Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010

No. 141, 2010

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

1 Short title 1
2 Commencement 2
3 Schedule(s) 3

Schedule 1—Exempting medical devices if substitutes are not widely available 4

Therapeutic Goods Act 1989 4

Schedule 1A—Product information for medicine 11

Therapeutic Goods Act 1989 11

Schedule 2—Other amendments 16

Part 1—Amendments commencing on the 28th day after Royal Assent 16

Therapeutic Goods Act 1989 16

Part 2—Amendments commencing on the day after Royal Assent 21

Therapeutic Goods Act 1989 21

Part 3—Amendments relating to biologicals 25

Therapeutic Goods Act 1989 25

Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010

No. 141, 2010

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

[*Assented to 15 December 2010*]

The Parliament of Australia enacts:

1 Short title

This Act may be cited as the *Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010*.

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 this Act receives the Royal Assent.	15 December 2010
2. Schedule 1	The day after this Act receives the Royal Assent.	16 December 2010
2A. Schedule 1A	The 28th day after this Act receives the Royal Assent.	12 January 2011
3. Schedule 2, Part 1	The 28th day after this Act receives the Royal Assent.	12 January 2011
4. Schedule 2, Part 2	The day after this Act receives the Royal Assent.	16 December 2010
5. Schedule 2, Part 3	The later of: (a) immediately after the commencement of the provision(s) covered by table item 2; and (b) immediately after the commencement of Schedule 1 to the *Therapeutic Goods Amendment (2009 Measures No. 3) Act 2010*.	31 May 2011 (paragraph (b) applies)

Note: This table relates only to the provisions of this Act as originally enacted.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

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

3 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—Exempting medical devices if substitutes are not widely available

Therapeutic Goods Act 1989

1 Section 41H

Omit "3 other", substitute "4 other".

2 At the end of section 41H

Add:

; (d) medical devices exempted if substitutes are unavailable or in short supply.

3 At the end of Part 4-7

Add:

41HD Approvals if substitutes for medical devices are unavailable or in short supply

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

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

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

if the Secretary is satisfied that:

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

(d) either:

(i) the medical device is registered or approved for general marketing in at least one foreign country specified in a determination under subsection (5); or

(ii) an application has been made in accordance with section 41FC for inclusion in the Register of the kind of medical device that includes the medical device; and

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

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

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

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

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

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

if the Secretary is satisfied that:

(c) there are no kinds of medical devices that are included in the Register that could act as a substitute for the medical device; and

(d) an application has been made in accordance with section 41FC for inclusion in the Register of the kind of medical device that includes the medical device; and

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

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

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

Application for approval

(3) An application for an approval must:

(a) be made to the Secretary; and

(b) be accompanied by such information relating to the medical device as is required by the Secretary.

Notification of Secretary's decision

(4) If an application for an approval is made, the Secretary must, as soon as practicable after deciding the application, notify the applicant of:

(a) the decision; and

(b) if the decision is not to grant the approval—the reasons for the decision.

Determinations

(5) The Secretary may, by legislative instrument, make a determination specifying foreign countries for the purposes of subparagraph (1)(d)(i).

(6) The Secretary may, by legislative instrument, make a determination specifying medical devices that can be the subject of an approval under this section.

Conditions

(7) The Secretary may grant an approval subject to any conditions that are specified in the notice of approval.

Note: Breach of the conditions may be an offence: see subsection 41MN(9).

Period of approval

(8) The Secretary may grant an approval for such period as is specified in the notice of approval.

When approval lapses

(9) The approval lapses if:
(a) the period specified in the notice of approval expires; or
(b) a decision has been made on an application that has been made for inclusion in the Register of the kind of medical device that includes the medical device.

(10) The approval lapses if:
(a) the Secretary is satisfied that paragraph (1)(c), (d), (e) or (f), or paragraph (2)(c), (d), (e) or (f), as the case requires, no longer applies in relation to the medical device, or that a condition of the approval has been contravened; and
(b) the Secretary has given to the person to whom the approval was granted a notice stating that the Secretary is so satisfied.

(11) The lapsing of the approval on the expiry of the period specified in the notice of approval does not prevent another approval being granted under this section in relation to the medical device before

that lapsing. The other approval may be expressed to take effect on the expiry of that period.

Approval not a legislative instrument

(12) An approval under subsection (1) or (2) is not a legislative instrument.

4 After section 41JF

Insert:

41JFA Secretary may require information relating to approvals under section 41HD

(1) The Secretary may give to a person who is granted an approval under subsection 41HD(1) or (2) in relation to a medical device a written notice requiring the person to give to the Secretary specified information or documents relating to one or more of the following:

(a) the supply of the medical device;

(b) the handling of the medical device;

(c) the monitoring of the supply of the medical device;

(d) the results of the supply of the medical device;

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

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

(3) 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.

5 Paragraph 41JG(a)

Omit "or 41JF", substitute ", 41JF or 41JFA".

6 Section 41JG (note)

Omit "and 41JF", substitute ", 41JF and 41JFA".

7 Section 41JH

Omit "or 41JF", substitute ", 41JF or 41JFA".

8 Paragraph 41JI(1)(c)

Omit "or 41JF", substitute ", 41JF or 41JFA".

9 Subsection 41JJ(1)

Omit "or 41JF", substitute ", 41JF or 41JFA".

10 Subsection 41KA(1) (at the end of paragraph (c) of the cell at table item 3, column headed "Circumstance relating to a kind of medical device")

Add "or".

11 Subsection 41KA(1) (after paragraph (c) of the cell at table item 3, column headed "Circumstance relating to a kind of medical device")

Insert:

(d) there is an approval under subsection 41HD(1) or (2) relating to devices of that kind;

12 Subsection 41KA(1) (at the end of paragraph (c) of the cell at table item 4, column headed "Circumstance relating to a kind of medical device")

Add "or".

13 Subsection 41KA(1) (after paragraph (c) of the cell at table item 4, column headed "Circumstance relating to a kind of medical device")

Insert:

(d) there is an approval under subsection 41HD(1) or (2) relating to devices of that kind;

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

Omit "kind.", substitute "kind; and".

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

Add:

(e) there is not an approval under subsection 41HD(1) or (2) relating to devices of that kind.

16 Subparagraph 41MI(1)(b)(iii)

Omit "and".

17 At the end of paragraph 41MI(1)(b)

Add:

(iv) the device is the subject of an approval under subsection 41HD(1) or (2) that is held by the person; and

18 Subparagraph 41MI(2)(b)(iii)

Omit "and".

19 At the end of paragraph 41MI(2)(b)

Add:

(iv) the device is the subject of an approval under subsection 41HD(1) or (2) that is held by the person; and

20 At the end of paragraph 41MI(4)(b)

Add:

; (iv) the device is the subject of an approval under subsection 41HD(1) or (2) that is held by the person.

21 At the end of paragraph 41MIB(1)(b)

Add:

; (iv) the device is the subject of an approval under subsection 41HD(1) or (2) that is held by the person.

22 Subparagraph 41MK(b)(iii)

Omit "and".

23 At the end of paragraph 41MK(b)

Add:

(iv) the device is the subject of an approval under subsection 41HD(1) or (2) that is held by the person; and

24 At the end of subsection 41MLA(2)

Add:

; (d) representations that medical devices are the subject of an approval under subsection 41HD(1) or (2).

25 At the end of paragraph 41MN(9)(b)

Add:

; or (iv) a condition of an approval under subsection 41HD(1) or (2).

26 After subparagraph 46A(4)(a)(iia)

Insert:

(iib) who has been granted an approval under subsection 41HD(1) or (2); or

27 After paragraph 56A(1)(ba)

Insert:

(bb) there was no approval under subsection 41HD(1) or (2) granted to a particular person in relation to particular medical devices; or

28 After subsection 57(8)

Insert:

(9) The powers of the Secretary under section 41HD may be delegated only to either or both of the following persons:

(a) the National Manager of the Therapeutic Goods Administration;

(b) a person who holds, occupies or performs the duties of a position in the Therapeutic Goods Administration prescribed by the regulations for the purposes of this paragraph.

Schedule 1A—Product information for medicine

Therapeutic Goods Act 1989

1 Subsection 3(1)

Insert:

product information, in relation to therapeutic goods, means information relating to the safe and effective use of the goods, including information regarding the usefulness and limitations of the goods.

2 Subsection 3(1)

Insert:

restricted medicine means:

(a) a medicine specified in an instrument under subsection (2A); or

(b) a medicine included in a class of medicine specified in an instrument under subsection (2B).

3 After subsection 3(2)

Insert:

(2A) The Minister may, by legislative instrument, specify medicines for the purposes of paragraph (a) of the definition of ***restricted medicine*** in subsection (1).

(2B) The Minister may, by legislative instrument, specify classes of medicine for the purposes of paragraph (b) of the definition of ***restricted medicine*** in subsection (1).

4 After section 7C

Insert:

7D Form for product information for medicine

(1) The Secretary may, by writing, approve a form for product information in relation to medicine.

(2) The Secretary may approve different forms for different medicines or different classes of medicine.

5 Subsection 9D(5)

Repeal the subsection (not including the note).

6 After paragraph 23(2)(b)

Insert:

(ba) if the application is for the registration of restricted medicine—the application is accompanied by product information, in relation to the medicine, that is in the form approved under section 7D in relation to the medicine; and

7 After paragraph 25(1)(d)

Insert:

(da) if:

(i) the applicant is applying for the registration of restricted medicine; or

(ii) the applicant is applying for the registration of medicine (other than restricted medicine) and the applicant has been given a notice in writing by the Secretary requiring the applicant to give to the Secretary product information, in relation to the medicine, that is in the form approved under section 7D in relation to the medicine;

the product information given by the applicant in relation to the medicine; and

8 After subparagraph 25(4)(d)(i)

Insert:

(ia) if the goods are restricted medicine or the goods are medicine in respect of which the applicant has been given a notice of the kind referred to in subparagraph (1)(da)(ii)—notify the applicant in writing

of the product information that is approved in relation to the medicine; and

9 After section 25

Insert:

25AA Approved product information for medicine

(1) If:

(a) the Secretary includes restricted medicine in the Register in relation to a person under subparagraph 25(4)(d)(ii); or

(b) an applicant for the registration of medicine (other than restricted medicine) is given a notice of the kind referred to in subparagraph 25(1)(da)(ii) and the Secretary includes the medicine in the Register in relation to the applicant under subparagraph 25(4)(d)(ii);

the product information that is approved under this section in relation to the medicine is the product information referred to in subparagraph 25(4)(d)(ia).

Note: Subsection (4) deals with variation of the product information.

Transitional

(2) If:

(a) at the start of the day the first instrument made under subsection 3(2A) or (2B) takes effect, there is medicine included in the Register in relation to a person; and

(b) before that day, the Secretary, in a notice given under subsection 25(4) to the person in relation to the registration of the medicine, specified the product information that was approved by the Secretary in relation to the medicine;

then that product information (including as varied before that day) is, on and after that day, the product information that is approved under this section in relation to the medicine.

Note: Subsection (4) deals with variation of the product information.

(3) If:

(a) before the day the first instrument made under subsection 3(2A) or (2B) takes effect, a person made an application to include medicine in the Register; and

(b) before that day and in relation to that application, the Secretary, in a notice given under subsection 25(4) to the person, specified the product information that was approved by the Secretary in relation to the medicine; and

(c) on or after that day and in relation to that application, the Secretary includes the medicine in the Register in relation to the person under subparagraph 25(4)(d)(ii);

then that product information (including as varied before that inclusion) is, on and after the day the registration of the medicine commences, the product information that is approved under this section in relation to the medicine.

Note: Subsection (4) deals with variation of the product information.

Variations

(4) If:

(a) there is medicine included in the Register in relation to a person and there is product information approved under this section in relation to the medicine; and

(b) either:

(i) under section 9D, the Secretary varies the entry in the Register in relation to the medicine; or

(ii) there is a change in the conditions to which the inclusion of the medicine is subject; and

(c) as a result of that variation or change, the Secretary is satisfied that a variation to that product information is required;

the Secretary may, by notice in writing given to the person, make any variations that the Secretary considers appropriate to the product information that is approved in relation to the medicine.

(5) To avoid doubt, if product information that is approved in relation to medicine is varied under this section, that product information, as varied, becomes the product information that is approved under this section in relation to the medicine.

10 Application

(1) Paragraph 23(2)(ba) and subparagraph 25(1)(da)(i) of the *Therapeutic Goods Act 1989*, as inserted by this Act, apply in relation to applications for registration of medicine that are made after the day on which the

first instrument made under subsection 3(2A) or (2B) of that Act takes effect.

(2) Subparagraph 25(1)(da)(ii) of the *Therapeutic Goods Act 1989*, as inserted by this Act, applies in relation to applications for registration of medicine that are made on or after the day on which the first instrument made under subsection 3(2A) or (2B) of that Act takes effect.

(3) Subparagraph 25(4)(d)(ia) of the *Therapeutic Goods Act 1989*, as inserted by this Act, applies on and after the day on which the first instrument made under subsection 3(2A) or (2B) of that Act takes effect (whether the application for registration was made before, on or after that day).

(4) Subsection 25AA(1) of the *Therapeutic Goods Act 1989*, as inserted by this Act, applies in relation to medicine included in the Register on or after the day on which the first instrument made under subsection 3(2A) or (2B) of that Act takes effect (where the notification (in relation to the medicine) referred to in subparagraph 25(4)(d)(ia) of that Act also occurred on or after that day).

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

Schedule 2—Other amendments

Part 1—Amendments commencing on the 28th day after Royal Assent

Therapeutic Goods Act 1989

1A Paragraph 9D(2)(a)

Omit "product".

1B After subsection 9D(2)

Insert:

(2A) Subsection (2), to the extent to which it relates to subparagraph (2)(b)(i), applies despite subsection 16(1).

1C Before subsection 9D(4)

Insert:

(3C) If:

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

(b) the only effect of the variation would be:

(i) to reduce the class of persons for whom the kind of medical device is suitable; or

(ii) to add a warning, restriction or precaution, that does not include any comparison of the kind of medical device with any other therapeutic goods by reference to quality, safety or performance;

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

(3D) If:

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

(b) subsection (3C) does not apply to the request; and

(c) the Secretary is satisfied that the variation requested does not indicate any reduction in the quality, safety or performance of the kind of medical device for the purposes for which it is to be used;

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

1D At the end of section 9D

Add:

Approved forms for requests

(6) The Secretary may, by writing, approve a form for particular kinds of requests under this section.

(7) If the Secretary has approved a form for a particular kind of request under this section, then any request of that kind must be in accordance with that form.

Fees

(8) A request under this section must be accompanied by any prescribed application fee or prescribed evaluation fee or both.

1E Subsection 25(1)

Omit all the words from and including "Where:" to and including "having regard to:", substitute "If an application is made for the registration of therapeutic goods in relation to a person in accordance with section 23, the Secretary must evaluate the goods for registration having regard to:".

1 Paragraphs 26(1)(ea) and (eb)

Repeal the paragraphs.

2 Paragraphs 26A(2)(ca) to (cd)

Repeal the paragraphs, substitute:

(ca) the medicine does not contain an ingredient that is not specified in a determination under paragraph 26BB(1)(a); and

(cb) if a determination under paragraph 26BB(1)(b) specifies requirements in relation to ingredients being contained in the

medicine—none of the requirements have been contravened; and

3 Section 26BB

Repeal the section, substitute:

26BB Permissible ingredients

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

(a) ingredients;

(b) for some or all of those ingredients—requirements in relation to those ingredients being contained in medicine.

Note: A person seeking the listing of a medicine under section 26A must certify that:

(a) the medicine does not contain an ingredient that is not specified in the determination; and

(b) none of the requirements specified in the determination in relation to ingredients being contained in the medicine have been contravened.

Requirements

(2) The requirements referred to in paragraph (1)(b) may relate to particular ingredients not being contained in particular medicine.

(3) The requirements referred to in paragraph (1)(b) may relate to permitted concentrations or permitted total amounts of ingredients.

(4) Subsections (2) and (3) do not limit paragraph (1)(b).

(5) A determination under paragraph (1)(b) may make different provision for different classes of medicine.

Limitations on determination under subsection (1)

(6) The Minister may, by legislative instrument, make a determination specifying either or both of the following:

(a) ingredients that must not be specified under paragraph (1)(a);

(b) requirements that must not be specified under paragraph (1)(b) in relation to ingredients being contained in medicine.

(7) A determination under paragraph (6)(b) may make different provision for different classes of medicine.

Incorporation of instruments

(8) 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.

Note: The heading to section 26BC is altered by omitting "**list of active ingredients**" and substituting "**determination under section 26BB**".

4 Subsection 26BD(1)

Omit "section 26BB", substitute "subsection 26BB(1)".

Note: The heading to section 26BD is altered by omitting "**list of active ingredients**" and substituting "**determination under section 26BB**".

4A After subsection 26BD(3)

Insert:

(3A) In deciding whether to vary the determination, the Minister must have regard to the quality and safety of the ingredients concerned. This subsection does not limit the matters to which the Minister may have regard to in deciding whether to vary the determination.

5 Section 26BE

Repeal the section.

6 Paragraph 30(1)(e)

Omit "(cc), (cd),".

6A After subsection 31(1A)

Insert:

(1B) If:

(a) a person makes an application under section 23 for the registration of therapeutic goods in accordance with a form referred to in paragraph 23(1)(a); and

(b) the form is described as a pre-submission form; and

(c) the person chooses a number of days specified in the form for the purposes of giving information or documents to the Secretary in the event that the person is given a notice under subsection (1) of this section in relation to the application;

then that number of days must be specified in any such notice as the time within which the person must give the required information or documents to the Secretary. The number of days so specified is taken to be a reasonable time for the purposes of subsection (1).

(1C) If:

(a) the person in relation to whom therapeutic goods are registered makes a request under subsection 9D(3) in accordance with a form referred to in subsection 9D(6); and

(b) the form is described as a pre-submission form; and

(c) the person chooses a number of days specified in the form for the purposes of giving information or documents to the Secretary in the event that the person is given a notice under subsection (1) of this section in relation to the request;

then that number of days must be specified in any such notice as the time within which the person must give the required information or documents to the Secretary. The number of days so specified is taken to be a reasonable time for the purposes of subsection (1).

7 Application

(1) The amendments made by items 1A to 1D apply in relation to requests made on or after the commencement of those items.

(2) The amendment made by item 1E applies in relation to applications for registration made on or after the commencement of that item.

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

(4) The amendment made by item 6A applies in relation to a notice given on or after the commencement of that item (whether the application or request was made before, on or after that commencement).

Part 2—Amendments commencing on the day after Royal Assent

Therapeutic Goods Act 1989

7A After subsection 7(1)

Insert:

(1A) In deciding whether particular goods or classes of goods:

(a) are therapeutic goods; or

(b) when used, advertised, or presented for supply in a particular way, are therapeutic goods;

the Secretary must disregard paragraphs (e) and (f) of the definition of ***therapeutic goods*** in subsection 3(1).

8 Subsection 26(1)

After "subject to", insert "this section and".

9 After subsection 26(1)

Insert:

(1AA) If:

(a) a medicine (the ***original medicine***) is included in the Register in relation to a person; and

(b) the person makes an application under section 23 for the listing of a medicine (the ***new medicine***) under this section; and

(c) the Secretary is satisfied that paragraphs (1)(a) to (ba) are satisfied in relation to the application; and

(d) the Secretary is satisfied that the new medicine has the same characteristics as the original medicine apart from the characteristics specified in an instrument under subsection (1AB);

the Secretary may list the new medicine in relation to the person.

(1AB) The Minister may, by legislative instrument, specify characteristics for the purposes of paragraph (1AA)(d).

10 After paragraph 31(1)(g)

Insert:

(ga) whether the goods comply with conditions (if any) on the registration of the goods;

11 After paragraph 31(1)(h)

Insert:

(ha) if the goods are registered in relation to the person—whether the goods are being:

(i) supplied in Australia; or

(ii) imported into Australia; or

(iii) exported from Australia;

12 After paragraph 31(2)(c)

Insert:

(ca) the quality of the goods;

14 After paragraph 31(2)(f)

Insert:

(fa) if the goods are medicine—the matters covered by a certification by the person under paragraph 26A(2)(j) in relation to the medicine;

(fb) whether the goods comply with conditions (if any) on the listing of the goods;

15 After paragraph 31(2)(g)

Insert:

(ga) if the goods are listed in relation to the person—whether the goods are being:

(i) supplied in Australia; or

(ii) imported into Australia; or

(iii) exported from Australia;

15A Paragraph 31(4)(a)

Repeal the paragraph, substitute:

(a) either:

(i) the person is given a notice under subsection (1) and the person is covered by paragraph (1)(ab) or (ac); or

(ii) the person is given a notice under subsection (2) and the person is covered by paragraph (2)(ab) or (ac); and

16 Paragraph 41EG(f)

Repeal the paragraph, substitute:

(f) for the whole or a part of the conformity assessment fee for the application that is due and payable in accordance with regulations made for the purposes of Part 4-10—the applicant fails to pay that whole or part in accordance with those regulations.

17 Paragraph 41FK(e)

Omit "within the period, specified in the regulations, after being notified of the decision to include the kind of medical device in the Register under section 41FJ", substitute "in accordance with section 41LB or 41LC".

18 After subsection 60(2)

Insert:

(2A) A request under subsection (2) may be accompanied by information in support of the request.

19 After subsection 60(3)

Insert:

(3A) Subject to subsection 60A(2), in reconsidering the initial decision:

(a) the Minister must take into account any information referred to in subsection (2A); and

(b) the Minister must not take into account any other information provided by, or on behalf of, the person after the making of the request, other than:

(i) information provided in response to a request from the Minister; or

(ii) information that indicates that the quality, safety or efficacy of therapeutic goods is unacceptable.

(3B) Paragraph (3A)(a) does not limit the information the Minister may take into account in reconsidering the initial decision.

20 Subsection 60(4)

Omit "is to be taken to have confirmed the original decision", substitute "is taken to have confirmed under subsection (3) the initial decision".

21 Application

(1) The amendments made by items 8 and 9 apply in relation to applications for listings made on or after the commencement of those items.

(2) The amendments made by items 10 to 15 apply in relation to notices given on or after the commencement of those items.

(2A) The amendment made by item 15A applies in relation to notices given on or after the commencement of that item.

(3) The amendments made by items 16 and 17 apply in relation to applications made on or after the commencement of those items.

(4) The amendments made by items 18 and 19 apply in relation to initial decisions made on or after the commencement of those items.

Part 3—Amendments relating to biologicals

Therapeutic Goods Act 1989

22 Before subsection 9D(3A)

Insert:

(3AA) If:

(a) the person in relation to whom a biological is included in the Register has requested the Secretary to vary information included in the entry in the Register that relates to the biological; and

(b) the only effect of the variation would be:

(i) to reduce the class of persons for whom the biological is suitable; or

(ii) to add a warning, or precaution, that does not include any comparison of the biological with any other therapeutic goods by reference to quality, safety or efficacy;

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

23 After paragraph 9D(3A)(a)

Insert:

(aa) subsection (3AA) does not apply to the request; and

[*Minister's second reading speech made in—*
House of Representatives on 30 September 2010
Senate on 15 November 2010]

(178/10)