substitute:

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

59 Section 42W (heading)

Repeal the heading, substitute:

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

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

Omit "recover", substitute "recall".

61 Paragraph 61(4A)(da)

Omit "recovery", substitute "recall".

62 After paragraph 61(4A)(da)

Insert:

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

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

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.

Schedule 11—Obtaining information etc.

Therapeutic Goods Act 1989

1 Paragraph 31(2)(fa)

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)".

2 Application of amendments

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.

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.

3 Subsection 19A(3)

Omit "this section", substitute "subsection (1)".

4 Paragraph 19A(9)(a)

After "(d)," (first occurring), insert "paragraph (1A)(a), (b), (c), (d), (e) or (f),".

5 At the end of section 19A

Add:

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

6 At the end of subsection 30(1)

Add:

; or (g) the Secretary is satisfied that a statement made in, or in connection with, the application for registration or listing of the goods was false or misleading in a material particular; or

(h) the annual registration or listing charge is not paid within 28 days after it becomes payable.

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

Omit "regulations; or", substitute "regulations.".

8 Paragraph 30(2)(f)

Repeal the paragraph.

9 After section 30A

Insert:

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

(1) If:

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

(b) before the end of the period of 90 days beginning on the day the goods ceased to be registered or listed, the person requests, in writing, the Secretary to revoke the cancellation; and

(c) the annual registration or listing charge has been paid; and

(d) the request is accompanied by the prescribed application fee;

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

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

10 At the end of subsection 30F(4)

Add "or on the Department's website".

11 After section 31B

Insert:

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

(1) The Secretary may give to a person who is granted an approval under subsection 19A(1), (1A) or (2) in relation to specified therapeutic goods a written notice requiring the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to one or more of the following:

(a) the supply of the goods;

(b) the handling of the goods;

(c) the monitoring of the supply of the goods;

(d) the results of the supply of the goods;

(e) any other matter prescribed by the regulations.

Compliance

(2) A person given a notice under subsection (1) must give the information, or produce the documents, to the Secretary:

(a) within the period specified in the notice (which must not be less than 14 days after the day the notice is given); and

(b) in the form specified in the notice.

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

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

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

12 Section 31C (heading)

Repeal the heading, substitute:

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

13 Paragraph 31C(a)

Omit "or 31B", substitute ", 31B or 31BA".

14 Subsection 31D(1)

Omit "or 31B", substitute ", 31B or 31BA".

15 Paragraph 31E(1)(c)

Omit "or 31B", substitute ", 31B or 31BA".

16 Subsection 31F(1)

Omit "or 31B", substitute ", 31B or 31BA".

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

After "32CO(1)", insert ", (1A)".

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

After "32CO(1)", insert ", (1A)".

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

After "32CO(1)", insert ", (1A)".

20 Subparagraph 32BH(b)(vi)

After "32CO(1)", insert ", (1A)".

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

After "32CO(1)", insert ", (1A)".

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.

26 Paragraph 32CO(8)(b)

After "(1)", insert ", (1A)".

27 Paragraph 32CO(11)(a)

After "(f)," (first occurring), insert "paragraph (1A)(c), (d), (e), (f), (g) or (h),".

28 Subsection 32CO(13)

After "(1)", insert ", (1A)".

29 After section 32GD

Insert:

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

(1) If:

(a) the Secretary cancels the entry of a biological from the Register because the annual charge payable under the *Therapeutic Goods (Charges) Act 1989* in respect of the inclusion of the biological in the Register was not paid within 28 days after it becomes payable; and

(b) before the end of the period of 90 days beginning on the day the biological ceased to be included in the Register, the person requests, in writing, the Secretary to revoke the cancellation; and

(c) the annual charge payable under the *Therapeutic Goods (Charges) Act 1989* in respect of the inclusion of the biological in the Register has been paid; and

(d) the request is accompanied by the prescribed application fee;

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

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

30 Subsection 32HA(1) (table item 3, column headed "Circumstance relating to biological", paragraph (e))

After "32CO(1)", insert ", (1A)".

31 Subsection 32HA(1) (table item 4, column headed "Circumstance relating to biological", paragraph (e))

After "32CO(1)", insert ", (1A)".

32 Subsection 32HA(1) (table item 5, column headed "Circumstance relating to biological", paragraph (f))

After "32CO(1)", insert ", (1A)".

33 Subsection 32JH(1)

After "32CO(1)", insert ", (1A)".

34 After section 41AA

Insert:

41AB Secretary may require information or documents

(1) If:

(a) a person is the holder of a licence; and

(b) the person has carried out, or is carrying out, one or more steps in the manufacture of therapeutic goods;

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

(c) give the Secretary information, or produce to the Secretary documents, relating to one or more of the following:

(i) the therapeutic goods;

(ii) if the therapeutic goods consist of a mixture of ingredients—those ingredients;

(iii) if the therapeutic goods consist of a mixture of ingredients—the suppliers of those ingredients;

(iv) if the therapeutic goods consist of a combination of component parts—those component parts;

(v) if the therapeutic goods consist of a combination of component parts—the suppliers of those component parts;

(vi) the containers or packages used, or proposed to be used, to contain the therapeutic goods;

(vii) the batch numbers of the therapeutic goods;

(viii) the expiry dates of the therapeutic goods;

(ix) the distribution of the therapeutic goods;

(x) the conformity of the therapeutic goods to a standard applicable to the goods;

(xi) the step or steps that the person has carried out, or is carrying out, in the manufacture of the therapeutic goods;

(xii) the premises used to carry out one or more steps in the manufacture of the therapeutic goods;

(xiii) the observance of the manufacturing principles;

(xiv) the names, qualifications and experience of individuals who have control of any of the steps that have been carried out, or are being carried out, in the manufacture of the therapeutic goods;

(xv) the measures for quality assurance and quality control employed in the taking of any of the steps that have been carried out, or are being carried out, in the manufacture of the therapeutic goods;

(xvi) compliance with the conditions of the licence;

(xvii) whether there are grounds for revoking or suspending the licence;

(xviii) any other matter that is prescribed by the regulations and that relates to the manufacture of the therapeutic goods; and

(d) do so:

(i) within such reasonable time as is specified in the notice; and

(ii) in such form as is specified in the notice.

(2) The time specified in the notice must not be shorter than 14 days after the notice is given.

(3) The rule in subsection (2) does not apply if the Secretary is satisfied that, because of circumstances of urgency, the time specified in the notice should be shorter than 14 days after the notice is given.

(4) An approval of a form may require or permit the information to be given, or the documents to be produced, in accordance with specified software requirements:

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

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

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

A person commits an offence if:

(a) the person has been given a notice under section 41AB; and

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

(c) the omission contravenes a requirement in the notice.

Penalty: 400 penalty units.

41AD False or misleading information—offence

(1) A person commits an offence if:

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

(b) the person gives information to the Secretary in compliance, or purported compliance, with the notice; and

(c) the person does so knowing that the information:

(i) is false or misleading; or

(ii) omits any matter or thing without which the information is misleading.

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

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

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

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

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

41AE False or misleading documents—offence

(1) A person commits an offence if:

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

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

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

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

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

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

41AF False or misleading information or documents—civil penalty

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

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

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

(a) stating that the document is, to the knowledge of the first-mentioned person, false or misleading in a material particular; and

(b) setting out, or referring to, the material particular in which the document is, to the knowledge of the first-mentioned person, false or misleading.

41AG Self-incrimination

(1) A person is not excused from giving information or a producing a document under a section 41AB notice on the ground that the giving of the information or the production of the document would tend to incriminate the person or expose the person to a penalty.

(2) However, in the case of an individual:

(a) the information given or the document produced; or

(b) the giving of the information or the production of the document; or

(c) any information, document or thing obtained as a direct or indirect consequence of giving the information or producing the document;

is not admissible in evidence in:

(d) criminal proceedings against the individual, except proceedings under, or arising out of, section 41AD or 41AE; or

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

35 After subsection 41FN(5)

Insert:

Conditions prescribed by the regulations

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

Conditions determined by the Minister

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

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

36 After section 41GLA

Insert:

41GLB Revocation of cancellation of entries—payment of annual charge

(1) If:

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

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

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

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

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

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

37 After subsection 41HD(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 medical device; or

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

if the Secretary is satisfied that:

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

(d) either:

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

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

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

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

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

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

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

38 Paragraph 41HD(10)(a)

After "(f)," (first occurring), insert "paragraph (1A)(c), (d), (e), (f), (g) or (h),".

39 Subsection 41HD(12)

After "(1)", insert ", (1A)".

40 Subsection 41JFA(1)

After "41HD(1)", insert ", (1A)".

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

After "41HD(1)", insert ", (1A)".

42 Subsection 41KA(1) (table item 4, column headed "Circumstance relating to a kind of medical device", paragraph (d))

After "41HD(1)", insert ", (1A)".

43 Subsection 41KA(1) (table item 5, column headed "Circumstance relating to a kind of medical device", paragraph (e))

After "41HD(1)", insert ", (1A)".

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

After "41HD(1)", insert ", (1A)".

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

After "41HD(1)", insert ", (1A)".

46 Subparagraph 41MK(b)(iv)

After "41HD(1)", insert ", (1A)".

47 Paragraph 41MLA(2)(d)

After "41HD(1)", insert ", (1A)".

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

After "41HD(1)", insert ", (1A)".

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

Omit "or the National Manager of the Therapeutic Goods Administration".

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

After "32CO(1)", insert ", (1A)".

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

After "41HD(1)", insert ", (1A)".

52 Section 54BA (after table item 27)

Insert:

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

(b) the determination was in force immediately before the commencement of this item;

the determination has effect, after the commencement of this item, as if a reference in the determination to a prerequisite for approval by the Secretary under that section 19A of that Act were a reference to a prerequisite for approval by the Secretary under subsection 19A(1) of that Act.

(2) If:

(a) regulations were made for the purposes of paragraph 57(8)(b) of the *Therapeutic Goods Act 1989*; and

(b) the regulations were in force immediately before the commencement of this item;

the regulations have effect, after the commencement of this item, as if they had been made for the purposes of subsection 57(8) of the *Therapeutic Goods Act 1989* as amended by this Act.

(3) If:

(a) regulations were made for the purposes of paragraph 57(9)(b) of the *Therapeutic Goods Act 1989*; and

(b) the regulations were in force immediately before the commencement of this item;

the regulations have effect, after the commencement of this item, as if they had been made for the purposes of subsection 57(9) of the *Therapeutic Goods Act 1989* as amended by this Act.

[*Minister's second reading speech made in—*
House of Representatives on 1 December 2016
Senate on 27 March 2017]

(194/16)