Therapeutic Goods Amendment (2009 Measures No. 1) Act 2009

No. 76, 2009

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

Note: An electronic version of this Act is available in ComLaw (http://www.comlaw.gov.au/)

Contents

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No. 76, 2009

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

[*Assented to 27 August 2009*]

The Parliament of Australia enacts:

1 Short title

This Act may be cited as the *Therapeutic Goods Amendment (2009 Measures No. 1) Act 2009*.

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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.	27 August 2009
2. Schedule 1	The day after this Act receives the Royal Assent.	28 August 2009
3. Schedule 2	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.	25 February 2010 (*see* F2009L03994)
4. Schedule 3	The day after this Act receives the Royal Assent.	28 August 2009
5. Schedule 4	1 July 2011.	1 July 2011
6. Schedule 5	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.	8 February 2010 (*see* F2009L03994)
7. Schedule 6	The day after this Act receives the Royal Assent.	28 August 2009
8. Schedule 7, Part 1	The day after this Act receives the Royal Assent.	28 August 2009

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Commencement information		
Column 1	**Column 2**	**Column 3**
Provision(s)	**Commencement**	**Date/Details**
9. Schedule 7, Part 2	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.	25 January 2010 (*see* F2009L03994)

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.

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Schedule 1—Suspending therapeutic goods from the Register

Therapeutic Goods Act 1989

1 At the end of section 29

Add:

Note: The goods are taken not to be included in the Register while their registration or listing is suspended: see section 29G.

2 After section 29C

Insert:

29D Suspension of registration or listing

(1) The Secretary may, by written notice given to a person in relation to whom therapeutic goods are included in the Register, suspend the registration or listing of the goods if:

(a) the Secretary is satisfied that:

(i) there is a potential risk of death, serious illness or serious injury if the therapeutic goods continue to be included in the Register; and

(ii) it is likely that the person will, within the period of the suspension, be able to take the action necessary to ensure that the therapeutic goods would not cause a potential risk of death, serious illness or serious injury if the therapeutic goods were to continue to be included in the Register; or

(b) the Secretary is satisfied that it is likely that there are grounds for cancelling the registration or listing of the goods under paragraph 30(1)(da), (e) or (f) or subsection 30(1A), (1C) or (2).

Notice of proposed suspension in some cases

(2) However, before suspending the registration or listing of the goods because of paragraph (1)(b), the Secretary must:

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(a) inform the person by written notice that the Secretary proposes the suspension and set out the reasons for it; and

(b) give the person a reasonable opportunity to make submissions to the Secretary in relation to the proposed suspension.

(3) The Secretary is not to make a decision relating to the proposed suspension until the Secretary has had regard to any submissions the person makes under paragraph (2)(b).

Period of suspension

(4) A notice under subsection (1) must specify the period of the suspension. The period must not exceed 6 months.

Note: Section 29E deals with when the suspension takes effect and extensions of the suspension.

Publication in Gazette

(5) As soon as practicable after giving a notice under subsection (1), the Secretary must cause to be published in the *Gazette* a notice setting out particulars of the suspension.

29E When suspension takes effect etc.

(1) A suspension under section 29D takes effect:

(a) if the notice under subsection 29D(1) states that the suspension is necessary to prevent a potential risk of death, serious illness or serious injury—on the day on which the notice is given to the person; or

(b) in any other case—on the day specified for the purpose in the notice, being a day not earlier than 20 working days after the notice is given to the person.

(2) The suspension has effect until:

(a) the Secretary revokes it under section 29F; or

(b) the end of:

(i) the period specified in the notice under subsection 29D(4); or

(ii) if the period is extended under subsection (3) of this section, the period as so extended.

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Extension of suspension

(3) The Secretary may, by written notice given to the person, extend the period specified in the notice under subsection 29D(4) by a further specified period not exceeding 6 months.

Publication in Gazette

(4) As soon as practicable after giving a notice under subsection (3), the Secretary must cause to be published in the *Gazette* a notice setting out particulars of the extension.

29F Revocation of suspension

(1) The Secretary must revoke a suspension under section 29D, by written notice given to the person in relation to whom the therapeutic goods are included in the Register, if the Secretary is satisfied that:

(a) the ground on which the registration or listing of the therapeutic goods was suspended no longer applies; and

(b) there are no other grounds for suspending the registration or listing of the therapeutic goods.

(2) The Secretary's power to revoke the suspension may be exercised:

(a) if the person in relation to whom the therapeutic goods are included in the Register applies in writing to the Secretary; or

(b) on the Secretary's own initiative.

Publication in Gazette

(3) As soon as practicable after giving a notice under subsection (1), the Secretary must cause to be published in the *Gazette* a notice setting out particulars of the revocation.

Notice of refusal to revoke suspension

(4) If the Secretary decides, after an application is made under paragraph (2)(a), not to revoke the suspension, the Secretary must:

(a) notify the applicant in writing of his or her decision; and

(b) state in the notice the reasons for the decision.

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29G Effect of suspension

(1) If the registration or listing of therapeutic goods is suspended under section 29D, the goods are taken, for the purposes of this Act (other than sections 28, 29A, 29AA, 29E, 29F, 30 and 31), not to be included in the Register while the suspension has effect.

Note: Dealing in therapeutic goods that are not included in the Register may be an offence or may contravene a civil penalty provision: see Division 1.

(2) While the suspension has effect, the Secretary's power under section 30 to cancel the registration or listing of the therapeutic goods is not affected.

3 Subsection 30EA(1) (after table item 6)

Insert:

6A.	The registration or listing of the goods has been suspended under this Part	The person in relation to whom the goods were included in the Register

4 Section 30ED

After "power to", insert "suspend or".

Note: The heading to section 30ED is altered by omitting "**Power of**" and substituting "**Powers of suspension and**".

5 Paragraph 56A(1)(g)

After "had been", insert "suspended or".

6 Paragraphs 61(4)(b) and (ba)

After "or the", insert "suspension or".

7 Application

The amendment made by item 2 applies in relation to therapeutic goods included in the Register before, on or after the commencement of that item.

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Schedule 2—Manufacturing licences

Therapeutic Goods Act 1989

1 Subsection 3(1) (definition of *manufacturing premises*)

Repeal the definition.

2 Subsection 3(1)

Insert:

manufacturing site means premises:

(a) that are for use in the manufacture of a particular kind of therapeutic goods; and

(b) at which the same persons have control of the management of the production of the goods and the procedures for quality control.

3 Subsection 3(1)

Insert:

manufacturing site authorisation means an authorisation referred to in subsection 38(2B) or 40B(4).

4 Paragraph 37(1)(c)

Omit "identify the manufacturing premises", substitute "in accordance with subsections (1A) and (1B), identify one or more manufacturing sites".

5 After subsection 37(1)

Insert:

Manufacturing sites

(1A) Subject to subsection (1B), an application under subsection (1) must relate to one manufacturing site only. This does not prevent other applications from relating to other manufacturing sites.

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(1B) If an applicant is of the view that, having regard to the guidelines under section 38A, a licence could be granted covering 2 or more manufacturing sites, the applicant may:

(a) identify those sites in the application; and

(b) state the applicant's reasons for the applicant's view.

6 Paragraph 37(2)(b)

Omit "the premises,", substitute "each manufacturing site identified in the application and the".

Note: The following heading to subsection 37(2) is inserted "*Further information*".

7 Paragraph 37(2)(b)

Omit "on those premises", substitute "at that site".

Note: The following heading to subsection 37(3) is inserted "*Applications or information may be given electronically*".

8 Paragraph 38(1)(a)

Omit "particular manufacturing premises", substitute "one or more manufacturing sites".

9 Subsection 38(1)

Omit "to carry out those steps at those premises", substitute "covering one or more manufacturing sites specified in the licence".

10 Paragraph 38(1)(f)

Omit "the premises", substitute "one or more of the manufacturing sites identified in the application".

Note 1: The following heading to subsection 38(1A) is inserted "*Interpretation*".

Note 2: The following heading to subsection 38(2) is inserted "*Special circumstances justifying grant of licence*".

11 After subsection 38(2)

Insert:

Guidelines

(2A) The Secretary must have regard to the guidelines under section 38A in granting licences under this section.

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What the licence authorises

(2B) For each manufacturing site covered by a licence, the Secretary must authorise, in the licence, the holder of the licence to carry out specified steps in the manufacture of specified therapeutic goods at that manufacturing site.

Note 1: For specification by class, see subsection 46(3) of the *Acts Interpretation Act 1901*.

Note 2: Sections 40A and 40B deal with variation of authorisations.

Note 1: The following heading to subsection 38(3) is inserted "*Notice of decision*".

Note 2: The following heading to subsection 38(4) is inserted "*Publication in Gazette*".

12 After section 38

Insert:

38A Guidelines for multi-site licences

The Secretary must, by legislative instrument, make guidelines setting out the circumstances in which a licence may cover 2 or more manufacturing sites.

38B Splitting multi-site licences

(1) This section applies if a licence (the ***old licence***):

(a) either:

(i) was in force under this Part immediately before the commencement of this section; or

(ii) was suspended under this Part immediately before that commencement; and

(b) related to premises that comprise 2 or more sites (the ***old sites***).

(2) As soon as practicable after the commencement of this section, the Secretary must:

(a) by writing, revoke the old licence; and

(b) on the day that the Secretary revokes the old licence, grant new licences (each of which is a ***new licence***) to the holder of the old licence which, when considered together, cover the old sites.

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The Secretary must give the holder written notice of the revocation and grant.

Note: Subsections (5) and (6) deal with when each new licence commences and when the old licence ends.

Guidelines

(3) The Secretary must have regard to the guidelines under section 38A in granting licences under this section.

Application of this Part

(4) Subject to this section, subsections 38(2B) and (4) and sections 39 to 41A apply to a new licence in the same way as they apply to a licence granted under section 38.

Note: This means, for example, that:

(a) the Secretary must give a manufacturing site authorisation under subsection 38(2B) in relation to each manufacturing site covered by a new licence; and

(b) the Secretary may impose conditions on a new licence under subsection 40(1) and the statutory conditions under subsection 40(4) will apply to a new licence; and

(c) the Secretary may revoke or suspend a new licence under section 41.

Commencement of new licence

(5) The day specified under subsection 39(1) for the commencement of each new licence granted to the holder of the old licence must be the day (the ***transition day*)** after the day each new licence is granted.

Note: Subsection (7) deals with suspending a new licence from the transition day.

When revocation of old licence takes effect

(6) The revocation of the holder's old licence takes effect immediately before the start of the transition day.

Suspension of new licence

(7) If:

(a) subparagraph (1)(a)(ii) applies in relation to an old licence; and

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(b) the period of suspension of the old licence is due to end at the end of a day (the ***relevant day***) after the transition day;

the Secretary may, on the day that the Secretary grants a new licence to the holder of the old licence and by notice in writing given to the holder, suspend the new licence for a period starting on the transition day and ending at the end of the relevant day.

(8) Subsection 41(2) does not apply in relation to a suspension under subsection (7) of this section. However, subsections 41(4) to (6) do apply in relation to the suspension.

(9) To avoid doubt, subsection (7) does not prevent subsection 41(1) from applying in relation to a new licence.

Licence charges

(10) Subsection 4(2) of the *Therapeutic Goods (Charges) Act 1989* does not apply in relation to a new licence for the financial year in which the new licence is granted.

No review of revocation of old licence

(11) The revocation of the old licence is taken not to be an initial decision for the purposes of section 60.

13 Subparagraph 40(4)(b)(i)

Omit "the manufacturing premises to which the licence relates", substitute "each manufacturing site covered by the licence".

14 Subparagraph 40(4)(b)(ii)

Repeal the subparagraph, substitute:

(ii) while at such a site, to inspect the site, any therapeutic goods at the site and the processes relating to the manufacture of therapeutic goods at the site and to examine, take measurements of, conduct tests on or take samples of any therapeutic goods at the site or any thing at the site that relates to any therapeutic goods; and

(iii) while at such a site, to make any still or moving image or any recording of that site or those goods or processes; and

15 Paragraph 40(4)(c)

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Omit “enters premises”, substitute “enters a site”.

16 Paragraph 40(4)(c)

Omit “those premises”, substitute “that site”.

17 Paragraph 40(4)(c)

Omit “the premises”, substitute “that site”.

18 Subparagraph 40(4)(d)(i)

Omit “those premises”, substitute “that site”.

19 After section 40

Insert:

40A Variation of manufacturing site authorisations—Secretary’s own initiative

(1) The Secretary may, on his or her own initiative and by notice in writing given to the holder of a licence, vary a manufacturing site authorisation in relation to the licence.

(2) A variation under subsection (1) takes effect:

(a) if the notice states that the variation is necessary to prevent imminent risk of death, serious illness or serious injury—on the day on which the notice is given to the holder; or

(b) in any other case—on the day specified in the notice (which must not be earlier than 28 days after the notice is given to the holder).

40B Variation of licences—application by licence holder

Addition of manufacturing sites

(1) If the holder of a licence is of the view that, having regard to the guidelines under section 38A, the licence could cover one or more additional manufacturing sites, the holder may apply to the Secretary for a variation of the licence so that it covers one or more additional manufacturing sites specified in the application.

(2) An application under subsection (1) must:

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(a) be made in accordance with a form approved by the Secretary; and

(b) identify the therapeutic goods or classes of therapeutic goods that the holder proposes to manufacture at each additional manufacturing site specified in the application; and

(c) identify the steps in the manufacture of those goods that the holder proposes to carry out under the licence; and

(d) if the holder proposes to carry out steps in the manufacture of blood or blood components under the licence—contain information relating to those steps set out in regulations made for the purposes of paragraph 37(1)(da); and

(e) state the names, qualifications and experience of the persons who are to have control of the manufacture of the goods and of the quality control measures that are to be employed; and

(f) be delivered to an office of the Department specified in the form; and

(g) be accompanied by the prescribed application fee.

(3) If an application is made under subsection (1) and any applicable prescribed inspection fees have been paid, the Secretary may, by notice in writing given to the holder of the licence, vary the licence so that the licence covers each additional manufacturing site specified in the notice.

(4) For each manufacturing site specified under subsection (3), the Secretary must, in the notice under that subsection, vary the licence to authorise the holder of the licence to carry out specified steps in the manufacture of specified therapeutic goods at that manufacturing site.

Note 1: For specification by class, see subsection 46(3) of the *Acts Interpretation Act 1901*.

Note 2: Section 40A and subsections (6) to (9) of this section deal with variation of authorisations.

(5) A variation under subsection (3) or (4) takes effect on the day on which the notice is given to the holder.

Variation of manufacturing site authorisations

(6) The holder of a licence may apply to the Secretary for a variation of a manufacturing site authorisation in relation to the licence.

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(7) An application under subsection (6) must:
  (a) be made in accordance with a form approved by the Secretary; and
  (b) set out the variation sought; and
  (c) be delivered to an office of the Department specified in the form; and
  (d) be accompanied by the prescribed application fee.

(8) If an application is made under subsection (6) and any applicable prescribed inspection fees have been paid, the Secretary may, by notice in writing given to the holder of the licence, vary the manufacturing site authorisation.

(9) A variation under subsection (8) takes effect on the day on which the notice is given to the holder.

Further information

(10) The Secretary may, by notice in writing given to the holder of a licence who has made an application under subsection (1) or (6), require the holder:
  (a) to give to the Secretary, within such reasonable time as is specified in the notice, such further information concerning the application as is specified in the notice; or
  (b) to allow an authorised person, at any reasonable time specified in the notice, to inspect each manufacturing site identified in the application and the equipment, processes and facilities that will be used in the manufacture of therapeutic goods at that site.

Applications or information may be given electronically

(11) An approval of a form mentioned in paragraph (2)(a) or (7)(a), or a notice mentioned in subsection (10), 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.

20 After paragraph 41(1)(e)

Insert:

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(ea) the holder contravenes a manufacturing site authorisation in relation to the licence; or

21 Before section 41A

Insert:

41AAA Transfer of licences

(1) The regulations may make provision for and in relation to the transfer of licences.

(2) Regulations made for the purposes of subsection (1) may make provision for and in relation to:

(a) the making of an application for the transfer of a licence; and

(b) the payment of a fee in respect of an application; and

(c) the assessment of an application; and

(d) the conditions of a licence upon the transfer of the licence; and

(e) the review of decisions made under the regulations.

(3) Subsection (2) does not limit subsection (1).

22 Section 41A

Omit "premises", substitute "sites".

23 Paragraph 58(3)(b)

Omit "manufacturing premises", substitute "a manufacturing site".

24 Paragraph 58(3)(b)

Omit "those premises", substitute "that site".

25 Application and transitional—amendments made by this Schedule

(1) The amendments made by items 4 to 7 apply in relation to applications for licences made on or after the commencement of those items.

(2) The amendments made by items 8 to 11 apply in relation to applications for licences:

(a) made on or after the commencement of those items; and

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(b) made before the commencement of those items that have not been decided by the Secretary before that commencement.

(3) In relation to an application covered by paragraph (2)(b) of this item, paragraph 38(1)(a) of the *Therapeutic Goods Act 1989* applies on and after the commencement of this item as if the application was in respect of the one or more manufacturing sites constituted by the manufacturing premises the subject of the application.

(4) The amendments made by items 13 to 22 apply in relation to licences granted before, on or after the commencement of those items.

26 Transitional—existing licences

(1) This item applies to a licence that:

(a) was in force under Part 3-3 of the *Therapeutic Goods Act 1989* immediately before the commencement of this item; or

(b) was suspended under that Part immediately before that commencement.

(2) The *Therapeutic Goods Act 1989* applies in relation to the licence on and after that commencement as if the licence covered the one or more manufacturing sites constituted by the manufacturing premises to which the licence related immediately before that commencement.

(3) Subitem (2) is subject to section 38B of the *Therapeutic Goods Act 1989* (about splitting multi-site licences).

(4) If section 38B of the *Therapeutic Goods Act 1989* does not apply in relation to the licence, that Act applies in relation to the licence on and after the commencement of this item as if:

(a) the licence authorised the holder of the licence, at the manufacturing site constituted by the manufacturing premises to which the licence related immediately before that commencement, to carry out the steps in the manufacture of therapeutic goods that the licence allowed the holder to carry out immediately before that commencement; and

(b) that authorisation were an authorisation referred to in subsection 38(2B) of that Act.

(5) Subitem (4) does not prevent the variation of that authorisation under section 40A or 40B of the *Therapeutic Goods Act 1989*.

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Note: A contravention of that authorisation may lead to the licence being revoked or suspended: see paragraph 41(1)(ea) of the *Therapeutic Goods Act 1989*.

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Schedule 3—Monitoring powers

Therapeutic Goods Act 1989

1 Subsection 28(5)

After "the registration or listing of therapeutic goods", insert "(the ***subject goods***)".

2 Subsection 28(5)

After "person in relation to whom the", insert "subject".

3 Subparagraph 28(5)(a)(i)

After "deals with the", insert "subject".

4 Subparagraph 28(5)(a)(ii)

Repeal the subparagraph, substitute:

(ii) while on those premises, to inspect those premises and any therapeutic goods on those premises and to examine, take measurements of, conduct tests on or take samples of any therapeutic goods on those premises or any thing on those premises that relates to any therapeutic goods; and

(iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises; and

5 Paragraph 28(5)(b)

After "relating to the", insert "subject".

6 Paragraph 28(5)(c)

After "each batch of the", insert "subject".

7 Paragraph 28(5)(e)

After "in relation to the", insert "subject".

8 Paragraph 28(5)(f)

After "not nominated as a manufacturer of the", insert "subject".

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9 Paragraph 28(5)(g)

After "not nominated as premises to be used in the manufacture of the", insert "subject".

10 Subparagraphs 41EJ(1)(a)(ii) and (iii)

Repeal the subparagraphs, substitute:

(ii) while on those premises, to inspect those premises and medical devices of any kind on those premises and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of medical devices of any kind on those premises or any thing on those premises that relates to medical devices of any kind; and

(iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises; and

11 Subparagraph 41EJ(1)(b)(i)

Omit "that kind", substitute "a kind covered by the certificate".

12 Subparagraph 41FN(1)(a)(ii)

Repeal the subparagraph, substitute:

(ii) while on those premises, to inspect those premises and medical devices of any kind on those premises and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of medical devices of any kind on those premises or any thing on those premises that relates to medical devices of any kind; and

(iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises; and

13 Paragraph 41FN(1)(b)

Omit "that kind", substitute "the kind included in the Register".

14 Paragraphs 46A(1)(b) and (c)

Repeal the paragraphs, substitute:

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(b) inspect, examine, take measurements of, conduct tests on or take samples of any therapeutic goods on the premises or any thing on the premises that relates to any therapeutic goods;

(c) make any still or moving image or any recording of the premises or any thing on the premises;

15 Paragraphs 48(1)(b) and (c)

Repeal the paragraphs, substitute:

(b) to inspect, examine, take measurements of, conduct tests on or take samples of any therapeutic goods on the premises or any thing on the premises that relates to any therapeutic goods;

(c) to make any still or moving image or any recording of the premises or any thing on the premises;

16 Application

(1) The amendments made by items 1 to 9 apply in relation to the registration or listing of therapeutic goods before, on or after the commencement of those items.

(2) The amendments made by items 10 and 11 apply in relation to conformity assessment certificates issued before, on or after the commencement of those items.

(3) The amendments made by items 12 and 13 apply in relation to the inclusion of a kind of medical device in the Register before, on or after the commencement of those items.

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Schedule 4—Homoeopathic and anthroposophic preparations

Therapeutic Goods Act 1989

1 Subsection 3(1)

Insert:

anthroposophic pharmacopoeia means:

(a) a publication specified under paragraph 3AB(3)(a), as that publication is in force from time to time; or

(b) a part of a publication specified under paragraph 3AB(3)(b), as that part is in force from time to time.

2 Subsection 3(1)

Insert:

anthroposophic preparation has the meaning given by subsection 3AB(1).

3 Subsection 3(1)

Insert:

anthroposophic standard has the meaning given by subsection 3AB(2).

4 Subsection 3(1)

Insert:

homoeopathic pharmacopoeia means:

(a) a publication specified under paragraph 3AA(3)(a), as that publication is in force from time to time; or

(b) a part of a publication specified under paragraph 3AA(3)(b), as that part is in force from time to time.

5 Subsection 3(1)

Insert:

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homoeopathic preparation has the meaning given by subsection 3AA(1).

6 Subsection 3(1)

Insert:

homoeopathic standard has the meaning given by subsection 3AA(2).

7 Subsection 3(1)

Insert:

mother substance means any of the following:

(a) an animal;
(b) a plant;
(c) an alga;
(d) a fungus;
(e) a micro-organism;
(f) a mineral;
(g) a mineral compound;
(h) a chemical;
(i) a product obtained from any of the things mentioned in paragraphs (a) to (h).

8 Subsection 3(1) (at the end of the definition of *standard*) (before the note)

Add:

; (e) a homoeopathic standard;
(f) an anthroposophic standard.

9 After section 3

Insert:

3AA Homoeopathic preparations and homoeopathic standards

Homoeopathic preparation

(1) For the purposes of this Act, a ***homoeopathic preparation*** is a preparation:

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(a) manufactured from a mother substance; and
(b) manufactured in accordance with a manufacturing procedure described in a homoeopathic pharmacopoeia.

Homoeopathic standard

(2) For the purposes of this Act, if:
(a) there are therapeutic goods that are a homoeopathic preparation; and
(b) the goods are the subject of one or more monographs (other than a monograph exempt under subsection (4)) in the homoeopathic pharmacopoeia describing the manufacturing procedure that the preparation was manufactured in accordance with;

then there is a ***homoeopathic standard***, in relation to the goods, that is constituted by the statements (other than statements exempt under subsection (5)) in those monographs, as interpreted in accordance with any interpretation sections of that homoeopathic pharmacopoeia.

Specifying publications

(3) The Minister may, by legislative instrument, specify either or both of the following for the purposes of the definition of ***homoeopathic pharmacopoeia*** in subsection 3(1):
(a) publications;
(b) parts of publications.

Exempting entire monographs

(4) The Minister may, by legislative instrument, determine that specified monographs in a specified homoeopathic pharmacopoeia are exempt for the purposes of paragraph (2)(b).

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

Exempting parts of monographs

(5) The Minister may, by legislative instrument, determine that specified statements in specified monographs in a specified homoeopathic pharmacopoeia are exempt for the purposes of subsection (2).

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3AB Anthroposophic preparations and anthroposophic standards

Anthroposophic preparation

(1) For the purposes of this Act, an ***anthroposophic preparation*** is a preparation:

(a) manufactured from a mother substance; and

(b) manufactured in accordance with a manufacturing procedure described in an anthroposophic pharmacopoeia.

Anthroposophic standard

(2) For the purposes of this Act, if:

(a) there are therapeutic goods that are an anthroposophic preparation; and

(b) the goods are the subject of one or more monographs (other than a monograph exempt under subsection (4)) in the anthroposophic pharmacopoeia describing the manufacturing procedure that the preparation was manufactured in accordance with;

then there is an ***anthroposophic standard***, in relation to the goods, that is constituted by the statements (other than statements exempt under subsection (5)) in those monographs, as interpreted in accordance with any interpretation sections of that anthroposophic pharmacopoeia.

Specifying publications

(3) The Minister may, by legislative instrument, specify either or both of the following for the purposes of the definition of ***anthroposophic pharmacopoeia*** in subsection 3(1):

(a) publications;

(b) parts of publications.

Exempting entire monographs

(4) The Minister may, by legislative instrument, determine that specified monographs in a specified anthroposophic pharmacopoeia are exempt for the purposes of paragraph (2)(b).

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

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Exempting parts of monographs

(5) The Minister may, by legislative instrument, determine that specified statements in specified monographs in a specified anthroposophic pharmacopoeia are exempt for the purposes of subsection (2).

10 Subsection 10(1)

Omit "or the United States Pharmacopeia-National Formulary", substitute ", the United States Pharmacopeia-National Formulary, a homoeopathic pharmacopoeia or an anthroposophic pharmacopoeia".

11 Subparagraph 10(2)(a)(iv)

Omit "or the United States Pharmacopeia-National Formulary", substitute ", the United States Pharmacopeia-National Formulary, a homoeopathic pharmacopoeia or an anthroposophic pharmacopoeia".

12 After section 13

Insert:

13A Special provisions relating to homoeopathic standards and anthroposophic standards

(1) For the purposes of this Act, if a statement (the ***main statement***) in a monograph in a homoeopathic pharmacopoeia or an anthroposophic pharmacopoeia 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 homoeopathic standard or an anthroposophic 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.

Note: The heading to section 13 is altered by omitting "**standards**" and substituting "**Ministerial standards and default standards**".

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13 Section 56

Omit "and the United States Pharmacopeia-National Formulary", substitute ", the United States Pharmacopeia-National Formulary, a homoeopathic pharmacopoeia and an anthroposophic pharmacopoeia".

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Schedule 5—Ingredients in therapeutic goods

Therapeutic Goods Act 1989

1 After paragraph 26(1)(e)

Insert:

(ea) the goods contain a component or ingredient that is specified in a determination under subsection 26BE(1) that applies in relation to the goods; or

(eb) the goods contain a component or ingredient:

(i) that is specified in a determination under subsection 26BE(2) that applies in relation to the goods; and

(ii) that exceeds the permitted concentration of that component or ingredient, or exceeds the permitted total amount of that component or ingredient, that is specified in that determination; or

2 After paragraph 26A(2)(c)

Insert:

(ca) if a determination under section 26BB applies in relation to the medicine—the only active ingredients the medicine contains are active ingredients specified in that determination in relation to the medicine; and

(cb) if:

(i) the medicine contains an active ingredient that is specified in a determination under section 26BB that applies in relation to the medicine; and

(ii) that determination specifies a permitted concentration of the active ingredient or a permitted total amount of the active ingredient;

the active ingredient does not exceed that permitted concentration or that permitted total amount; and

(cc) if a determination under subsection 26BE(1) applies in relation to the medicine—the medicine does not contain a component or ingredient specified in that determination in relation to the medicine; and

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(cd) if the medicine contains a component or ingredient that is specified in a determination under subsection 26BE(2) that applies in relation to the medicine—the component or ingredient does not exceed the permitted concentration of that component or ingredient, or the permitted total amount of that component or ingredient, that is specified in that determination; and

3 After section 26BA

Insert:

26BB Permissible active ingredients

(1) The Minister may, by legislative instrument, make a determination specifying:

(a) active ingredients in relation to medicine; and

(b) either or both of the following:

(i) permitted concentrations of some or all of those ingredients;

(ii) permitted total amounts of some or all of those ingredients.

Note: Under section 26A, a person seeking the listing of medicine must certify that the only active ingredients the medicine contains are active ingredients specified in such a determination. If relevant, the person must also certify that an active ingredient does not exceed the permitted concentration of the ingredient or the permitted total amount of the ingredient.

Scope of determination

(2) A determination under this section may make different provision for different classes of medicine.

Incorporation of instruments

(3) Despite subsection 14(2) of the *Legislative Instruments Act 2003*, a determination under this section may make provision in relation to a matter by applying, adopting or incorporating any matter contained in an instrument or other writing as in force or existing from time to time.

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26BC Variation of list of active ingredients—Minister's initiative

The Minister may, on his or her own initiative and by legislative instrument, vary a determination under section 26BB.

26BD Variation of list of active ingredients—application by person

(1) A person may apply to the Minister for a variation of a determination under section 26BB.

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

(3) If an application is made under subsection (1) and any applicable prescribed evaluation fee has been paid, the Minister may, by legislative instrument, vary the determination.

Further information

(4) The Minister may, by notice in writing given to the person, require the person to give to the Minister, within such reasonable time as is specified in the notice, such further information concerning the application as is specified in the notice.

Applications or information may be given electronically

(5) An approval of a form mentioned in paragraph (2)(a), or a notice mentioned in subsection (4), 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.

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26BE Prohibited or limited components or ingredients

Prohibited components or ingredients

(1) The Minister may, by legislative instrument, make a determination specifying either or both of the following in relation to therapeutic goods:

(a) components;

(b) ingredients.

Note 1: Under section 26, the Secretary may refuse to list therapeutic goods if the goods contain a component or ingredient specified in such a determination.

Note 2: Under section 26A, a person seeking the listing of medicine must certify that the medicine does not contain a component or ingredient specified in such a determination.

Limited components or ingredients

(2) The Minister may, by legislative instrument, make a determination specifying either or both of the following in relation to therapeutic goods:

(a) components and either or both of the following:

(i) permitted concentrations of those components;

(ii) permitted total amounts of those components;

(b) ingredients and either or both of the following:

(i) permitted concentrations of those ingredients;

(ii) permitted total amounts of those ingredients.

Note 1: Under section 26, the Secretary may refuse to list therapeutic goods if the goods contain a component or ingredient that exceeds the permitted concentration of that component or ingredient or exceeds the permitted total amount of that component or ingredient.

Note 2: Under section 26A, a person seeking the listing of medicine must certify that the medicine does not contain a component or ingredient that exceeds the permitted concentration of that component or ingredient or exceeds the permitted total amount of that component or ingredient.

Scope of determination

(3) A determination under this section may make different provision for different classes of therapeutic goods.

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Incorporation of instruments

(4) Despite subsection 14(2) of the *Legislative Instruments Act 2003*, a determination under this section may make provision in relation to a matter by applying, adopting or incorporating any matter contained in an instrument or other writing as in force or existing from time to time.

Variation

(5) The Minister may, by legislative instrument, vary a determination under subsection (1) or (2).

4 Paragraph 30(1)(e)

After "26A(2)(a),", insert "(ca), (cb), (cc), (cd),".

5 Application

The amendments made by items 1 and 2 apply in relation to applications for listings made on or after the commencement of those items.

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Schedule 6—Amendments relating to legislative instruments

Therapeutic Goods Act 1989

1 Subsection 10(1)

Omit "by order published in the *Gazette*, determine", substitute "by legislative instrument, make an order determining".

2 At the end of subsection 10(1)

Add:

Note: Section 12 of the *Legislative Instruments Act 2003* deals with when a legislative instrument takes effect.

3 After subsection 10(3)

Insert:

(3A) The Minister may, by legislative instrument, vary or revoke an order made under subsection (1).

Note: Section 12 of the *Legislative Instruments Act 2003* deals with when a legislative instrument takes effect.

4 Subsection 10(4)

Omit "The Minister must not determine a standard or amend or revoke a standard", substitute "The Minister must not make an order under subsection (1), or vary or revoke an order made under subsection (1),".

5 Sections 11 and 12

Repeal the sections.

6 Subsection 19A(5)

Omit "disallowable instruments for the purposes of section 46A of the *Acts Interpretation Act 1901*", substitute "legislative instruments".

7 Subsection 36(4)

Omit "disallowable instruments for the purposes of section 46A of the *Acts Interpretation Act 1901*", substitute "legislative instruments".

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8 Subsection 41CB(1)

Omit "by order published in the *Gazette*, determine", substitute "by legislative instrument, make an order determining".

9 At the end of subsection 41CB(1)

Add:

Note: Section 12 of the *Legislative Instruments Act 2003* deals with when a legislative instrument takes effect.

10 Subsections 41CB(2) and (3)

Repeal the subsections, substitute:

(2) The Minister may, by legislative instrument, vary or revoke an order made under subsection (1).

11 Subsection 41DC(1)

Omit "by order published in the *Gazette*, determine", substitute "by legislative instrument, make an order determining".

12 At the end of subsection 41DC(1)

Add:

Note: Section 12 of the *Legislative Instruments Act 2003* deals with when a legislative instrument takes effect.

13 Subsections 41DC(3) and (4)

Repeal the subsections, substitute:

(3) The Minister may, by legislative instrument, vary or revoke an order made under subsection (1).

14 Saving and transitional

Standards

(1) The amendment made by item 1 does not affect the validity of an order made under section 10 of the *Therapeutic Goods Act 1989* before the commencement of this item.

(2) The repeal of section 11 of the *Therapeutic Goods Act 1989* by this Schedule does not apply to an order made under section 10 of that Act before the commencement of this item.

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Medical device standards

(3) The amendment made by item 8 does not affect the validity of an order made under section 41CB of the *Therapeutic Goods Act 1989* before the commencement of this item.

(4) Subsection 41CB(2) 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 an order made under section 41CB of that Act before that commencement.

Conformity assessment standards

(5) The amendment made by item 11 does not affect the validity of an order made under section 41DC of the *Therapeutic Goods Act 1989* before the commencement of this item.

(6) Subsection 41DC(3) 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 an order made under section 41DC of that Act before that commencement.

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Schedule 7—Other amendments

Part 1—Amendments commencing on the day after Royal Assent

Therapeutic Goods Act 1989

1 Subsection 3(1) (definition of *accessory*)

Repeal the definition, substitute:

> ***accessory***, in relation to a medical device covered by paragraph 41BD(1)(a), (aa) or (ab), means a thing that the manufacturer of the thing specifically intended to be used together with the device to enable the device to be used as the manufacturer of the device intended.

2 Subsection 3(1) (paragraph (b) of the definition of *listable goods*)

Omit "subsection 17(5)", substitute "subsection 9A(5)".

3 After section 7B

Insert:

7C Secretary may arrange for use of computer programs to make decisions

(1) The Secretary may arrange for the use, under the Secretary's control, of computer programs for any purposes for which the Secretary may make decisions under this Act or the regulations.

(2) A decision made by the operation of a computer program under such an arrangement is taken to be a decision made by the Secretary.

(3) The Secretary may substitute a decision (the ***substituted decision***) for a decision (the ***initial decision***) made by the operation of a computer program under such an arrangement if the Secretary is satisfied that the initial decision is incorrect.

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(4) However, the substituted decision may only be made before the end of the period of 60 days beginning on the day the initial decision is made.

4 Subsection 24D(5)

After "subsection 25(3)", insert "or (4)".

5 Paragraph 26A(1)(c)

Omit "subsection (3)", substitute "subsections (2A), (3) and (4A)".

6 Paragraph 26A(2)(e)

Omit "granted under section 38".

7 Paragraph 26A(2)(f)

After "criteria", insert "that are applicable to the medicine".

8 After paragraph 26A(2)(f)

Insert:

(fa) the medicine's specifications comply with any requirements that are prescribed by the regulations for the purposes of this paragraph and that are applicable to the medicine; and

(fb) the medicine's label:

(i) complies with any requirements that are prescribed by the regulations for the purposes of this subparagraph and that are applicable to the medicine; and

(ii) does not make a claim that is inconsistent with any claim made by the applicant in relation to the medicine in, or in connection with, the application; and

(fc) the applicant holds information or evidence showing the medicine's specifications will be maintained under the conditions set out on the medicine's label until the medicine's expiry date; and

9 After subsection 26A(2)

Insert:

(2A) The applicant must also certify any other matters prescribed by the regulations for the purposes of this subsection.

10 After subsection 26A(4)

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Insert:

(4A) If the medicine includes any ingredient of animal origin, the Secretary must have certified, prior to the application being made, that he or she is satisfied of the safety of the ingredient.

11 Paragraph 30(1)(e)

After "subsection 26A(3)", insert "or (4A)".

12 Paragraph 30(2)(ba)

After "(f),", insert "(fa), (fb), (fc),".

13 Paragraph 30(2)(ba)

After "(k)", insert "or subsection 26A(2A)".

14 After section 30

Insert:

30A Revocation of cancellation of registration or listing upon request

(1) If:

(a) the Secretary cancels the registration or listing of therapeutic goods because of the request of a person made under paragraph 30(1)(c); 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 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.

15 Subsection 30EA(1) (table item 5)

Omit ", 42E(1) or 42EA(1)", substitute "or 42E(1) or section 42EA".

16 Subparagraph 41BD(1)(a)(ii)

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Omit "handicap", substitute "disability".

17 After paragraph 41BD(1)(a)

Insert:

(aa) any instrument, apparatus, appliance, material or other article specified under subsection (2A); or

(ab) any instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B); or

18 Paragraph 41BD(1)(b)

Omit "such".

19 At the end of paragraph 41BD(1)(b)

Add "covered by paragraph (a), (aa) or (ab)".

20 Subsection 41BD(2)

Repeal the subsection, substitute:

(2) For the purposes of paragraph (1)(a), the purpose for which an instrument, apparatus, appliance, material or other article (the ***main equipment***) is to be used is to be ascertained from the information supplied, by the person under whose name the main equipment is or is to be supplied, on or in any one or more of the following:

(a) the labelling on the main equipment;

(b) the instructions for using the main equipment;

(c) any advertising material relating to the main equipment;

(d) technical documentation describing the mechanism of action of the main equipment.

21 After subsection 41BD(2)

Insert:

(2A) The Secretary may, by notice published in the *Gazette*, specify a particular instrument, apparatus, appliance, material or other article for the purposes of paragraph (1)(aa). The notice is not a legislative instrument.

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(2B) The Secretary may, by legislative instrument, specify a particular class of instruments, apparatus, appliances, materials or other articles for the purposes of paragraph (1)(ab).

22 Subsection 41BE(3)

Repeal the subsection, substitute:

Device nomenclature codes

(3) The Minister may, by legislative instrument, determine device nomenclature codes for medical devices.

23 At the end of paragraphs 41BG(2)(f) and (3)(c)

Add:

; (iv) technical documentation describing the mechanism of action of the device.

24 At the end of section 41BG

Add:

(4) A person is not the manufacturer of a medical device if the person is included in a class of persons prescribed by the regulations for the purposes of this subsection.

25 Subsection 60(1) (after paragraph (a) of the definition of *initial decision*)

Insert:

(aa) under subsection 7C(3); or

26 Application—listings of medicines

The amendments made by items 5 to 10 apply in relation to applications for listings of medicines made on or after the commencement of those items.

27 Application—revocation of cancellation of registration or listing upon request

The amendment made by item 14 applies in relation to cancellations occurring before, on or after the commencement of that item.

28 Saving—device nomenclature codes

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Despite the amendment made by item 22, regulations in force for the purposes of subsection 41BE(3) of the *Therapeutic Goods Act 1989* immediately before the commencement of this item continue in force, after that commencement, until the first determination made under that subsection (as inserted by this Act) takes effect.

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Part 2—Amendments commencing on a day to be fixed by Proclamation

Therapeutic Goods Act 1989

29 Subsection 3(1) (definition of *Therapeutic Goods Advertising Code*)

Repeal the definition, substitute:

> ***Therapeutic Goods Advertising Code*** means the code in force under section 42BAA.

30 Subsections 28(1) and (2)

Repeal the subsections, substitute:

(1) The registration or listing of therapeutic goods is subject to the conditions set out in a determination under subsection (2).

(2) The Minister may, by legislative instrument, make a determination setting out conditions for the purposes of subsection (1), being conditions that relate to:

(a) the manufacture of the goods; or

(b) the custody, use, supply, disposal or destruction of the goods; or

(c) the keeping of records relating to the goods; or

(d) matters dealt with in, or matters additional to matters dealt with in, standards applicable to the goods; or

(e) such other matters relating to the goods as the Minister thinks appropriate.

(2A) Without limiting subsection (2), different conditions may be specified for:

(a) the registration of therapeutic goods; and

(b) the listing of therapeutic goods; and

(c) different classes of therapeutic goods.

(2B) If the Secretary includes therapeutic goods in the Register in relation to a person, the Secretary may, by notice in writing given

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to the person, impose conditions on the registration or listing of those goods.

31 Subsection 28(3)

Omit "existing conditions", substitute "conditions imposed under subsection (2B) or this subsection".

32 Subsection 28(4)

After "variation", insert "or removal".

33 Subsection 28(5)

After "subsection (1)", insert ", (2B)".

34 Before paragraph 28(5)(a)

Insert:

(aa) not supply a batch of the subject goods in Australia, or export a batch of the subject goods from Australia, after the expiry date for the goods; and

(ab) not, by any means, advertise the subject goods for an indication other than those accepted in relation to the inclusion of the goods in the Register; and

35 Subsection 28(5A)

After "subsection (1),", insert "(2B),".

36 After subsection 28(5A)

Insert:

(5B) The listing of a medicine under section 26A is subject to a condition that:

(a) each step in the manufacture of the medicine that is carried out in Australia is carried out by a person who is the holder of a licence to carry out that step or who is exempt from the operation of Part 3-3 in relation to that step; and

(b) each step in the manufacture of the medicine that is carried out outside Australia is the subject of a certification in force under subsection 26A(3) or 28A(2).

(5C) Subsection (5B) does not apply if the medicine is exempt from the operation of Part 3-3.

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37 After section 28

Insert:

28A Certification of manufacturing steps outside Australia following application for listing

(1) The person in relation to whom medicine is listed under section 26A may apply to the Secretary for a certification under this section of a step in the manufacture of the medicine that is to be carried out outside Australia.

Note: The listing of medicine is subject to the condition that each step in the manufacture of the medicine that is carried out outside Australia is the subject of a certification in force under subsection 26A(3) or subsection (2) of this section: see subsection 28(5B).

(2) If an application is made to the Secretary under this section, the Secretary may, by writing, certify that the manufacturing and quality control procedures used in that step are acceptable. The Secretary must give the person written notice of the certification.

(3) In deciding whether to give the certification, subsection 26A(4) applies in a way corresponding to the way in which it applies for the purposes of subsection 26A(3).

38 After paragraph 41JA(1)(b)

Insert:

(ba) who held, at any time during the notice period under subsection (2), a conformity assessment certificate that related to a kind of medical device; or

39 Paragraph 41JA(1)(d)

Omit ", or was at any time during the notice period under subsection (2),".

40 After paragraph 41JA(1)(d)

Insert:

or (da) in relation to whom a kind of medical device was, at any time during the notice period under subsection (2), included in the Register;

41 After paragraph 41JA(1)(i)

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Insert:

(ia) the safety and efficacy of the devices for the purposes for which they are to be used;

(ib) the regulatory history of the devices in another country;

42 After subsection 41JA(1)

Insert:

(1AA) If a notice is given under subsection (1) to a person covered by paragraph (1)(ba), then paragraphs (1)(e) to (j) (to the extent to which they are relevant) apply in relation to the period the person held the certificate.

(1AB) If a notice is given under subsection (1) to a person covered by paragraph (1)(da), then paragraphs (1)(e) to (j) (to the extent to which they are relevant) apply in relation to the period the kind of medical device was included in the Register.

43 Subsection 41JA(2)

Omit "paragraph (1)(d)", substitute "paragraphs (1)(ba) and (da)".

44 Paragraph 42AA(1)(a)

Omit "veterinary surgeons,".

45 Paragraph 42AA(1)(a)

After "pharmacists,", insert "optometrists, chiropractors,".

46 Paragraph 42AA(1)(a)

Omit "dietitians, scientists working in medical laboratories or nurses", substitute "nurses, midwives, dental hygienists, dental prosthetists, dental therapists or osteopaths".

47 Paragraph 42AA(1)(c)

Omit "chiropractors,".

48 Paragraph 42AA(1)(c)

Omit ", podiatrists or osteopaths", substitute "or podiatrists".

49 At the end of subsection 42AA(1)

Add:

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; or (d) a class of persons specified under subsection (1A).

50 After subsection 42AA(1)

Insert:

(1A) The Minister may, by legislative instrument, specify a class of persons for the purposes of paragraph (1)(d).

51 At the end of Division 1 of Part 5-1

Add:

42BAA Therapeutic Goods Advertising Code

The Minister may, by legislative instrument, make a code relating to advertisements about therapeutic goods.

52 Section 42DD

Omit "a serious form of a disease, condition, ailment or defect specified in a part of the Therapeutic Goods Advertising Code that is prescribed by the regulations for the purposes of this section", substitute "a form of a disease, condition, ailment or defect identified in a part of the Therapeutic Goods Advertising Code as a serious form of a disease, condition, ailment or defect".

53 Paragraph 42DF(4)(b)

Repeal the paragraph, substitute:

(b) any advice of a committee that is established under the regulations and is prescribed by the regulations for the purposes of this paragraph; and

54 Paragraph 42DF(4)(c)

Omit "a part of the Therapeutic Goods Advertising Code that is prescribed by the regulations made for the purposes of this paragraph", substitute "the part of the Therapeutic Goods Advertising Code dealing with restricted representations".

55 Part 6-4

Repeal the Part.

56 Saving—Therapeutic Goods Advertising Code

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(1) Despite the amendment made by item 29, the Therapeutic Goods Advertising Code as in force immediately before the commencement of this item continues in force, after that commencement, until the first instrument made under section 42BAA of the *Therapeutic Goods Act 1989*, as inserted by this Act, takes effect.

(2) Despite the amendment made by item 52, regulations in force for the purposes of section 42DD of the *Therapeutic Goods Act 1989* immediately before the commencement of this item continue in force, after that commencement, until the first instrument made under section 42BAA of the *Therapeutic Goods Act 1989*, as inserted by this Act, takes effect.

(3) Despite the amendment made by item 54, regulations in force for the purposes of paragraph 42DF(4)(c) of the *Therapeutic Goods Act 1989* immediately before the commencement of this item continue in force, after that commencement, until the first instrument made under section 42BAA of the *Therapeutic Goods Act 1989*, as inserted by this Act, takes effect.

57 Application and transitional—registration or listing conditions

(1) Subsection 28(1) of the *Therapeutic Goods Act 1989*, as inserted by this Act, applies in relation to the registration or listing of therapeutic goods occurring before, on or after the commencement of this item.

(2) Subsection 28(2B) of the *Therapeutic Goods Act 1989*, as inserted by this Act, applies in relation to the registration or listing of therapeutic goods occurring on or after the commencement of this item.

(3) Conditions in force under subsection 28(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 had been imposed, on that commencement, under subsection 28(2B) of the *Therapeutic Goods Act 1989*.

(4) Subitem (3) does not prevent the variation or removal of the conditions under subsection 28(3) of the *Therapeutic Goods Act 1989* on or after the commencement of this item.

(5) The amendment made by item 31 applies in relation to:

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(a) conditions imposed under subsection 28(2B) of the *Therapeutic Goods Act 1989* on or after the commencement of that item (including because of subitem (3)); and

(b) conditions imposed under subsection 28(3) of the *Therapeutic Goods Act 1989* before, on or after the commencement of that item.

(6) The amendment made by item 34 applies in relation to the registration or listing of therapeutic goods occurring before, on or after the commencement of that item.

(7) The amendment made by item 36 applies in relation to the listing of medicine occurring before, on or after the commencement of that item.

(8) This item does not affect the conditions to which the registration or listing of therapeutic goods is subject before the commencement of this item.

58 Application—information gathering

(1) The amendments made by items 38 and 40 apply in relation to periods beginning before, on or after the commencement of those items.

(2) The amendment made by item 41 applies in relation to things occurring before, on or after the commencement of that item.

(3) Regulations in force for the purposes of subsection 41JA(2) of the *Therapeutic Goods Act 1989* immediately before the commencement of this item continue in force for the purposes of that subsection on and after that commencement.

59 Application—advertisements

The amendments made by items 44 to 50 apply in relation to advertisements published or broadcast on or after the commencement of those items.

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[*Minister's second reading speech made in—*
House of Representatives on 19 March 2009
Senate on 15 June 2009]

(37/09)

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