



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

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Contents

Purpose	2
Summary of proposed amendments	2
Committee consideration	4
Financial implications	5
Main provisions	5
Schedule 1 – Exempting medical devices if substitutes are not widely available	5
Schedule 2, Part 1 – Amendments commencing the 28 th day after Royal Assent	8
Schedule 2, Part 2 – Amendments commencing on the day after Royal Assent	9
Concluding comments	11

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

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House: House of Representatives

Portfolio: Health and Ageing

Commencement: Sections 1–3: on Royal Assent; Schedule 1 and Part 2 of Schedule 2: the day after Royal Assent; Part 1 of Schedule 2: the 28th day after Royal Assent

Links: The [links](#) to the Bill, its Explanatory Memorandum and second reading speech can be found on the Bills page, which is at <http://www.aph.gov.au/bills/>. When Bills have been passed they can be found at ComLaw, which is at <http://www.comlaw.gov.au/>.

Purpose

The Therapeutic Goods Amendment (2010 Measures No. 1) Bill 2010 (the Bill) proposes to amend the *Therapeutic Goods Act 1989* (the Act) in various ways as part of the Government's regulatory reform plan relating to therapeutic goods in Australia.

A major proposal in this Bill is to enable the Secretary to the Department of Health and Ageing (the Secretary) to approve the import and supply of certain medical devices, where:

- other medical devices included in the Australian Register of Therapeutic Goods (the Register), which could act as substitute for the medical device in question, are either unavailable or in short supply, or
- there are no kinds of medical devices included in the Register that could act as a substitute for the medical device in question.¹

Summary of proposed amendments

The Bill seeks to amend the Act so that the Therapeutic Goods Administration (TGA) can continue to meet emerging challenges and have the necessary powers to function fairly and effectively. The Parliament has previously passed a 'regulatory reform package' to update and streamline the regulatory framework for therapeutic goods in Australia.² This

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1. Explanatory Memorandum, Therapeutic Goods Amendment (2010 Measures No. 1) Bill 2010, p. 1.
 2. See Therapeutic Goods Administration (TGA), 'Regulatory reform', TGA website, 7 April 2010, viewed 18 May 2010, <http://www.tga.gov.au/regreform/index.htm>

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package largely reflected the arrangements that were agreed in the context of a joint regulatory agency with New Zealand but were postponed as a result of the agency not proceeding. To date, three Acts have been passed and two Bills and amendments to the regulations are before the Parliament.³

The Bill seeks to ensure consistency between the treatment of medicines and devices which are unavailable or in short supply. The proposed amendments introduce a short-term exemption so that medical devices that are unavailable or in short supply are able to be substituted with a device that is not yet registered in Australia. It is envisaged that these amendments will be used to cover short-term shortages of approved devices and is to be relied upon when there are supply chain problems or problems with manufacturing. The proposed amendments allow the Secretary to approve the import (or import and supply) of a device that has met marketing requirements in approved jurisdictions. Before giving this approval, the Secretary must be satisfied that it is in the interests of public health.⁴

The following other amendments in the Bill are largely administrative:

- sponsors will now be able to list on the Register export-only variants of the medicine. It is anticipated that the variant must differ from existing medicines in the following characteristics: colourings, flavourings and excipients.⁵ These characteristics will be specified by legislative instrument
- the TGA will have improved capacity to obtain information from persons who have registered or listed medicines. The amendments give the TGA the power to obtain information relating to compliance with the conditions on the registration or listing of medicines

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3. Refer to following Bills digests for an explanation: R de Boer and S Scully, *Therapeutic Goods Amendment (Medical Devices and Other Measures) Bill 2008*, Bills digest, no. 84, 2008–2009; Parliamentary library, Canberra, 2009, viewed 24 May 2010, <http://www.aph.gov.au/Library/pubs/bd/2008-09/09bd084.pdf>; R de Boer and S Scully, *Therapeutic Goods Amendments (2009 Measures No. 1) Bill 2009*, Bills digest, no. 122, 2008–2009; Parliamentary library, Canberra, 2009, viewed 24 May 2010, <http://www.aph.gov.au/Library/pubs/bd/2008-09/09bd122.pdf>; R de Boer and S Scully, *Therapeutic Goods Amendments (2009 Measures No. 2) Bill 2009*, Bills digest, no. 8, 2009–2010; Parliamentary library, Canberra, 2009, viewed 24 May 2010, <http://www.aph.gov.au/Library/pubs/bd/2009-10/10bd008.pdf>; and R de Boer and S Scully, *Therapeutic Goods Amendments (2009 Measures No. 3) Bill 2009*, Bills digest, no. 83, 2009–2010; Parliamentary library, Canberra, 2010, viewed 24 May 2010, <http://www.aph.gov.au/Library/pubs/bd/2009-10/10bd083.pdf>.
 4. See **proposed section 41HD** of the Bill (**item 3 of Schedule 1** to the Bill).
 5. ‘Excipient’ means ‘any component of a finished dosage form other than an active ingredient’: Therapeutic Goods Administration, *Glossary of terms, definitions and acronyms*, 24 February 2009, viewed 17 May 2010, <http://www.tga.gov.au/web/glossary.htm#e>

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- the amendments also give the TGA the power to obtain information on whether registered or listed medicines have been imported into or supplied in Australia, or exported from Australia. Previously, sponsors have refused to supply this information and this can compromise the TGA's ability to assess the risk of a known deficiency with a medicine⁶
- persons applying for reconsideration by the Minister of an initial decision by the TGA must now provide all the information they wish the Minister to reconsider at the time of application.⁷ The amendments also preclude the Minister from considering any additional information in relation to the reconsideration, unless it has been specifically requested or if the information provided is unacceptable
- there is also minor, technical amendment, which allows the Minister to determine lists of 'permissible ingredients' to be included in medicines, and
- finally, there are amendments that clarify when a medical device is required to be audited, what the associated assessment fees are and when these are payable.

Committee consideration

On 18 March 2010, the Senate Committee for the Selection of Bills resolved *not* to refer the Bill to a parliamentary committee for inquiry and report.⁸

The Senate Standing Committee for the Scrutiny of Bills (the Committee) has reviewed the Bill and expressed concern that **proposed subsection 26BB(7) (item 3 in Schedule 2)** effectively provides for incorporating material by reference. The Committee stated:

The Committee has, in the past, expressed concern about provisions which allow a change in obligations imposed without the Parliament's knowledge, or without the opportunity for the Parliament to scrutinise the variation. In addition, such provisions can create uncertainty in the law and those obliged to obey the law may have inadequate access to its terms. In this case, no explanation for the need for these determinations to incorporate material by reference to other instruments or documents is outlined in the explanatory memorandum. Therefore, the Committee **seeks the Minister's advice** about the justification for this approach.⁹

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6. For example, concerns about safety, quality and efficacy.
 7. The term 'initial decision' is defined in section 60 of the Act to include a range of decisions that may be made by the TGA/Secretary and includes a decision to register (or not to register) a medical device.
 8. Senate Selection of Bills Committee, *Report No. 5 of 2010*, 18 March 2010, p. 3, viewed 30 March 2010, http://www.aph.gov.au/senate/committee/selectionbills_ctte/reports/2010/report0510.pdf
 9. Senate Standing Committee for the Scrutiny of Bills, *Alert Digest*, no. 5, 12 May 2010, p. 48, <http://www.aph.gov.au/senate/committee/scrutiny/alerts/2010/d05.pdf>. For a brief explanation of what **proposed section 26BB** provides, see pp. 8–9 of this Digest.

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Financial implications

The Government states that the proposed amendments in the Bill will not have any financial impact on the Commonwealth, as the TGA operates on a cost recovery basis.¹⁰

Main provisions

Schedule 1 – Exempting medical devices if substitutes are not widely available

Schedule 1 to the Bill contains proposed amendments relating to exemptions for medical devices if substitutes are unavailable or in short supply.

Item 3 proposes to insert **new section 41HD** into **Part 4-7** of the Act (which deals with other exemptions from having to include medical devices in the Register).

Proposed subsection 41HD(1) provides that if the Secretary is satisfied that:

- the kinds of medical devices in the Register that could be a substitute for a particular medical device are either in short supply or unavailable
- either:
 - the medical device in question is registered or approved for general marketing in at least one foreign country as specified by the Secretary in a determination made under **proposed subsection 41HD(5)**, or
 - an application has been made as per section 41FC for inclusion in the Register of the kind of medical device that includes the medical device in question, and
- the medical device is specified by the Secretary under proposed subsection 41HD(6), the approval is necessary for public health interests,

the Secretary may, on application by a person, approve the importation into (or import and supply in) Australia of the medical device in question by that person.

Proposed subsection 41HD(2) provides similarly to **proposed subsection 41HD(1)**, in relation to a situation where there are no substitutes at all for a medical device in the Register.

According to **proposed subsection 41HD(12)**, such approval would not be a legislative instrument. The Explanatory Memorandum explains that this is because the approvals apply the law to a particular case and do not create a general exemption.¹¹

10. Explanatory Memorandum, op. cit., p. 1.

11. Ibid., p. 4.

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In addition, the Secretary may grant such approvals conditionally under **proposed subsection 41HD(7)**.

Under **proposed paragraph 41HD(4)(b)**, if the Secretary decides not to approve such an application, the Secretary must give the applicant the reasons for his or her decision with the notice of the decision itself. It is noted that under existing paragraph 60(2)(h) of the Act, decisions made by the Secretary or his or her delegate under Part 4-7 of the Act fall within the definition of ‘initial decision’, which would be reviewable by the Minister.

Proposed subsections 41HD(9) and (10) provide that an approval lapses if:

- the period of time specified in the notice of approval expires
- a decision has been made on an application made for inclusion in the Register of the kind of medical device that includes the medical device in question, and/or
- either:
 - the Secretary is no longer satisfied that a condition leading to the approval applies, or
 - the Secretary is satisfied that a condition of the approval has been contravened, and the Secretary has so notified the person to whom approval had been granted.

Item 4 proposes to insert **new section 41JFA** into Division 2 of Part 4-8 of the Act (obtaining information relating to medical devices covered by exemptions).

Under **proposed subsection 41JFA(1)**, the Secretary may require a person to whom approval had been given under **proposed section 41HD**, by written notice, to give the Secretary specific information or documents about any of the following:

- supply of the medical device and/or monitoring thereof
- handling of the medical device
- results of the supply of the medical device, and/or
- anything else prescribed by regulations relating to obtaining information about the kind of medical device that includes the medical device in question.

Under **proposed subsection 41JFA(2)**, the person must be given a reasonable period of time within which he or she would have to comply with such request—at least 10 working days from the day the notice is given.

In addition, under **proposed subsection 41JFA(3)**, the notice may also require information to be given in accord with specific software requirements, such as via a specific kind of electronic transmission.

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Other amendments proposed in **Schedule 1** of the Bill are essentially consequential to the **proposed new sections 41HD** and **41JFA**. Examples of such consequential amendments are as follows.

Items 5–8 propose to amend **sections 41JG–41JI** so as to include references to **proposed section 41JFA**. Sections 41JG–41JI relate to criminal offences for failure to provide information or documents under Part 4–7 as requested, and for providing false or misleading information or documents in response to any such request.

In addition, **item 9** proposes to amend **subsection 41JJ(1)** (which deals with self-incrimination) to include a reference to **proposed section 41JFA**.

Items 10–15 propose to amend **section 41KA**, which deals with the recall of medical devices under particular circumstances. The proposed amendment means that medical devices approved under **proposed section 41HD** would be covered by the existing provision.

Items 16–20 propose to amend **section 41MI**, which establishes criminal offences for importing, exporting, supplying or manufacturing medical devices not included in the Register. The proposed amendments mean that a person would not be regarded as committing such an offence if the medical device is one approved under **proposed section 41HD**.

Item 21 proposes to amend **paragraph 41MIB(1)(b)**, which imposes a civil penalty for importing, exporting, supplying or manufacturing medical devices not included in the Register. The proposed amendment means that a person would not be regarded as contravening this section if the medical device is one approved under **proposed section 41HD**.

Items 22 and 23 propose to amend **section 41MK**, which establishes criminal offences for the wholesale supply of medical devices not included in the Register. As in **items 16–20** above, these proposed amendments mean that a person would not be regarded as committing such an offence if the medical device is one approved under **proposed section 41HD**.

Item 24 proposes to amend **subsection 41MLA(2)**. Section 41MLA imposes civil penalties for making misrepresentations about medical devices. The proposed amendment means that a person would contravene this section if he or she makes a false or misleading representation that a medical device is covered by an approval under **proposed section 41HD**.

Item 25 proposes to amend **paragraph 41MN(9)(b)**. Section 41MN establishes criminal offences for breach of conditions of an exemption. The proposed amendment means that it would be an offence to breach a condition of approval under **proposed section 41HD**.

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Schedule 2, Part 1 – Amendments commencing the 28th day after Royal Assent

These proposed, largely technical, amendments would commence on the 28th day after Royal Assent.

Item 2 proposes to substitute **new paragraphs 26A(2)(ca) and (cb)** in place of existing paragraphs 26A(2)(ca)-(cd) in the Act. Section 26A deals with applications for the listing of certain medicines. Currently, subsection 26A(2) sets out those matters that an applicant must certify when applying for a medicine to be listed, including:

- eligibility of the medicine to be listed
- safety of the medicine for the purposes for which it is to be used, and
- its presentation not being unacceptable.

Paragraphs 26A(2)(ca) and (cb) currently relate to the presence of permissible active ingredients; and permitted concentrations or total amounts of such ingredients, in the medicine.

Paragraphs 26A(2)(cc) and (cd) currently relate to the presence of prohibited or limited components or ingredients (including permitted concentrations or total amounts of limited components or ingredients), in the medicine.

Under **proposed new paragraphs 26A(2)(ca) and (cb)**, when applying to have a medicine listed, the applicant would have to certify that (among other things):

- the medicine does not contain an ingredient that is not specified in a determination under **proposed new paragraph 26BB(1)(a)**, and
- any restrictions specified under **proposed new paragraph 26BB(1)(b)** have not been contravened.

Item 3 proposes to repeal current section 26BB and substitute **new section 26BB** in its place in the Act. Currently, section 26BB enables the Minister to specify:

- active ingredients in relation to a medicine, and
- either or both of:
 - permitted concentrations some or all of those ingredients, or
 - permitted total amounts of some or all of those ingredients.

Proposed new section 26BB essentially covers both permissible and restricted ingredients, including permitted concentrations and total amounts of ingredients, thereby covering both existing sections 26BB and 26BE (which deals with prohibited or limited components or ingredients).

It is noted that **item 5** proposes to repeal **section 26BE**.

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The Explanatory Memorandum states that the effect of **proposed new section 26BB** is:

... that the Minister may make a determination specifying, for example, that an ingredient may only be used in topical preparations at less than a particular concentration and cannot be used in other forms of medicine, or may be used in both topical and oral preparations but at different maximum concentrations.¹²

It is noted that the Minister states:

These amendments are essentially technical changes to improve the workability of the provisions by allowing the list of permitted ingredients to include ingredients with restrictions or conditions on them.¹³

It is noted that under **proposed subsection 26BB(6)**, such determinations would be legislative instruments. In general, these determinations could be open to parliamentary scrutiny and disallowance under the *Legislative Instruments Act 2003*.

Schedule 2, Part 2 – Amendments commencing on the day after Royal Assent

Item 9 proposes to insert **new subsection 26(1AA)** into the Act. Section 26 deals with listing of therapeutic goods. The proposed amendment would provide an explicit path for listing export-only variants of medicines already included in the Register.

According to the Minister's second reading speech:

... Although section 26 currently allows medicines to be listed for export, there is no link between these medicines and a medicine already on the Register.

The new provision will allow the Secretary to list a variation of an existing medicine as long as the variant differs from the existing medicine only in respect of characteristics specified in a legislative instrument. The Government intends that these characteristics will be colourings, flavourings and excipients.

This provision will support Australian companies wishing to export medicines by allowing them to state to authorities in the importing country that the medicines are a minor variation on a medicine available on the Australian domestic market, and point to the provision in the Act that allows the listing of such variants.¹⁴

Items 10–11 propose to insert **new paragraphs 31(1)(ga)** and **(ha)**, so as to enable the Secretary to seek information from a person who is applying for registration of therapeutic goods (or in relation to whom such goods are already registered) relating to:

12. Ibid., p. 6.

13. N Roxon (Minister for Health and Ageing), 'Second reading speech: Therapeutic Goods Amendment (2010 Measures No. 1) Bill 2010', House of Representatives, *Debates*, 17 March 2010, p. 19.

14. Ibid., p. 18.

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- whether the goods comply with compliance with registration conditions, and/or
- whether the goods are being supplied, imported or exported.

Currently, section 31 of the Act enables the Secretary to seek certain other types of information from a person who is applying for registration of therapeutic goods (or in relation to whom such goods are already registered).

The Minister explains that:

... while the Secretary's delegates in the TGA can impose conditions on the registration or listing of medicines, there is no explicit power for the TGA to obtain information relating to compliance with these conditions. The amendments include such a power.

The amendments also add a power for the TGA to obtain information on whether registered or listed medicines have been imported into or supplied in Australia, or exported from Australia. While this information can be very important in assessing the risk arising from an identified deficiency with a medicine, sponsors have in the past refused to provide it. These amendments put beyond doubt the TGA's ability to obtain the information.¹⁵

Items 12–15 propose to amend **subsection 31(2)**. These proposed amendments would have the effect that the Secretary would be able to seek information or documents, from a person who has applied to list the therapeutic goods in the Register or in relation to whom the goods are already listed, about the:

- quality of the goods (**item 12**)
- safety and efficacy of the goods for the purposes for which they are listed (**item 13**)
- whether the goods comply with any conditions on the listing of the goods (**item 14**), and/or
- if the goods are listed in relation to the person—whether the goods are being supplied, imported or exported (**item 15**).

In relation to **items 12** and **13**, the Explanatory Memorandum states that:

Regulations made under paragraph 31(2)(h) already allow the Secretary to seek this information, and these powers are now being included in the Act for greater transparency.¹⁶

In relation to **items 14** and **15**, the Explanatory Memorandum states that:

15. Ibid., p. 19.

16. Explanatory Memorandum, op. cit., p. 8.

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This information is important in ensuring compliance with the Act, and in assessing the extent of risk if problems with a medicine are detected.¹⁷

Items 18–20 propose amendments to **section 60** of the Act, which deals with reconsideration by the Minister of certain initial decisions made by the Secretary.

These amendments proposed in **items 18** and **19**:

- enable requests for reconsideration of decisions by the Minister to be accompanied by supporting information, and
- subject to subsection 60A(2) (new information on review-Minister’s discretion to remit or to consider new information):
 - require the Minister to consider any such supporting information, and
 - prevent the Minister from considering other information provided by or on behalf of the person requesting the review *after* making the request, except for:
 - information sought by the Minister, or
 - information indicating that the quality, safety or efficacy of the therapeutic goods is unacceptable.

The Explanatory Memorandum states:

The amendment at item 19 to prevent supporting information from being considered where it is provided after the request for reconsideration is made is necessary as such information is often complex and highly technical. As a result, it can require detailed consideration, assessment and analysis. This cannot readily occur where the Minister, or her or his delegate, is afforded less than the full 60 days in which to consider it. This is a particular problem in cases involving an initial decision on an application for registration, as the original information supplied in such cases often includes voluminous technical data and supporting information.¹⁸

Concluding comments

The proposed amendments are largely technical in nature and seek to enhance the operation of the Act and the efficiency of the TGA. The absence of any stakeholder commentary and the decision not to refer the Bill to any parliamentary committee suggest that the proposed amendments are largely uncontroversial.

17. Ibid.

18. Ibid., p. 9.

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