Therapeutic Goods Amendment (Medical Devices and Other Measures) Act 2009

No. 38, 2009

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

Contents

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[*Assented to 17 June 2009*]

The Parliament of Australia enacts:

1 Short title

This Act may be cited as the *Therapeutic Goods Amendment (Medical Devices and Other Measures) Act 2009*.

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
Provision(s)	**Commencement**	**Date/Details**
1. Sections 1 to 3 and anything in this Act not elsewhere covered by this table	The day on which this Act receives the Royal Assent.	17 June 2009
2. Schedules 1 and 2	The day after this Act receives the Royal Assent.	18 June 2009
3. Schedule 3	A single day to be fixed by Proclamation. However, if any of the provision(s) do not commence within the period of 6 months beginning on the day on which this Act receives the Royal Assent, they commence on the first day after the end of that period.	1 December 2009 (*see* F2009L03387)
4. Schedule 4	1 July 2009.	1 July 2009
5. Schedules 5 to 7	The day after this Act receives the Royal Assent.	18 June 2009

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

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

3 Schedule(s)

Each Act that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.

Schedule 1—Medical devices

Therapeutic Goods Act 1989

1 After paragraph 41BB(c)

Insert:

(ca) exempting medical devices from various provisions of this Chapter to deal with emergency situations; and

2 After Part 4-6

Insert:

Part 4-6A—Exempting medical devices to deal with emergencies

41GR What this Part is about

The Minister may exempt certain medical devices from various provisions of this Chapter so that the devices may be stockpiled to deal with possible future emergencies or made available urgently to deal with actual emergencies.

Note 1: There are offences and civil penalty provisions related to the making of exemptions under this Part: see Division 3A of Part 4-11.

Note 2: Some of the other provisions of this Act about medical devices exempt under this Part are:

(a) section 41JCA (providing information to the Secretary); and

(b) section 41KA (public notification and recovery of medical devices); and

(c) section 46A (search of premises).

41GS Minister may make exemptions

(1) The Minister may, by writing, exempt specified kinds of medical devices from the operation of the following:

(a) Division 1 of Part 4-2 (essential principles);

(b) Division 1 of Part 4-3 (conformity assessment procedures);

(c) Part 4-4 (conformity assessment certificates);
(d) Part 4-5 (including medical devices in the Register).

(2) The Minister may make an exemption under subsection (1) only if the Minister is satisfied that, in the national interest, the exemption should be made so that:
(a) the devices may be stockpiled as quickly as possible in order to create a preparedness to deal with a potential threat to public health that may be caused by a possible future emergency; or
(b) the devices can be made available urgently in Australia in order to deal with an actual threat to public health caused by an emergency that has occurred.

Period of exemption

(3) An exemption under subsection (1) comes into force:
(a) on the day the exemption is made; or
(b) on a later day specified in the exemption.

(4) An exemption under subsection (1) remains in force for the period specified in the exemption, unless revoked earlier.

Note: Section 41GU deals with variation and revocation of the exemption.

Effect of inclusion of kind of medical device in the Register

(5) An exemption under subsection (1) ceases to have effect in relation to a particular kind of medical device when that kind of medical device becomes included in the Register under Part 4-5.

Exemption not a legislative instrument

(6) An exemption under subsection (1) is not a legislative instrument.

Disregard section 41BE

(7) For the purposes of this Act, disregard section 41BE in working out the kinds of medical devices covered by an exemption under subsection (1) of this section.

41GT Conditions of exemptions

An exemption under section 41GS is subject to conditions specified in the exemption about any of the following:

(a) the quantity of medical devices that are exempt;

(b) the source of those medical devices;

(c) the persons or class of persons who may import, manufacture, supply or export those medical devices;

(d) the supply of those medical devices (including the persons or class of persons to whom medical devices may be supplied for use and the circumstances under which a stockpile of medical devices may be supplied for use);

(e) the storage and security of those medical devices;

(f) the keeping and disclosure of, and access to, records about those medical devices;

(g) the disposal of those medical devices;

(h) the manner in which any of those medical devices are to be dealt with if a condition of the exemption is breached;

(i) any other matters that the Minister thinks appropriate.

Whether or not medical devices are exempt under section 41GS is not affected by whether or not there is a breach of a condition under this section in relation to those medical devices.

Note 1: There are offences and civil penalty provisions related to the breach of a condition of an exemption: see Division 3A of Part 4-11.

Note 2: Section 41GU deals with variation and revocation of the conditions.

41GU Variation or revocation of exemption

Variation of exemption

(1) The Minister may, by writing, vary an exemption made under section 41GS by removing specified kinds of medical devices from the exemption.

Revocation of exemption

(2) The Minister may, by writing, revoke an exemption made under section 41GS.

Variation or revocation of conditions

(3) The Minister may, by writing:

(a) vary the conditions of an exemption made under section 41GS (including by imposing new conditions); or

(b) revoke the conditions of an exemption made under section 41GS.

When variation or revocation takes effect

(4) A variation or revocation under this section takes effect:

(a) if the Minister states in the variation or revocation that the variation or revocation is necessary to prevent imminent risk of death, serious illness or serious injury—on the day the variation or revocation is made; or

(b) in any other case—on a later day specified in the variation or revocation (which must not be earlier than 28 days after the day the variation or revocation is made).

41GV Informing persons of exemption etc.

If the Minister makes an exemption under section 41GS, the Minister must take reasonable steps to give a copy of the following to each person covered by paragraph 41GT(c):

(a) the exemption;

(b) any variation or revocation of the exemption under section 41GU.

41GW Notification and tabling

Notification

(1) The Secretary must cause a notice setting out particulars of the following:

(a) an exemption made under section 41GS because of paragraph 41GS(2)(b);

(b) a variation or revocation under section 41GU, to the extent that the variation or revocation relates to an exemption made under section 41GS because of paragraph 41GS(2)(b);

to be published in the *Gazette* within 5 working days after the day on which the exemption, variation or revocation is made. However,

the exemption, variation or revocation is not invalid merely because of a failure to comply with this subsection.

Tabling

(2) The Minister must cause a document setting out particulars of the following:

(a) an exemption made under section 41GS because of paragraph 41GS(2)(b);

(b) a variation or revocation under section 41GU, to the extent that the variation or revocation relates to an exemption made under section 41GS because of paragraph 41GS(2)(b);

to be tabled in each House of the Parliament within 5 sitting days of that House after the day on which the exemption, variation or revocation is made. However, the exemption, variation or revocation is not invalid merely because of a failure to comply with this subsection.

41GX Exclusion of liability of the Commonwealth etc.

An exemption under section 41GS does not render the Commonwealth, the Minister or a delegate of the Minister liable to a person for loss, damage or injury of any kind suffered by the person as a result of, or arising out of, the use by that person or another person of a medical device of a kind covered by the exemption.

41GY Disposal of unused medical devices

(1) This section applies to a medical device if:

(a) an exemption under section 41GS in relation to that kind of medical device ceases to have effect otherwise than because that kind of medical device becomes included in the Register under Part 4-5; and

(b) the medical device has not been used before the exemption so ceases to have effect.

(2) The Secretary may arrange for the disposal of the medical device in accordance with the regulations.

(3) Regulations made for the purposes of subsection (2) may set out the methods by which the medical device is to be stored, supplied, destroyed, exported or otherwise disposed of.

(4) A method set out in the regulations under subsection (3) must not enable or permit any benefit to be conferred on a person (including the Commonwealth) other than the owner of the medical device.

3 Part 4-7 (heading)

Repeal the heading, substitute:

Part 4-7—Other exemptions from including medical devices in the Register

4 Section 41H

Omit "There are 3", substitute "In addition to Part 4-6A, there are 3 other".

5 Section 41J

After "exemptions under", insert "Part 4-6A or".

6 Before section 41JD

Insert:

41JCA Secretary may require information etc. about medical devices exempt under Part 4-6A

(1) This section applies to a person who is required to comply with a condition of an exemption of a kind of medical device under section 41GS.

(2) The Secretary may, by written notice given to the person, require the person to give to the Secretary specified information or documents relating to one or more of the following:

(a) the supply of devices of that kind;

(b) the handling of devices of that kind;

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

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

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

(3) The notice must specify a reasonable period within which the person to whom the notice is given must comply. The period must be at least 10 working days starting on the day on which the notice is given.

(4) The notice may require information to be given in accordance with specified software requirements:

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

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

7 Paragraph 41JG(a)

After "section", insert "41JCA,".

8 Section 41JG (note)

After "sections", insert "41JCA,".

9 Section 41JH

After "section", insert "41JCA,".

10 Paragraph 41JI(1)(c)

After "section", insert "41JCA,".

11 Subsection 41JJ(1)

After "section", insert "41JCA,".

12 Subsection 41KA(1) (after paragraph (a) of the cell at table item 5, column headed "Circumstance relating to a kind of medical device")

Insert:

(aa) it is not covered by an exemption in force under section 41GS; and

13 Subsection 41KA(1) (after table item 5)

Insert:

5A.	It is supplied while it is covered by an exemption in force under section 41GS, and the Secretary is satisfied that it is not fit to be used for its intended purpose	The person supplying the kind of medical device

14 Section 41M

After "Divisions 3", insert ", 3A".

15 After paragraphs 41MA(1)(c) and (2)(c)

Insert:

(ca) the device is not of a kind covered by an exemption in force under section 41GS; and

16 After paragraph 41MA(4)(c)

Insert:

; and (d) the device is not of a kind covered by an exemption in force under section 41GS.

17 After paragraphs 41MA(5)(c) and (6)(c)

Insert:

(ca) the device is not of a kind covered by an exemption in force under section 41GS; and

18 After paragraph 41MA(8)(c)

Insert:

; and (d) the device is not of a kind covered by an exemption in force under section 41GS.

19 After paragraphs 41MA(9)(c) and (10)(c)

Insert:

(ca) the device is not of a kind covered by an exemption in force under section 41GS; and

20 After paragraph 41MA(12)(c)

Insert:

; and (d) the device is not of a kind covered by an exemption in force under section 41GS.

21 After paragraphs 41MAA(1)(c), (2)(c) and (3)(c)

Insert:

; and (d) the device is not of a kind covered by an exemption in force under section 41GS.

22 After paragraphs 41ME(1)(c) and (2)(c)

Insert:

(ca) the device is not of a kind covered by an exemption in force under section 41GS; and

23 After paragraph 41ME(4)(c)

Insert:

; and (d) the device is not of a kind covered by an exemption in force under section 41GS.

24 After paragraphs 41ME(5)(c) and (6)(c)

Insert:

(ca) the device is not of a kind covered by an exemption in force under section 41GS; and

25 After paragraph 41ME(8)(c)

Insert:

; and (d) the device is not of a kind covered by an exemption in force under section 41GS.

26 After paragraphs 41MEA(1)(c) and (2)(c)

Insert:

; and (d) the device is not of a kind covered by an exemption in force under section 41GS.

27 After paragraph 41MF(1)(b)

Insert:

(ba) the device is not of a kind covered by an exemption in force under section 41GS; and

28 After paragraph 41MF(2)(b)

Insert:

; and (c) the device is not of a kind covered by an exemption in force under section 41GS.

29 After paragraph 41MF(3)(b)

Insert:

(ba) the device is not of a kind covered by an exemption in force under section 41GS; and

30 After paragraph 41MF(4)(b)

Insert:

; and (c) the device is not of a kind covered by an exemption in force under section 41GS.

31 After subparagraphs 41MI(1)(b)(i), (2)(b)(i) and (4)(b)(i)

Insert:

(ia) the device is of a kind covered by an exemption in force under section 41GS;

32 Paragraph 41MIB(1)(b)

Omit "paragraphs", substitute "subparagraphs".

33 After subparagraph 41MIB(1)(b)(i)

Insert:

(ia) the device is of a kind covered by an exemption in force under section 41GS;

34 After subparagraph 41MK(b)(i)

Insert:

(ia) the device is of a kind covered by an exemption in force under section 41GS;

35 After Division 3 of Part 4-11

Insert:

Division 3A—Offences and civil penalties related to exemptions under Part 4-6A

41MNB Criminal offences for breaching a condition of an exemption

(1) A person commits an offence if:

(a) the person does an act or omits to do an act in relation to a medical device; and

(b) the device is of a kind covered by an exemption in force under section 41GS; and

(c) the act or omission results in the breach of a condition of the exemption; and

(d) the act or omission is likely to cause a serious risk to public health.

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

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

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

(3) A person commits an offence if:

(a) the person does an act or omits to do an act in relation to a medical device; and

(b) the device is of a kind covered by an exemption in force under section 41GS; and

(c) the act or omission results in the breach of a condition of the exemption.

Penalty: Imprisonment for 4 years or 240 penalty units, or both.

(4) Strict liability applies to paragraph (3)(b).

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

(5) A person commits an offence if:

(a) the person does an act or omits to do an act in relation to a medical device; and

(b) the device is of a kind covered by an exemption in force under section 41GS; and

(c) the act or omission results in the breach of a condition of the exemption.

Penalty: 60 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

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

41MNC Civil penalty for breaching a condition of an exemption

A person contravenes this section if:

(a) the person does an act or omits to do an act in relation to a medical device; and

(b) the device is of a kind covered by an exemption in force under section 41GS; and

(c) the act or omission results in the breach of a condition of the exemption.

Maximum civil penalty:

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

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

41MND Civil penalty for making misrepresentations about medical devices

A person contravenes this section if:

(a) the person makes a representation that medical devices are of a kind covered by an exemption in force under section 41GS; and

(b) the representation is false or misleading.

Maximum civil penalty:

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

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

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

Insert:

(iiaa) who is required to comply with a condition of an exemption of a kind of medical device under section 41GS; or

37 After paragraph 56A(1)(a)

Insert:

(aaa) there was no exemption in force under section 41GS in relation to a particular kind of medical device; or

38 Subsection 57(1)

Omit "(10)", substitute "(11)".

39 At the end of section 57

Add:

(11) The power of the Minister under subsection 41GS(1) may be delegated only to the Secretary.

40 Subsection 61(3A)

After "31B,", insert "41JCA,".

Schedule 2—Emergency exemption for therapeutic goods that are not medical devices

Therapeutic Goods Act 1989

1 Subsection 18A(9A)

Repeal the subsection, substitute:

Exemption not a legislative instrument

(9A) An exemption under subsection (1) is not a legislative instrument.

Informing persons of exemption etc.

(9B) If the Minister makes an exemption under subsection (1), the Minister must take reasonable steps to give a copy of the following to each person covered by paragraph (7)(d):

(a) the exemption;

(b) any revocation or variation of the exemption under this section.

2 Paragraphs 18A(10)(b) and (11)(b)

Omit "subsection (8)", substitute "this section".

3 Subsection 57(10)

Omit "paragraph 18A(2)(a)", substitute "subsection 18A(1)".

4 Application

(1) The amendment made by item 1 applies in relation to an exemption made on or after the commencement of that item.

(2) The amendment made by item 2 applies in relation to a revocation or variation made on or after the commencement of that item (whether the exemption was made before, on or after that commencement).

Schedule 3—Fit and proper person test

Therapeutic Goods Act 1989

1 Subsection 3(1)

Insert:

major interest holder of a body corporate means a person who:

(a) is in a position to cast, or control the casting of, more than one-fifth of the maximum number of votes that might be cast at a general meeting of the body corporate; or

(b) holds more than one-fifth of the issued share capital of the body corporate (excluding any part of that issued share capital that carries no right to participate beyond a specified amount in a distribution of either profits or capital).

2 Paragraphs 38(1)(g) to (i)

Repeal the paragraphs, substitute:

(g) at least one of the following persons:

(i) the applicant;

(ii) a person (a ***manager***) who makes, or participates in making, decisions that affect the whole, or a substantial part, of the applicant's affairs;

(iii) if the applicant is a body corporate—a major interest holder of the body corporate;

has, within the 10 years immediately before the application:

(iv) been convicted of an offence against this Act or a corresponding State law; or

(v) been convicted of an offence against a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(vi) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of this Act or a corresponding State law; or

(vii) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of a law of the

Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(viii) breached a condition of a manufacturing licence; or

(ix) had a manufacturing licence suspended or revoked; or

(x) been a manager, or a major interest holder, of a body corporate in respect of which subparagraph (iv), (v), (vi), (vii), (viii) or (ix) applies in that 10 year period, if the conduct resulting in that subparagraph applying occurred when the person was a manager or major interest holder of the body corporate; or

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

3 Subsection 38(1A)

Repeal the subsection, substitute:

(1A) A reference in paragraph (1)(g) to a person convicted of an offence includes a reference to a person in respect of whom an order has been made relating to the offence under:

(a) section 19B of the *Crimes Act 1914*; or

(b) a corresponding provision of a law of a State or Territory.

Note: Section 19B of the *Crimes Act 1914* empowers a court that has found a person to have committed an offence to take action without proceeding to record a conviction.

(1AA) Paragraph (1)(g) does not limit paragraph (1)(h).

4 Subsection 38(1B)

Omit "subsection (1A)", substitute "paragraph (1)(g)".

5 Subsection 38(2)

Omit "paragraphs (1)(g), (h) and (i)", substitute "paragraph (1)(g)".

6 Subsection 38(2)

Omit "one or more of those paragraphs", substitute "that paragraph".

7 After paragraph 40(4)(ab)

Insert:

(ac) give the Secretary the information specified in a notice under subsection (6) within the period, and in the manner, specified in the notice; and

8 At the end of section 40

Add:

(6) The Secretary may, by notice in writing given to the holder of a licence, require the holder to give the Secretary, within the specified period and in the specified manner, specified information to be used by the Secretary in deciding whether to revoke or suspend the licence under section 41 in the circumstances referred to in paragraph 41(1)(a).

(7) The period specified in a notice given under subsection (6) must be at least 14 days after the notice is given.

9 Paragraphs 41(1)(a) to (cd)

Repeal the paragraphs, substitute:

(a) at least one of the following persons:

(i) the holder;

(ii) a person (a ***manager***) who makes, or participates in making, decisions that affect the whole, or a substantial part, of the holder's affairs;

(iii) if the holder is a body corporate—a major interest holder of the body corporate;

has:

(iv) been convicted of an offence against this Act or a corresponding State law; or

(v) been convicted of an offence against a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(vi) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of this Act or a corresponding State law; or

(vii) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(viii) breached a condition of a manufacturing licence; or

(ix) had a manufacturing licence suspended or revoked; or

(x) been a manager, or a major interest holder, of a body corporate in respect of which subparagraph (iv), (v), (vi), (vii), (viii) or (ix) applies, if the conduct resulting in that subparagraph applying occurred when the person was a manager or major interest holder of the body corporate; or

10 At the end of subsection 41(1)

Add:

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

11 Subsection 41(1A)

Repeal the subsection, substitute:

(1A) A reference in paragraph (1)(a) to a person convicted of an offence includes a reference to a person in respect of whom an order has been made relating to the offence under:

(a) section 19B of the *Crimes Act 1914*; or

(b) a corresponding provision of a law of a State or Territory.

Note: Section 19B of the *Crimes Act 1914* empowers a court that has found a person to have committed an offence to take action without proceeding to record a conviction.

(1B) Paragraph (1)(a) does not limit paragraph (1)(h).

(1C) In paragraph (1)(a):

manufacturing licence means:

(a) a licence granted under this Part; or

(b) a licence, granted under a law of a State or Territory relating to therapeutic goods, relating to manufacturing therapeutic goods.

12 After section 41

Insert:

41AA Spent convictions scheme

Nothing in section 40 or 41 affects the operation of Part VIIC of the *Crimes Act 1914* (which includes provisions that, in certain circumstances, relieve persons from the requirement to disclose spent convictions and require persons aware of such convictions to disregard them).

13 Paragraphs 41EC(3)(a) to (c)

Repeal the paragraphs, substitute:

(a) whether at least one of the following persons:

(i) the applicant;

(ii) a person (a ***manager***) who makes, or participates in making, decisions that affect the whole, or a substantial part, of the applicant's affairs;

(iii) if the applicant is a body corporate—a major interest holder of the body corporate;

has, within the 10 years immediately before the application:

(iv) been convicted of an offence against this Act or a corresponding State law; or

(v) been convicted of an offence against a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(vi) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of this Act or a corresponding State law; or

(vii) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(viii) breached a condition of a conformity assessment certificate; or

(ix) had a conformity assessment certificate suspended or revoked; or

(x) been a manager, or a major interest holder, of a body corporate in respect of which subparagraph (iv), (v), (vi), (vii), (viii) or (ix) applies in that 10 year period, if the conduct resulting in that subparagraph applying occurred when the person was a manager or major interest holder of the body corporate; or

(b) whether any other circumstances prescribed by the regulations for the purposes of this paragraph exist.

14 Subsection 41EC(4)

Repeal the subsection, substitute:

(4) A reference in paragraph (3)(a) to a person convicted of an offence includes a reference to a person in respect of whom an order has been made relating to the offence under:

(a) section 19B of the *Crimes Act 1914*; or

(b) a corresponding provision of a law of a State or Territory.

Note: Section 19B of the *Crimes Act 1914* empowers a court that has found a person to have committed an offence to take action without proceeding to record a conviction.

(5) Paragraph (3)(a) does not limit paragraph (3)(b).

15 Paragraph 41EG(c)

Omit "relating to a kind of medical device to which the application relates".

16 After subsection 41EJ(5)

Insert:

Conditions in regulations

(5A) A conformity assessment certificate is subject to any conditions prescribed by the regulations for the purposes of this subsection.

17 Paragraph 41ET(1)(c)

Repeal the paragraph, substitute:

(c) the Secretary gives to the person a notice under section 41JA that requires the person to give to the Secretary information or documents and the person fails to comply with that notice within a further 10 working days from the day specified in that notice; or

18 Paragraphs 41ET(1)(e) to (g)

Repeal the paragraphs, substitute:

(e) at least one of the following persons:

(i) the person (the ***holder***) in relation to whom the certificate is issued;

(ii) a person (a ***manager***) who makes, or participates in making, decisions that affect the whole, or a substantial part, of the holder's affairs;

(iii) if the holder is a body corporate—a major interest holder of the body corporate;

has:

(iv) been convicted of an offence against this Act or a corresponding State law; or

(v) been convicted of an offence against a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(vi) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of this Act or a corresponding State law; or

(vii) been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or

(viii) breached a condition of a conformity assessment certificate; or

(ix) had a conformity assessment certificate suspended or revoked; or

(x) been a manager, or a major interest holder, of a body corporate in respect of which subparagraph (iv), (v), (vi), (vii), (viii) or (ix) applies, if the conduct resulting in that subparagraph applying occurred when the person was a manager or major interest holder of the body corporate; or

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

19 Subsection 41ET(1A)

Repeal the subsection, substitute:

(1A) A reference in paragraph (1)(e) to a person convicted of an offence includes a reference to a person in respect of whom an order has been made relating to the offence under:

(a) section 19B of the *Crimes Act 1914*; or

(b) a corresponding provision of a law of a State or Territory.

Note: Section 19B of the *Crimes Act 1914* empowers a court that has found a person to have committed an offence to take action without proceeding to record a conviction.

(1B) Paragraph (1)(e) does not limit paragraph (1)(f).

20 At the end of section 41ET

Add:

(4) Nothing in this section affects the operation of Part VIIC of the *Crimes Act 1914* (which includes provisions that, in certain circumstances, relieve persons from the requirement to disclose spent convictions and require persons aware of such convictions to disregard them).

21 After subsection 41JA(1)

Insert:

(1A) The Secretary may, by written notice given to a person who is an applicant for a conformity assessment certificate, require the person to give to the Secretary such further information concerning the application as is specified in the notice.

(1B) Requirements under subsections (1) and (1A) may be included in the same notice.

(1C) The Secretary may, by written notice given to a person who holds a conformity assessment certificate, require the person to give to the Secretary specified information to be used by the Secretary in deciding whether to suspend the certificate under section 41EM, or to revoke the certificate under section 41ET, in relation to the circumstances referred to in paragraph 41ET(1)(e).

(1D) Requirements under subsections (1) and (1C) may be included in the same notice.

22 At the end of section 41JA

Add:

(3) Nothing in this section affects the operation of Part VIIC of the *Crimes Act 1914* (which includes provisions that, in certain circumstances, relieve persons from the requirement to disclose

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

23 Application and transitional

(1) The amendments of section 38 of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to applications for licences made on or after the commencement of this item.

(2) The amendments of sections 40 and 41 of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to licences granted before, on or after the commencement of this item.

(3) The amendments of section 41EC of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to applications for conformity assessment certificates made on or after the commencement of this item.

(4) The amendment of section 41EG of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to notices given on or after the commencement of this item.

(5) The amendment of section 41EJ of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to conformity assessment certificates issued before, on or after the commencement of this item.

(6) The amendments of section 41ET of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to conformity assessment certificates issued before, on or after the commencement of this item.

(7) Paragraph 41ET(1)(c) of the *Therapeutic Goods Act 1989*, as in force immediately before the commencement of this item, continues to apply on and after that commencement in relation to a notice given before that commencement.

(8) Subsection 41JA(1A) of the *Therapeutic Goods Act 1989* applies in relation to applications for conformity assessment certificates made on or after the commencement of this item.

(9) Subsection 41JA(1C) of the *Therapeutic Goods Act 1989* applies in relation to conformity assessment certificates issued before, on or after the commencement of this item.

Schedule 4—Additional default standards

Therapeutic Goods Act 1989

1 Subsection 3(1) (definition of *British Pharmacopoeia*)

Repeal the definition, substitute:

> ***British Pharmacopoeia*** means the edition of the publication of that name, including any additions or amendments, that was in effect for the purposes of this Act immediately before the commencement of Schedule 4 to the *Therapeutic Goods Amendment (Medical Devices and Other Measures) Act 2009* and, if additions or amendments of that publication are made after that commencement, or new editions of that publication are published after that commencement, includes those additions or amendments, or those new editions, from the effective date published by the British Pharmacopoeia Commission or any replacement body.

2 Subsection 3(1) (definition of *British Pharmacopoeia (Veterinary)*)

Repeal the definition.

3 Subsection 3(1)

Insert:

> ***default standard*** means any of the following:
>
> (a) a standard referred to in paragraph (b) of the definition of ***standard*** in this subsection;
>
> (b) a standard referred to in paragraph (c) of that definition;
>
> (c) a standard referred to in paragraph (d) of that definition.

4 Subsection 3(1)

Insert:

> ***European Pharmacopoeia*** means the English edition of the publication of that name, including any additions or amendments, that was in effect immediately before the commencement of this definition and, if additions or amendments of that publication are made after that commencement, or new editions of that publication

are published after that commencement, includes those additions or amendments, or those new editions, from the effective date published by the Council of Europe or any replacement body.

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

Omit "or animal".

6 Subsection 3(1) (definition of *standard*)

Repeal the definition, substitute:

standard, in relation to therapeutic goods, means any of the following:

(a) a standard that is constituted by the matters specified in an order under section 10 that is applicable to the goods;

(b) if the goods are the subject of one or more monographs (other than a monograph exempt under subsection 3C(1)) in the British Pharmacopoeia—a standard that is constituted by the statements (other than statements exempt under subsection 3C(2)) in those monographs, as interpreted in accordance with the General Notices section of the British Pharmacopoeia;

(c) if the goods are the subject of one or more monographs (other than a monograph exempt under subsection 3C(1)) in the European Pharmacopoeia—a standard that is constituted by the statements (other than statements exempt under subsection 3C(2)) in those monographs, as interpreted in accordance with the General Notices section of the European Pharmacopoeia;

(d) if the goods are the subject of one or more monographs (other than a monograph exempt under subsection 3C(1)) in the United States Pharmacopeia-National Formulary—a standard that is constituted by the statements (other than statements exempt under subsection 3C(2)) in those monographs, as interpreted in accordance with the General Notices section of the United States Pharmacopeia-National Formulary.

Note: See also section 13.

7 Subsection 3(1) (paragraph (c) of the definition of *supply*)

Omit "or animals".

8 Subsection 3(1) (paragraph (d) of the definition of *supply*)

Omit "or animal".

9 Subsection 3(1) (definition of *therapeutic use*)

Omit "or animals" (wherever occurring).

10 Subsection 3(1)

Insert:

United States Pharmacopeia-National Formulary means the English edition of the publication of that name, including any additions or amendments, that was in effect immediately before the commencement of this definition and, if additions or amendments of that publication are made after that commencement, or new editions of that publication are published after that commencement, includes those additions or amendments, or those new editions, from the effective date published by the United States Pharmacopeial Convention or any replacement body.

11 Subsection 3(2)

Repeal the subsection, substitute:

(2) For the purposes of this Act, therapeutic goods are taken to be for use in humans if they are not solely for use in animals.

12 After section 3B

Insert:

3C Exempting monographs in pharmacopoeias

Exempting entire monographs

(1) The Minister may, by legislative instrument, determine that specified monographs in the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopeia-National Formulary are exempt for the purposes of paragraph (b), (c) or (d) of the definition of ***standard*** in subsection 3(1).

Note: For specification by class, see subsection 13(3) of the *Legislative Instruments Act 2003*.

Exempting parts of monographs

(2) The Minister may, by legislative instrument, determine that specified statements in specified monographs in the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopeia-National Formulary are exempt for the purposes of paragraph (b), (c) or (d) of the definition of ***standard*** in subsection 3(1).

13 Subsection 10(1)

Omit "or the British Pharmacopoeia (Veterinary)", substitute ", the European Pharmacopoeia or the United States Pharmacopeia-National Formulary".

14 Subparagraph 10(2)(a)(iv)

Omit "or the British Pharmacopoeia (Veterinary)", substitute ", the European Pharmacopoeia or the United States Pharmacopeia-National Formulary".

15 Section 13

Repeal the section, substitute:

13 Special provisions relating to standards

(1) For the purposes of this Act, if a statement (the ***main statement***) in a monograph in the British Pharmacopoeia, the European Pharmacopoeia or the United States Pharmacopeia-National Formulary refers to a statement in a monograph in another publication, the main statement is taken to include the other statement.

(2) If:

(a) a standard under section 10 (the ***Ministerial standard***) applies to therapeutic goods; and

(b) requirements applicable to the goods are specified in a default standard; and

(c) those requirements are inconsistent with the requirements specified in the Ministerial standard;

the requirements referred to in paragraph (b) are, so far as they are inconsistent, to be disregarded for the purposes of this Act.

(3) If:

(a) a default standard applies to a class of therapeutic goods; and

(b) another default standard applies to only some of the therapeutic goods within that class; and

(c) those standards are inconsistent;

the standard referred to in paragraph (a) does not apply in relation to the goods referred to in paragraph (b).

(4) If:

(a) therapeutic goods consist, or are represented to consist, of a mixture of ingredients or of a combination of component parts; and

(b) a default standard is applicable to one or more of the ingredients or one or more of the component parts; and

(c) a default standard is applicable to the mixture or combination;

the standard referred to in paragraph (b) does not apply in relation to the goods.

(5) If:

(a) therapeutic goods consist, or are represented to consist, of a mixture of ingredients or of a combination of component parts; and

(b) there is no standard applicable to the mixture or combination but a standard is applicable to one or more of the ingredients or one or more of the component parts;

the Minister may, by order published in the *Gazette*, determine that the standard does not apply to the goods. The order has effect accordingly.

(6) An order under subsection (5) is not a legislative instrument.

(7) For the purposes of this Act, in working out at a particular time if therapeutic goods conform with a default standard applicable to the goods, if:

(a) after applying subsections (2) to (5), 2 or more default standards are applicable to the goods at that time; and

(b) at that time, the goods conform with at least one of those standards but do not conform with at least one of those standards;

then the default standards that the goods do not conform with are taken not to apply to the goods at that time.

16 Subsection 30F(2)

Omit "or animal".

17 Paragraph 41CC(1)(b)

Omit "United States Pharmacopoeia", substitute "United States Pharmacopeia-National Formulary".

18 Subsection 42V(3)

Omit "or animal".

19 Section 56

Omit "and of the British Pharmacopoeia (Veterinary)", substitute ", the European Pharmacopoeia and the United States Pharmacopeia-National Formulary".

20 Application and transitional

(1) If:

(a) immediately before the commencement of this item, therapeutic goods were registered goods or listed goods; and

(b) at a particular time within the period of 12 months beginning on the day on which this item commences:

(i) a standard referred to in paragraph (c) or (d) of the definition of ***standard*** in subsection 3(1) of the *Therapeutic Goods Act 1989* (as amended by this Act) would, apart from this subitem, apply to the goods; and

(ii) the goods do not conform with that standard;

then that standard is taken not to apply to the goods at that time.

(2) To avoid doubt, paragraph (a) of the definition of ***standard*** in subsection 3(1) of the *Therapeutic Goods Act 1989* (as amended by this Act) applies in relation to orders made under section 10 of the *Therapeutic Goods Act 1989* before, on or after the commencement of this item.

(3) An order in force under paragraph 13(7)(c) of the *Therapeutic Goods Act 1989* immediately before the commencement of this item has effect,

on and after that commencement, as if it were an order in force under subsection 13(5) of that Act.

Schedule 5—Information disclosure provisions

Therapeutic Goods Act 1989

1 Subsection 9C(1)

Omit "The Register is not open for public inspection, but a", substitute "A".

2 Subsection 61(1) (definition of *therapeutic goods information*)

Omit "came into the possession of the Department in connection with", substitute "is held by the Department and relates to".

3 Application

The amendment made by item 2 applies in relation to information held by the Department on or after the commencement of this item (regardless of whether the information came into existence before, on or after that commencement).

4 Paragraphs 61(2)(a) and (b)

Omit "the Director-General of".

5 Subsection 61(3)

Omit "the head of".

6 Paragraph 61(3A)(a)

Omit "the head of an authority, or an authority,", substitute "an authority".

7 Subsection 61(4)

Omit "the head of".

8 Paragraphs 61(4A)(a), (b) and (ba)

Omit "the head of".

9 After paragraph 61(4A)(d)

Insert:

(da) action taken by the Secretary under section 30EA (about notification and recovery of therapeutic goods);

10 Paragraph 61(4A)(e)

After "of", insert "Part 5-2 or".

11 After paragraph 61(4A)(f)

Insert:

(fa) any cases, or possible cases, of counterfeit therapeutic goods;

12 Subsection 61(5)

Omit "the head of" (wherever occurring).

13 After subsection 61(5)

Insert:

(5AA) The Secretary may release to a person, body or authority that is specified, or is of a kind specified, under subsection (5AB) therapeutic goods information of a kind specified under that subsection for a purpose specified under that subsection.

(5AB) For the purpose of subsection (5AA), the Minister may, by legislative instrument, specify one or more of the following:

(a) a person, body or authority;

(b) kinds of persons, bodies or authorities;

(c) kinds of therapeutic goods information;

(d) purposes.

14 After subsection 61(5B)

Insert:

(5C) The Secretary may release to the public therapeutic goods information of a kind specified under subsection (5D).

(5D) The Minister may, by legislative instrument, specify kinds of therapeutic goods information for the purpose of subsection (5C).

15 Paragraph 61(6A)(b)

Omit "persons; and", substitute "persons.".

16 Paragraph 61(6A)(c)

Repeal the paragraph.

17 At the end of section 61

Add:

(12) The subsections of this section permitting the release of information have effect independently of each other.

Schedule 6—Advertising

Therapeutic Goods Act 1989

1 Subsection 42AC(2)

Omit "Section 42DC", substitute "Section 42DKB".

2 Section 42B (definition of *restricted representation*)

Omit "subsection 42DD(1)", substitute "section 42DD".

3 Section 42DA

Repeal the section, substitute:

42DA Simplified outline

The following is a simplified outline of this Division:

> This Division has 2 kinds of application.
>
> First, Part 2 of the *Therapeutic Goods Regulations 1990* deals with the Secretary approving certain advertisements and it refers to provisions of this Division.
>
> Second, the offences in Division 3A of this Part refer to provisions of this Division.

4 Section 42DC

Repeal the section.

5 Subsection 42DD(1)

Omit "(1)".

6 Subsection 42DD(1)

Omit "subsection", substitute "section".

7 At the end of subsection 42DD(1)

Add:

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

8 Subsection 42DD(2)

Repeal the subsection.

9 Before section 42DL

Insert:

Division 3A—Therapeutic goods advertisements for which an approval is not required

42DKA Application of Division

This Division applies to advertisements about therapeutic goods other than advertisements for which an approval is required under Part 2 of the *Therapeutic Goods Regulations 1990*.

42DKB Certain representations not to be published or broadcast

(1) If a representation in an advertisement about therapeutic goods is false or misleading, the Secretary may, by notice given to the person apparently responsible for publishing or broadcasting the advertisement, prevent that person from publishing or broadcasting, or causing to be published or broadcast, an advertisement containing that representation (whether express or implied) about those goods.

(2) A notice under subsection (1) is not a legislative instrument.

10 Paragraph 42DL(1)(d)

Repeal the paragraph, substitute:

(d) that is in contravention of a notice referred to in section 42DKB that was given to the person; or

11 Paragraph 42DL(2)(b)

Repeal the paragraph, substitute:

(b) that the notice referred to in paragraph (1)(d) is a notice referred to in section 42DKB;

12 Saving and transitional

(1) A notice in force under section 42DC of the *Therapeutic Goods Act 1989* immediately before the commencement of this item has effect, on and after that commencement, as if it were a notice given and in force under section 42DKB of that Act.

(2) Regulations in force for the purposes of subsection 42DD(1) of the *Therapeutic Goods Act 1989* immediately before the commencement of this item continue in force on and after that commencement as if they were regulations in force for the purposes of section 42DD of that Act.

Schedule 7—Other amendments

Therapeutic Goods Act 1989

1 Subsection 3(8)

Repeal the subsection.

2 Subsection 8(2) (penalty)

Omit "Maximum penalty", substitute "Penalty".

3 Subsections 14(1), (2), (4), (6), (7), (9), (10), (11) and (13) (penalty)

Omit "Maximum penalty", substitute "Penalty".

4 Subsections 15(2), (3) and (5) (penalty)

Omit "Maximum penalty", substitute "Penalty".

5 Subsections 19B(1), (2) and (4) (penalty)

Omit "Maximum penalty", substitute "Penalty".

6 Subsections 20(1B), (2A) and (2C) (penalty)

Omit "Maximum penalty", substitute "Penalty".

7 Section 21 (penalty)

Omit "Maximum penalty", substitute "Penalty".

8 Subsections 21A(1), (2), (4), (5), (6), (8), (9), (10), (12) and (13) (penalty)

Omit "Maximum penalty", substitute "Penalty".

9 Subsections 22(1), (5), (6), (7AB), (7AD), (7A) and (8) (penalty)

Omit "Maximum penalty", substitute "Penalty".

10 Subsections 22A(1), (2) and (4) (penalty)

Omit "Maximum penalty", substitute "Penalty".

11 Subsection 26B(2) (penalty)

Omit "Maximum penalty", substitute "Penalty".

12 Subsection 26C(5) (penalty)

Repeal the penalty.

13 After subsection 26C(5)

Insert:

(5A) A pecuniary penalty ordered under subsection (5) must not exceed $10,000,000.

14 Subsection 29A(1) (penalty)

Omit "Maximum penalty", substitute "Penalty".

15 Subsections 29B(3) and (4) (penalty)

Omit "Maximum penalty", substitute "Penalty".

16 Subsections 30EC(1), (2) and (4) (penalty)

Omit "Maximum penalty", substitute "Penalty".

17 Subsections 30F(4B), (4C) and (5) (penalty)

Omit "Maximum penalty", substitute "Penalty".

18 Subsections 30H(1) and (3) (penalty)

Omit "Maximum penalty", substitute "Penalty".

19 Subsections 31(4), (5A), (5B) and (6) (penalty)

Omit "Maximum penalty", substitute "Penalty".

20 Section 31C (penalty)

Omit "Maximum penalty", substitute "Penalty".

21 Subsection 31D(1) (penalty)

Omit "Maximum penalty", substitute "Penalty".

22 Subsection 31E(1) (penalty)

Omit "Maximum penalty", substitute "Penalty".

23 Subsections 35(1), (2), (4), (5), (7) and (9) (penalty)

Omit "Maximum penalty", substitute "Penalty".

24 Subsections 35B(1), (2) and (4) (penalty)

Omit "Maximum penalty", substitute "Penalty".

25 Subsections 41EI(1), (2) and (4) (penalty)

Omit "Maximum penalty", substitute "Penalty".

26 Subsections 41FE(1), (2) and (4) (penalty)

Omit "Maximum penalty", substitute "Penalty".

27 Subsections 41JB(3), (4), (5) and (7) (penalty)

Omit "Maximum penalty", substitute "Penalty".

28 Sections 41JG and 41JH (penalty)

Omit "Maximum penalty", substitute "Penalty".

29 Subsection 41JI(1) (penalty)

Omit "Maximum penalty", substitute "Penalty".

30 Subsections 41KC(1), (2) and (4) (penalty)

Omit "Maximum penalty", substitute "Penalty".

31 Subsections 41MA(1), (2), (4), (5), (6), (8), (9), (10) and (12) (penalty)

Omit "Maximum penalty", substitute "Penalty".

32 Subsections 41MC(2), (3) and (5) (penalty)

Omit "Maximum penalty", substitute "Penalty".

33 Subsections 41ME(1), (2), (4), (5), (6) and (8) (penalty)

Omit "Maximum penalty", substitute "Penalty".

34 Subsections 41MF(1), (2), (3) and (4) (penalty)

Omit "Maximum penalty", substitute "Penalty".

35 Section 41MH (penalty)

Omit "Maximum penalty", substitute "Penalty".

36 Subsections 41MI(1), (2) and (4) (penalty)

Omit "Maximum penalty", substitute "Penalty".

37 Section 41MK (penalty)

Omit "Maximum penalty", substitute "Penalty".

38 Subsection 41ML(3)

Omit "(3)".

39 Subsection 41ML(3) (penalty)

Omit "Maximum penalty", substitute "Penalty".

40 Section 41MM (penalty)

Omit "Maximum penalty", substitute "Penalty".

41 Subsections 41MN(1), (2), (4), (5), (6), (8) and (9) (penalty)

Omit "Maximum penalty", substitute "Penalty".

42 Subsections 41MO(1), (2), (4), (5), (6) and (8) (penalty)

Omit "Maximum penalty", substitute "Penalty".

43 Subsection 41MP(1) (penalty)

Omit "Maximum penalty", substitute "Penalty".

44 Subsections 41MQ(3) and (4) (penalty)

Omit "Maximum penalty", substitute "Penalty".

45 Subsection 42E(1) (penalty)

Omit "Maximum penalty", substitute "Penalty".

46 Subsections 42T(1) and (2) (penalty)

Omit "Maximum penalty", substitute "Penalty".

47 Subsections 42V(6), (6A) and (6C) (penalty)

Omit "Maximum penalty", substitute "Penalty".

48 Subsections 42W(1) and (2) (penalty)

Omit “Maximum penalty”, substitute “Penalty”.

49 Subsection 42YE(5) (penalty)

Omit “Maximum penalty”, substitute “Penalty”.

50 Subsection 48(3) (penalty)

Omit “Maximum penalty”, substitute “Penalty”.

51 Subsections 51B(1) and (2) (penalty)

Omit “Maximum penalty”, substitute “Penalty”.

52 Subsection 52(3) (penalty)

Omit “Maximum penalty”, substitute “Penalty”.

53 Subsection 54AB(1) (penalty)

Omit “Maximum penalty”, substitute “Penalty”.

[*Minister’s second reading speech made in—*
Senate on 3 December 2008
House of Representatives on 26 May 2009]

(230/08)